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## **Application Proof of**

# **3D Medicines Inc.**

*(Incorporated in the Cayman Islands with limited liability)*

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(Incorporated in the Cayman Islands with limited liability)

[REDACTED]

Number of [REDACTED] under the : [REDACTED] Shares (subject to the  
[REDACTED] [REDACTED])  
Number of [REDACTED] : [REDACTED] Shares (subject to  
reallocation)  
Number of [REDACTED] : [REDACTED] Shares (subject to  
reallocation and the [REDACTED])  
Maximum [REDACTED] : HK\$[REDACTED] per [REDACTED], plus  
brokerage of 1%, FRC transaction levy  
of 0.00015%, SFC transaction levy of  
0.0027%, and Stock Exchange trading  
fee of 0.005% (payable in full on  
application in Hong Kong dollars and  
subject to refund)  
Nominal value : HK\$0.001 per Share  
Stock code : [REDACTED]

Joint Sponsors, [REDACTED] and [REDACTED]



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The [REDACTED] is expected to be determined by agreement between the [REDACTED] (for themselves and on behalf of the [REDACTED]) and our Company on or before [REDACTED] or such later time as may be agreed between the parties, but in any event, not later than [REDACTED]. The [REDACTED] will not be more than HK\$[REDACTED] per [REDACTED] and is expected to be not less than HK\$[REDACTED] per [REDACTED], unless otherwise announced. Applicants for [REDACTED] are required to pay, on application, maximum [REDACTED] of HK\$[REDACTED] per [REDACTED] for each [REDACTED] together with brokerage of 1%, FRC transaction levy of 0.00015%, SFC transaction levy of 0.0027%, and Stock Exchange trading fee of 0.005%, subject to refund if the [REDACTED] as finally determined is less than HK\$[REDACTED] per [REDACTED].

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The obligations of the [REDACTED] under the [REDACTED] are subject to termination by the [REDACTED] (for themselves and on behalf of the [REDACTED]) if certain grounds arise prior to 8:00 a.m. on the [REDACTED]. Please see the section headed “[REDACTED].”

[REDACTED]

[REDACTED]

**IMPORTANT**

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[REDACTED]

## EXPECTED TIMETABLE<sup>(1)</sup>

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[REDACTED]

## EXPECTED TIMETABLE<sup>(1)</sup>

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[REDACTED]

## EXPECTED TIMETABLE<sup>(1)</sup>

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[REDACTED]

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*You should rely only on the information contained in this document and the [REDACTED] to make your investment decision. We have not authorized anyone to provide you with information that is different from what is contained in this document. Any information or representation not made in this document must not be relied on by you as having been authorized by us, the [REDACTED], the [REDACTED], the [REDACTED], the Joint Sponsors, the [REDACTED], any of our or their respective directors, officers, employees, partners, agents or representatives, or any other party involved in the [REDACTED].*

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## SUMMARY

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*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 [REDACTED] carefully before making your investment decision.*

*There are risks associated with any investment. Some of the particular risks in investing in the [REDACTED] are set out in the section headed “Risk Factors” in this document. You should read that section carefully before you decide to invest in the [REDACTED]. In particular, we are a biotechnology company seeking a [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05 (1), (2) or (3) of the Listing Rules.*

## OVERVIEW

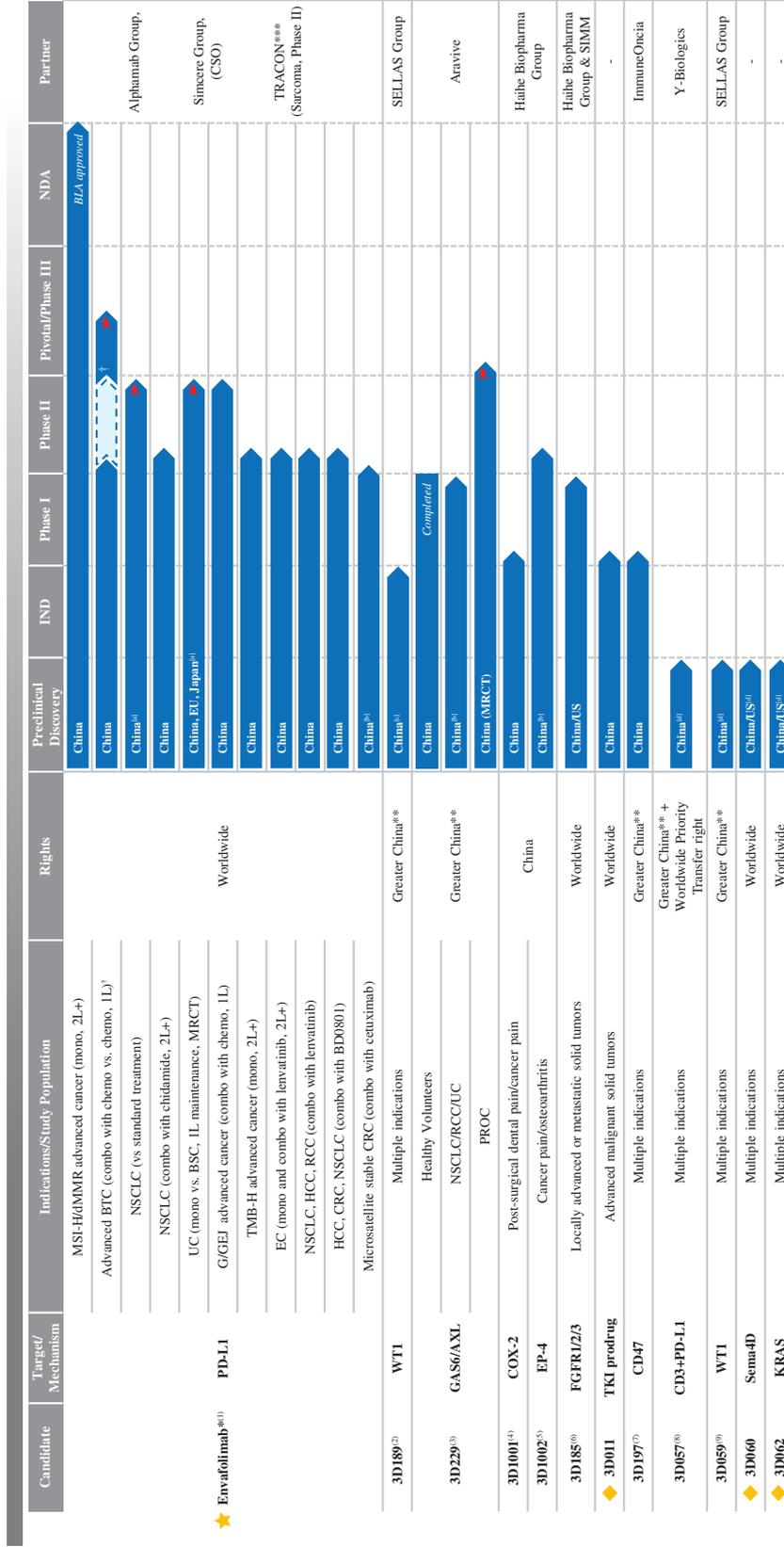
Founded in 2014, we are a bio-pharmaceutical company with research and development capabilities and are committed to the development and commercialization of oncology therapies with differentiated clinical profile in response to the trend of treating cancer as a chronic disease. Our core business model is to develop and commercialize oncology products and drug candidates through a combination of co-development, in-licensing and in-house discovery. As of the Latest Practicable Date, we have built a pipeline consisting of one Core Product and 11 drug candidates, among which, the Core Product envafolimab (brand name: ENWEIDA, 恩維達®), as our backbone, was approved in November 2021 and commercialized in December 2021, and seven are in clinical stage. Our Core Product envafolimab is a subcutaneously injectable PD-L1 antibody that has the potential to address an unmet medical need for the treatment of cancer as a chronic disease and it has been approved in China for the treatment of previously treated microsatellite instability-high (MSI-H)/mismatch repair deficiency (dMMR) advanced solid tumors. As of the Latest Practicable Date, our Core Product was approved for this one indication only, the incidence of which in China reached approximately 146,100 in 2021 and is expected to reach approximately 186,000 in 2030. We may face fierce competition from existing products and potential drug candidates in the entire oncology market and the market opportunities in respect of the Core Product may be small as it targets late line treatment for most of its targeted indications.

**WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCT ENVAFOLIMAB FOR INDICATIONS OTHER THAN THE APPROVED INDICATION IN PREVIOUSLY TREATED MSI-H/DMMR ADVANCED SOLID TUMORS.**

SUMMARY

Our Pipeline

The following chart summarizes the development status of our product, clinical-stage drug candidates and selected pre-clinical stage drug candidates as of the Latest Practicable Date:



★ Co-owned Asset    ◆ Proprietary Asset    🇺🇸 Pivotal Trial

\* Denotes our Core Product  
 \*\* Greater China includes China, Hong Kong, Macau and Taiwan region.  
 \*\*\* TRACON is a licensee of envalfolimab for the U.S., Canada and Mexico.

## SUMMARY

- [a] Preparing for Phase III clinical trial
- [b] Preparing for Phase II clinical trial
- [c] Preparing for IND filing
- [d] Pre-clinical stage

*Abbreviations:* MSI-H/dMMR = microsatellite instability-high/mismatch repair deficiency; BTC = biliary tract cancer; NSCLC = non-small cell lung cancer; UC = urothelial cancer; BSC = best supportive care; MRCT = multi-regional clinical trial; G/GEJ = gastric or gastroesophageal junction; TMB-H = tumor mutational burden-High; EC = endometrial cancer; HCC = hepatocellular carcinoma; RCC = renal cell carcinoma; CRC = colorectal cancer; PROC = platinum resistant ovarian cancer; IND = investigational new drug application; BLA = biologics license application; 1L = first-line; 2L+ = second-line or later

*Notes:*

- (1) We maintain the rights to develop envafolimab globally in oncology field through our co-development agreement with Alphamab Group. On December 17, 2020, the NMPA accepted the BLA for envafolimab for previously treated MSI-H/dMMR advanced solid tumors, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors. On January 16, 2020, the U.S. Food and Drug Administration (FDA) granted envafolimab with orphan drug designation for the treatment of advanced BTC. On June 28, 2021, the FDA granted envafolimab with orphan drug designation for the treatment of soft tissue sarcoma. The commencement of each of the clinical trials for the treatment of previously treated MSI-H/dMMR advanced solid tumors, advanced BTC and G/GEJ cancer were based on the initial safety and efficacy data across multiple dose levels from the three then-ongoing Phase I clinical trials in advanced solid tumors in China, the U.S., and Japan.
- (2) We own the exclusive rights to develop, manufacture and commercialize 3D189 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses through our exclusive license agreement with SELLAS Group. We obtained the IND approval for 3D189 in China in March 2022 and we plan to join the multi-regional clinical trial (MRCT) with our partner SELLAS Group. 3D189 has been granted fast track and orphan drug designations by the FDA for the treatment of AML.
- (3) We own the exclusive rights to develop, manufacture and commercialize products that contain 3D229 as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in China, Hong Kong, Macau and Taiwan region through our collaboration and license agreement with Aravive. Stanford licensed the technology that is used by Aravive to develop 3D229 and Aravive licensed 3D229 to us. We completed the Phase I clinical trial in healthy volunteers in China in May 2022. In addition, we received the IND approval for 3D229 for a Phase III clinical trial in patients with PROC in China in July 2021 to participate in the MRCT, and we initiated this Phase III clinical trial in China in February 2022.
- (4) We own the exclusive rights to develop, manufacture and commercialize 3D1001 in China in the pain indication field through our license agreement with Haihe Biopharma Group.
- (5) We own the exclusive rights to develop, manufacture and commercialize 3D1002 in China in the pain indication field through our license agreement with Haihe Biopharma Group.

## SUMMARY

- (6) We own the exclusive rights to develop, manufacture and commercialize 3D185 globally in the oncology and pulmonary fibrosis treatment through our patent license agreements with Haihe Biopharma and Shanghai Institute of Materia Medica, Chinese Academy of Sciences.
  - (7) We own the exclusive rights to develop, manufacture and commercialize 3D197 in China, Hong Kong, Macau and Taiwan region in respect of oncology indications through our exclusive license agreement with ImmuneOncia.
  - (8) We own the exclusive rights to develop, manufacture and commercialize 3D057 in China, Hong Kong, Macau and Taiwan region for all therapeutic areas through our license agreement with Y-Biologics.
  - (9) We own the exclusive rights to develop and commercialize 3D059 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses through our exclusive license agreement with SELLAS Group. MSK licensed certain know-how relating to 3D059 to SELLAS, which in turn sub-licensed the same to us.
- † The study included an interim analysis after the first 100 patients were enrolled (considered to be equivalent to a Phase II clinical trial) in the pivotal Phase III clinical trial for the treatment of advanced BTC, which has been designed with reference to the sufficient regulatory basis as described below. As advised by our PRC Legal Advisers, according to the Technical Guiding Principles of Clinical Trials of Anti-tumor Drugs (抗腫瘤藥物臨床試驗技術指導) effective as of May 15, 2012, the clinical studies of anti-tumor drugs are generally divided into phase I, phase II and phase III clinical trials. The primary objectives of a phase I clinical trial include the preliminary studies of the tolerability and pharmacokinetics profile of the drugs, which provides data support to the dosage regimen design of subsequent studies. A phase II clinical trial is typically an exploratory study, such as the exploration of administration dosage, the exploration of dosage regimen and the exploration of efficacy, and includes the observation of safety. A phase III clinical trial further confirms the benefits for cancer patients on top of the results of the phase II clinical trial, and provide adequate evidence for obtaining marketing approval. However, the phases of the aforementioned clinical studies are not necessarily fixed. For instance, an exploratory study (i.e. phase II clinical trial) may also be a part of a phase III clinical trial. Specifically, a phase III clinical trial requires to generate efficacy data of clinical benefit and the duration of the phase III trial is relatively long. Therefore, a phase III clinical trial may include an element of exploratory research allowing the adjustments of its the clinical trial protocol or conduct pursuant to the interim analysis and accumulated information. In the field of oncology clinical research, the objectives of a traditional phase II study are increasingly commonly achieved through an expanded Phase I study design or by introducing an interim analysis in the phase III study. This approach has enabled a more efficient clinical development of oncology drugs in recent years.

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## SUMMARY

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### Our Core Product and Other Drug Candidates

#### *Envafolimab – Our Core Product*

Our envafolimab (brand name: ENWEIDA, 恩維達®) is a subcutaneously-injectable PD-L1 inhibitor for the treatment of tumor-agnostic indications, and it has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Envafolimab is a fusion protein of single domain PD-L1 antibody and we are solely responsible for, and are conducting its clinical development in the oncology field. Envafolimab was in pre-clinical stage when the Co-Development Agreements were first entered into between the Company and Alphamab Group in February 2016. Since then, we have independently completed and been independently conducting a number of clinical trials in relation to envafolimab and achieved a number of major R&D milestones on our own and at our own cost, which amounted to approximately RMB614.9 million as of May 31, 2022, and we have significantly increased our R&D team to 151 members as of the Latest Practicable Date. On November 24, 2021, we received BLA approval for this indication from the NMPA. In addition, envafolimab has undergone an exploratory Phase II clinical trial in China in advanced gastric or gastroesophageal junction (G/GEJ) cancer, and is currently being evaluated in two ongoing pivotal clinical trials including a Phase III clinical trial in patients with advanced biliary tract carcinoma (BTC) in China, and a Phase II clinical trial in selected types of advanced sarcoma (SC) in the U.S. sponsored by our partner TRACON. On January 16, 2020, the U.S. Food and Drug Administration (FDA) granted envafolimab with orphan drug designation for the treatment of advanced BTC. On June 28, 2021, the FDA granted envafolimab with orphan drug designation for the treatment of soft tissue sarcoma. For more details, please refer to the paragraphs headed “Business – Our Core Product and Other Drug Candidates – 1. Our Core Product – a. Envafolimab” in this document.

#### *Our Other Drug Candidates*

- **3D189:** Our 3D189 is a peptide cancer vaccine with potential to create synergies in combination with PD-1/PD-L1 therapies including with our envafolimab.
  - **3D229:** Our 3D229 is a high-affinity, soluble Fc-fusion protein designed to bind Growth Arrest Specific 6 (GAS6), intercept the binding of GAS6 to its receptor AXL and block the activation of the GAS6-AXL signaling pathway.
  - **3D011:** Our 3D011 is an in-house discovered tyrosine kinase inhibitor (TKI) prodrug that will be developed as monotherapy and in combination with other agents for the treatment of solid tumors.
  - **3D185:** Our 3D185 is a fibroblast growth factor receptors (FGFR) 1-3 and colony stimulating factor 1 receptor (CSF1R) inhibitor that is expected to both inhibit tumor cells and remodel the tumor microenvironment to synergistically antagonize tumors and delay the development of resistance to FGFR inhibitors alone.

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## SUMMARY

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- **3D1001:** Our 3D1001 is a third-generation cyclooxygenase-2 (COX-2) inhibitor with rapid onset of action and prolonged pain relief to patients with post-surgical dental pain in clinical study attributable to a favorable PK profile.
- **3D1002:** Our 3D1002 is an E-type prostanoid receptor 4 (EP4) inhibitor that has the potential for improved safety profile compared to COX1/2 inhibitors.
- **3D197:** Our 3D197 is a next-generation fully human anti-CD47 IgG4 monoclonal antibody with potentially better safety profile that is expected to treat hematological malignancies and solid tumors.
- **Our Pre-Clinical Stage Drug Candidates:** In addition to our clinical-stage drug candidates, we are also evaluating a number of promising pre-clinical stage drug candidates in our rich pipeline, including, (a) 3D057, our bispecific antibody drug which targets CD3 receptor of T-cells and PD-L1 of tumor cells, (b) 3D059, our next-generation immunotherapeutic which targets the WT1 protein in hematological malignancies and solid tumors, (c) 3D060, our in-house developed monoclonal antibody which targets Semaphorin 4D (Sema4D) of tumor cells, and (d) 3D062, our in-house developed small molecule for patients with KRAS mutation.

Please refer to the paragraphs headed “Business – Our Core Product and Other Drug Candidates” in this Document.

### Our Business Model

Focusing on the trend of treating cancer as a chronic disease, we have strategically carried out a forward-looking plan for our product and drug candidate pipeline. We have built a pipeline consisting of one Core Product and 11 drug candidates, including a fully validated immuno-oncology monotherapy, innovative drug candidates with mechanisms of action amenable to combination within the pipeline, and pain management assets. Among our product and drug candidates, the Core Product enavafolimab, as our backbone, was approved in November 2021 and commercialized in December 2021, and seven are in clinical stage. Three of these product and clinical-stage drug candidates have entered into Phase II/III pivotal trials, two of which are conducted by our collaboration partners.

We are quite focused on and have contributed to the development of immuno-oncology therapies. Employing a combination approach, immuno-oncology therapies have improved therapeutic efficacy and life expectancy of patients with a variety of cancer types and have stood out as particularly influential in recent years. Enavafolimab can be used in combination with other treatments, including chemotherapy, targeted therapies, and other immunotherapies, which would potentially benefit more patients. Other drug candidates in our pipeline have promising potential to synergize with enavafolimab through varied complementary mechanism of actions.

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## SUMMARY

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We are led by an experienced management team with a proven track record of leadership responsibilities and successful performance at international drug regulatory agencies, global pharmaceutical and biotech companies. Our management team has an average of over 20 years of industry and regulatory experience at global organizations such as the FDA, Bristol Myers Squibb (BMS), AstraZeneca and Celgene. Our founder, CEO and Chairman, Dr. Gong, has more than 30 years of global industry and academic experience leading and participating in the entire process of new drug development at regulatory agency, various pharmaceutical and biotech companies, and institutions. Led by our management team and supported by our full team with strong execution capabilities, we have adopted a highly systematic approach to the process of screening, identifying, evaluating and developing drug candidates that enhances our comprehensive portfolio for chronic cancer treatment. Our pre-clinical and clinical teams work collaboratively to ensure a seamless transition from discovery to clinical development. We apply efficient clinical study design and disciplined trial execution to achieve shortened timeline in a more cost-effective manner.

We plan to continue to accelerate the development and commercialization of our pipeline products, and further promote our comprehensive competitive capabilities. We have been establishing our internal manufacture capability and sales force, and further enhancing our in-house innovative R&D capability. We believe that these efforts will allow us to reinforce our position in innovative pharmaceutical industry. Our continuous R&D commitments will enhance our competitive advantages in the race to discover, develop and commercialize innovative cancer therapies and help us create and capture more opportunities in the chronic cancer market.

### **Addressable Markets and Competitive Landscape**

#### ***The Competitive Landscape for Our Core Product and Other Drug Candidates***

According to Frost and Sullivan, at present, several major options are available for oncology therapy, including surgery, radiotherapy, chemotherapy, small molecule drugs and biologics. Though we specialize in developing biologics drugs, we face fierce competition from existing products and potential drug candidates throughout the entire oncology market that target the same indications as our Core Product and other drug candidates. Our competitors include pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations that conduct research on competitive drugs and therapies to our drug candidates worldwide. Many of them have significantly greater financial, technical and human resources capabilities than we do, enabling them to develop and commercialize drugs as well as obtain approval from regulatory authorities faster and more effectively, reducing or eliminating our commercial opportunity. Moreover, mergers and acquisitions, as well as collaborative arrangements among pharmaceutical companies make the competition even fiercer for us in every major aspect of our operation, from talent recruitment to clinical trial matters. For more details, please refer to the paragraphs headed “Risk Factors – Key Risks Relating to Our Business, Business

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## SUMMARY

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Operations, Intellectual Property Rights and Financial Prospects – We face substantial competition in the entire oncology market and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do” in this document.

As our Core Product envafolimab targets late line treatment, i.e., second line or later stage of treatment, for most of its targeted indications, its market opportunities may be small as it is limited to those patients who have failed prior treatments. In addition, it was only approved for previously treated MSI-H/dMMR advanced cancer patients, which may limit its market opportunity. However, the indications that envafolimab targets are not limited by tumor types, i.e., tissue-agnostic, and its applicable patient population could be broadened when more patients are tested for MSI-H/dMMR status. For more details, please refer to the paragraphs headed “Risk Factors – Key Risk Relating to Our Business, Business Operations, Intellectual Property Rights and Financial Prospects – The market opportunities for our Core Product may be small as it mainly targets late line treatment for most of its targeted indications and is limited to those patients who have failed prior treatments.” Our Core Product face competition from a number of marketed competitive products globally and in China, including nivolumab, pembrolizumab and dostarlimab. Despite the approvals of the former drugs in the U.S. by the FDA, envafolimab nevertheless remains the only PD-1/PD-L1 antibody approved in previously treated MSI-H/dMMR advanced solid tumors in China. For more details, please refer to the paragraphs headed “Industry Overview – Competitive Landscape of PD-1/PD-L1 Inhibitors Globally and in China”.

### *Competitive Landscape of Our Core Product Associated with Subcutaneous Injection*

Our Core Product envafolimab is a subcutaneously-injectable PD-L1 inhibitor for the treatment of tumor-agnostic indications. Compared with other competitive products, our Core Product adopts subcutaneous injection rather than intravenous injection.



## SUMMARY

The following table sets out a comparison of between intravenous injection and subcutaneous injection:

○ Low ● High	Intravenous Injection	Subcutaneous Injection
Location	Vein	Subcutaneous tissue
Administration Angle	25°	45° or 90°
Capacity for Osmolarity	1,000 mOsm /kg	600 mOsm /kg
Injection Time	●	○
Absorption Speed	●	○
Aseptic Conditions & Medical Staff Requirement	●	○
Suitable Scenarios	<ul style="list-style-type: none"> <li>• Emergency situations or situations that require immediate releases of drug effect</li> <li>• High concentration and large amount administrations</li> <li>• Continuous medication deliveries</li> </ul>	<ul style="list-style-type: none"> <li>• Drug deliveries that need slow release and long work time</li> <li>• Situations where patients need to periodically use a drug for a long term and the convenience of injection is important</li> </ul>

Source: *Patient Prefer Adherence*. 2015; 9: 923–942., *The Patient*, 8 (2). pp. 145-153., Frost & Sullivan analysis

- *Administration capacity.* Solutions with higher osmolarity can be injected through intravenous injection with an upper limit of 1,000 mOsm/kg, compared to an upper limit of 600 mOsm/kg for subcutaneous injection.
- *Efficiency.* Currently, drugs can be injected subcutaneously for only several minutes, while intravenous injection takes up to hours. Compared to intravenous injection, subcutaneous injection could bring great convenience to patients. Alternatively, drugs can be delivered at a uniform rate using intravenous injection.
- *Absorption speed.* Intravenous injection can enable drugs to access the entire body and release in a short period of time, rendering it to be more efficient in life-threatening situations. Comparatively, subcutaneous injection is not suitable for emergency needs but is especially widely used in drug delivery systems that need the feature of slow-release and long work time, such as the injection of long-acting insulin.
- *Cost & Coverage.* Intravenous injection imposes strict requirements on the aseptic conditions and the professional capabilities of the medical staff, making it comparatively more costly for patients and harder to adopt. Subcutaneous injection can cover more patients for its cheaper cost and lighter requirements on the aseptic conditions as it poses relatively fewer risks.

## SUMMARY

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In contrast to all of the marketed PD-1/PD-L1 inhibitors that are required to be administered intravenously, our subcutaneously-injectable envafolimab offers advantages in better patient compliance with increased convenience, wider patient coverage, and cost-effectiveness.

- *Better patient compliance with increased convenience.* Subcutaneous injection brings convenience to patients and is therefore preferred. According to Roche, its Herceptin Hylecta is a ready-to-use formulation that can be administered in two to five minutes through subcutaneous injection, compared to 30 to 90 minutes for intravenous Herceptin. Similarly, our Core Product can usually be delivered within 30 seconds in 0.75ml (150mg), compared with at least 30-minute’s delivery for drugs targeting the same indications through intravenous injection. In Roche’s PrefHer study, it is found that the majority (86%) of people preferred Herceptin Hylecta over intravenous Herceptin. For cancer patients who need to receive long-term treatments, the accumulated saved time using the subcutaneous route of injection makes it much more appealing than the intravenous injection method.
- *Wider patient coverage.* Subcutaneous injection can cover more patients in terms of oncology drug treatments. According to Journal of Infusion Nursing and Annals of Emergency Medicine, and Anticancer Research. 2014, 34: 1579-1586, peripheral intravenous injection is associated with an overall failure rate of 35-50% and approximately 10% of cancer patients may be unsuitable for intravenous administration. Meanwhile, oncology drugs are often given in non-life-threatening situations so that fast absorption of drugs is not always necessary, rendering subcutaneous injection suitable for almost all cancer patients. Our subcutaneously-injectable Core Product has low incidence rate of injection site reaction, and could be applied in broader scenarios for patients, as well as used for ambulatory treatment and self-administration, catering to the particular needs of certain patients.
- *More cost-effective.* Subcutaneous injection helps cut down expenses. According to British Journal of Cancer, derived costs for healthcare providers’ time and consumables per intravenous treatment were £132.05 and £12.92, respectively, compared with £31.99 and £1.17 per subcutaneous treatment, respectively, resulting in a total difference of £111.81 between two formulations per treatment. According to a study comparing subcutaneous and intravenous formulation of trastuzumab, published on European Journal of Obstetrics & Gynecology and Reproductive Biology, the administration of trastuzumab subcutaneous was translated in a cost saving of €212.93 (\$231.73) per patient episode compared to trastuzumab IV, which could lead to a total potential saving of €3,832.74 (\$4,171.06) over a full course of treatment (18 cycles).

## SUMMARY

The following tables set out the lists of approved and clinical-stage PD-1/PD-L1 mAbs indicated for the treatment of MSI-H/dMMR in China:

Competitive Landscape for Approved PD-1/PD-L1 mAbs Indicated for the Treatment of MSI-H/dMMR in China

Drugs	Drug Type	Company	Indications	Injection Method	Marketed/ First Posted Date	NRDL	Price (RMB)	Dosage	Annual Cost (Thousand RMB)
Envafohimab/ KN035	PD-L1 mAb	3DMed/ Alphamab	Unresectable or metastatic MSI-H/dMMR solid tumors	Subcutaneous	2021-11-24	-	200mg/ml 1ml: 5,980.0	150mg/ week	311.0 <sup>(1)</sup>
Pembrolizumab	PD-1 mAb	MSD	Unresectable or metastatic MSI-H/dMMR colorectal cancer	Intravenous	2021-06-15	-	100mg/4ml 4ml: 17,918.0	200mg/ 3 weeks	621.2
Tislelizumab/ BGB-A317	PD-1 mAb	Beigene	Unresectable or metastatic MSI-H/dMMR solid tumors	Intravenous	2022-03-11	2022 NRDL: Class B	100mg/10ml 10ml: 1,450	200mg/ 3 weeks	50.3
Serplulimab/ HLX-10	PD-1 mAb	Shanghai Henlius Biotech	Unresectable or metastatic MSI-H/dMMR solid tumors	Intravenous	2022-03-22	-	100mg/10ml 10ml: 5,588	3mg/kg/ 2 weeks	283.3

Notes: As of the Latest Practicable Date.

The annual cost is calculated based on the assumptions that each patient weighs 65kg and the annual medication time is 52 weeks.

- (1) Assuming that each patient use one 1-ml sized KN035 per week.

Source: NMPA, Annual Reports of Listed Pharmaceutical Companies, Company Official Websites, NRDL, Frost & Sullivan

Competitive Landscape for Clinical-Stage PD-1/PD-L1 mAbs Indicated for the Treatment of MSI-H/dMMR in China

Drugs	Drug Type	Company	Indications	Injection Method	Clinical Stage	Location	First Posted Date
HX008/ Pucotenlimab	PD-1 mAb	Akeso Biopharma, HanX Bio, Lepu Biopharma	Locally advanced or metastatic gastric adenocarcinoma; MSI-H/dMMR solid tumor	Intravenous	NDA	China	2021-10-26
Nivolumab	PD-1 mAb	BMS	Unresectable or metastatic dMMR/MSI-H CRC	Intravenous	Phase III	MRCT	2020-06-23
					Phase II	China	2019-12-18
Pembrolizumab	PD-1 mAb	MSD	MSI-H/dMMR solid tumors	Intravenous	Phase III	China	2022-02-11
AK-104/ Cadonilimab	PD-1 bi-specific Ab	Akeso, Inc	Locally advanced unresectable or metastatic MSI-H/dMMR	Intravenous	Phase II	China	2020-02-25
QL1604	PD-1 mAb	Qilu Pharmaceutical	Advanced dMMR/MSI-H solid tumor	Intravenous	Phase II	China	2020-05-22
RB-0004	PD-1 mAb	Reyoung (Suzhou) Biopharmaceuticals	MSI-H/dMMR solid tumors; TMB-H solid tumors; lymphomas	Intravenous	Phase I	China	2020-12-18

Note: As of the Latest Practicable Date.

Source: CDE, Annual Reports of Listed Pharmaceutical Companies, Company Official Websites, NRDL, Frost & Sullivan

For more details, please refer to the paragraphs headed “Industry Overview – Oncology Drug Market – Future Trends of Oncology Drug Market – Managing Cancer as a Chronic Disease”, “Industry Overview – Major Cancer Types and Indications – PD-1/PD-L1 Monoclonal Antibodies – Major Indications for PD-1/PD-L1 Inhibitors – MSI-H/dMMR” and “Business – Our Strengths – A major market player in the treatment of cancer as a chronic disease” in this document.

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## SUMMARY

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### *Our Commercialization Strategy*

We plan to accelerate the commercialization progress of our Core Product with combining efforts through a physician-targeted marketing strategy by interacting with physicians directly and hosting academic-oriented marketing events to educate them, so as to achieve hospital entrance for our Core Product. We also plan to work on getting the Core Product into the NRDL and other relevant catalogues and win recognition from third-party payers to reduce the cost for patients using it. For more details, please refer to the paragraphs headed “Business – Commercialization”.

### **Our Research and Development**

Our management team has a global vision and extensive industry experience at global organizations including the FDA and global pharmaceutical companies, and has led us to build capabilities from discovery to commercialization with proven track record.

Our R&D platform has strong molecule screening and design capabilities that increase the possibility of success of moving molecules from pre-clinical studies to market, enable innovative therapeutic approaches and support rich pipeline assets built around key pathways and targets. Our R&D centers in Shanghai and Beijing include large and small molecule platforms, complete cell line screening platforms, high-throughput compound screening platforms and comprehensive animal models.

We believe that R&D is key to maintaining competitiveness in our industry. We have built a platform to enable our R&D in the areas of chronic cancer treatment. Leveraging our proprietary R&D platform, we are able to conduct pre-clinical R&D activities including drug activity screening, studies of cellular functions of drugs, drug biochemical studies and biomolecule detection. Our drug discovery and translational research function is led by Dr. Yihui Lin, our Head of Translational Medicine Center, who holds a Ph.D. from the Center for Excellence in Molecular Cell Science of Chinese Academy of Sciences.

We employ a clinical-demand-oriented and market-driven approach to our clinical research and development efforts. Our clinical development team is composed of scientists and physicians with years of experience in drug development. Our clinical development team carefully customizes clinical development plan for each of our candidate drugs by taking into consideration of unmet medical needs, scientific rationale, and probability of technical and regulatory success, competition, commercial assessment, expert feedback, timeline and cost. Our clinical development team is led by Dr. Dongfang Liu, who holds a Ph.D degree from Massachusetts Institute of Technology, a master’s degree in pharmaceutical sciences from the University of Toledo, and a bachelor’s degree in clinical medicine from Peking University School of Medicine (formerly Beijing Medical University).

## SUMMARY

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### **Our Commercialization**

We have been establishing our sales and marketing department dedicated to the commercialization of our pipeline products. As we already received BLA approval for the treatment of previously treated MSI-H/dMMR advanced solid tumors on November 24, 2021, we have been building our qualified and capable sales and marketing department in place with rich experience in the commercialization of oncology treatment, and to be mainly responsible for product positioning, market strategy, promotional activity planning and patient assistance. As of the Latest Practicable Date, the leadership team of sales and marketing department was in place.

We provide our envafolimab to end-users through our collaborations with Simcere Group, and through distributors. As we commercially launched envafolimab in China only after we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors in November 2021, we primarily cooperated with Simcere Group with respect to the sales of envafolimab during the Track Record Period and up to the Latest Practicable Date. In addition, we cooperated with distributors who purchase envafolimab from us and resell to their customers, such as certain hospitals and pharmacies, during the Track Record Period and up to the Latest Practicable Date. For more details, please refer to the paragraphs headed “Business – Commercialization.”

### **Our Manufacturing**

During the Track Record Period and as of the Latest Practicable Date, Alphamab Group manufactured and supplied envafolimab to us pursuant to our collaboration with Alphamab Group. For details of the arrangements with Alphamab Group in connection with the manufacturing of envafolimab, please refer to the paragraph headed “Our Research and Development – Collaboration Agreements – Collaboration with Alphamab Group for Envafolimab”. In addition, we have been establishing our in-house manufacturing capability in Xuzhou, Jiangsu Province and work with qualified CMOs to manufacture and test drug candidates for pre-clinical and clinical supply. In the near future, we plan to continue outsourcing the manufacturing of our product and drug candidates, including commercial-scale manufacturing of our approved drugs, to qualified CMOs/CDMOs.

We have been building our in-house production facilities in Xuzhou, Jiangsu province, with current Good Manufacturing Practice (cGMP) compliant manufacturing system and facilities throughout the drug development process, including chemical drugs and biologics, to meet stringent global standards. In anticipation of large needs of our drugs upon commercialization, we purchased the use right to land in Xuzhou with an aggregate area of 65,637.97 square meters. We have obtained the construction permit and started construction of new manufacturing facilities in Xuzhou. We expect to complete building the facilities and commence operation by 2024. As of the Latest Practicable Date, our manufacturing facilities in Xuzhou did not have production capacity as we are still in the process of construction. We

## SUMMARY

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expect that their total production capacity will reach 6,000 L (3x2,000 L) by 2024 and we also plan to further expand the production capacity in the later stage, which will be sufficient to meet commercial manufacturing needs of all our pipeline products in the foreseeable future.

### OUR STRENGTHS

We believe that the following core competitive strengths form the foundation of our past success and will continue to help us solidify and enhance our position in a rapidly-growing chronic cancer treatment market: (i) a major market player in the treatment of cancer as a chronic disease; (ii) a multi-mechanism and highly synergetic pipeline of innovative drugs; (iii) successful exploration of innovative oncology therapies with resources consolidation, business development, clinical development and registration capabilities; (iv) full research and clinical development capabilities with proven track record from discovery to NDA stage; and (v) internationally skilled management and R&D team.

### OUR STRATEGIES

We are committed to the discovery, development, and commercialization of safe and effective innovative drugs for chronic cancer treatment, and will further strengthen our position in this market by implementing the following strategies: (i) further expand the commercial potential of envafolimab and explore market opportunities; (ii) accelerate the product development to commercialization and further enrich our pipeline; (iii) further enhance our in-house innovative R&D capability; (iv) further establish GMP manufacturing capability and strengthen commercialization capability; and (v) continue to attract, cultivate and retain talents.

### COLLABORATION AGREEMENTS

#### Collaboration with Alphamab Group for Envafolimab

In February 2016, we entered into a co-development agreement, as amended, with Alphamab Group for envafolimab (collectively with the subsequent amendments and supplemental agreements thereto, the “**Co-Development Agreements**”).

Under the Co-Development Agreements, we agreed to co-own the patent rights under a PCT application and its multiple national phase applications (including the ones in China and the U.S.) covering the molecule of envafolimab with Alphamab Group (the “**Patent Rights**”). Under the Co-Development Agreements, we are responsible for, among other things, designing, conducting and monitoring clinical trials, reviewing registration filings, and conducting commercialization of envafolimab globally at our own cost, while Alphamab Group is responsible for, among other things, completing CMC studies and pre-clinical studies and manufacturing envafolimab samples for clinical trials at its own cost. We are entitled to obtain the new drug certificate and have exclusive commercialization rights for envafolimab worldwide.

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## SUMMARY

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Alphamab Group is entitled to apply for and obtain the GMP certificate to manufacture envafolimab, and is obligated to manufacture and supply envafolimab to us. During the clinical stage, Alphamab Group is obligated to supply envafolimab drug samples for free. After envafolimab enters into the commercialization stage, Alphamab Group will supply envafolimab to us on a cost-plus basis.

The Co-Development Agreements can be terminated in the following situations: (i) if a contracting party breaches the agreements, (ii) if the obligations under the Co-Development Agreements cannot be performed due to force majeure, or (iii) if a party fails to perform its obligations related to the intellectual property rights. For further details on the Co-Development Agreements, please refer to the paragraph headed “Business – Collaboration Agreements – Collaboration with Alphamab Group for Envafolimab.”

### **Collaboration with Alphamab Group and TRACON for Envafolimab**

In December 2019, we, Alphamab Group and TRACON entered into a collaboration and clinical trial agreement (the “**3D Alphamab TRACON Agreement**”) for the development of envafolimab for the treatment of sarcoma in the U.S., Canada, Mexico and each of their dependent territories (the “**TRACON Territory**”).

Pursuant to the 3D Alphamab TRACON Agreement, TRACON was granted an exclusive and non-transferable license to develop and commercialize envafolimab for the treatment of sarcoma in the TRACON Territory.

TRACON will be responsible for commercializing envafolimab for sarcoma in the TRACON Territory, including booking of sales revenue, unless (a) envafolimab is first approved in the TRACON Territory for an indication other than sarcoma and launched in the TRACON Territory, or (b) envafolimab is first approved in the TRACON Territory for sarcoma and subsequently approved in the TRACON Territory for an additional non-orphan indication and sold commercially by us and/or Alphamab Group, or licensee, in which case we and Alphamab Group will be responsible for commercializing envafolimab for sarcoma in the TRACON Territory, including booking of sales revenue.

For further details on the 3D Alphamab TRACON Agreement, please refer to the paragraph headed “Business – Collaboration Agreements – Collaboration with Alphamab and TRACON for Envafolimab.”

### **Collaboration with Alphamab Group and Simcere Group for Envafolimab**

In March 2020, we entered into a tripartite collaboration agreement with Alphamab Group and Simcere Group, together with a separate marketing and promotion agreement with Simcere Group in respect of envafolimab (the “**Promotion Agreement**” and collectively, the “**3D Alphamab Simcere Agreements**”).

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## SUMMARY

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Under the 3D Alphamab Simcere Agreements, Simcere Group was granted an exclusive promotion right and the rights of first refusal for inlicenses or transfers of envafolimab in respect of oncology indications in China, subject to the terms and conditions of the 3D Alphamab Simcere Agreements. To facilitate sales and marketing and in line of with general practice in the industry, Simcere is entitled to decide on general matters with respect to the routine and day-to-day marketing of envafolimab in China but is not entitled to make any final decisions on specific matters that affect the commercial success of envafolimab such as its initial pricing and availability to centralized procurement or volume purchase catalogue.

For further details on the 3D Alphamab Simcere Agreements, please refer to the paragraph headed “Business – Collaboration Agreements – Collaboration with Alphamab Group and Simcere Group for Envafolimab.”

### **Other Collaboration Agreements**

For further details on our other Collaboration Agreements, please refer to the paragraphs headed “Business – Collaboration Agreements.”

## **INTELLECTUAL PROPERTY**

We have an extensive portfolio of patents to protect our product, drug candidates and technologies. As of the Latest Practicable Date, we owned (including co-owned) (i) ten granted patents in China, (ii) 14 granted patents in other jurisdictions, and (iii) 20 pending patent applications, including five Chinese patent applications, one U.S. patent application and 14 patent applications in other jurisdictions, relating to certain of our product, drug candidates and technologies. Specifically, in relation to our Core Product, envafolimab, as of the Latest Practicable Date, we co-owned with Alphamab Group one granted Chinese patent, nine granted patents and ten patent applications in other jurisdictions.

Certain of our collaboration partners or their sub-licensors are responsible for or have the first right to prosecute, maintain and/or enforce the certain patents relevant to our product, drug candidates and technologies. For example, we and Alphamab Group are jointly responsible for the prosecution and maintenance of the patents we co-own. Further, with respect to any patents and/or patent applications in-licensed from Alphamab Group to us, Alphamab Group as the patentee is legally responsible for the prosecution, maintenance and enforcement of such licensed patents and/or patent applications according to patent laws and regulations. If we or any of our collaboration partners or sub-licensors fail to obtain or maintain patent protection, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to our product and drug candidates in the worst case scenario. For details, please refer to the paragraphs headed “Risk Factors – Other Risks Relating to Our Business – Risks Relating to Our Intellectual Property Rights.”



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## SUMMARY

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As of the Latest Practicable Date, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent. Our Directors confirm that we were not aware of any instances of infringement of any third parties’ intellectual property rights by us during the Track Record Period and up to the Latest Practicable Date. For details of relevant risks, please refer to the paragraphs headed “Risk Factors – Other Risks Relating to Our Business – Risks Relating to Our Intellectual Property Rights.”

### CUSTOMERS

We commercially launched envafolimab in China only after we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors in November 2021, and started to generate revenue from the sales of envafolimab to pharmacy stores, which we consider as our customers. As of the Latest Practicable Date, our customers covered 30 provinces and municipalities in China.

As of the Latest Practicable Date, we had just started the commercialization of envafolimab, and we had marketed envafolimab during the Track Record Period to our customers through our cooperation with Simcere Group, and through our distributors. For details of the arrangements with Simcere Group and our distributor in connection with the commercialization of envafolimab, please refer to the paragraph headed “Commercialization – Our Sales Operations” and “Our Research and Development – Collaboration Agreements – Collaboration with Alphamab Group and Simcere Group for Envafolimab”. Our five largest customers in 2021 and for the five months ended May 31, 2022 are China-based pharmaceutical companies. The revenue generated from our five largest customers in 2021 and for the five months ended May 31, 2022 was RMB14.6 million and RMB44.0 million, respectively, which accounted for 24.2% and 27.3% of our total revenue in 2021 and for the five months ended May 31, 2022, respectively. The revenue generated from our largest customer in 2021 and for the five months ended May 31, 2022 was RMB3.9 million and RMB13.7 million, respectively, which accounted for 6.4% and 8.5% of our total revenue in the same periods.

### RAW MATERIALS AND SUPPLIERS

During the Track Record Period, we primarily procured raw materials and equipment for the development and manufacture of our product and drug candidates from manufacturers and suppliers around the world. Our purchases mainly include third-party contracting services for research and development of our product and drug candidates and manufacturing of certain drug substances for clinical supply, as well as raw materials, consumables, machines and equipment. We also engage qualified CROs and CMOs to support our internal team in managing and conducting pre-clinical and clinical studies and of our pipeline candidates, as well as the manufacturing activities. During the Track Record Period, our purchases from our five largest suppliers in the aggregate in each year/period accounted for 78.5%, 49.6% and 75.4% of our total purchases (including value added tax), respectively.

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## SUMMARY

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### RELATIONSHIP WITH CROs

In line with industry practice, we collaborate with contract research organizations (CROs) that manage, conduct and support our clinical trials in China, the U.S. and other jurisdictions. We selected our CROs taking into consideration various factors, such as their qualifications, academic and professional experience, industry reputation and service fees. The CROs provide us with an array of products and services necessary for complex clinical trials. In addition to the scope, depth and quality of their service and product offerings, we place a high value on our CROs’ ability to facilitate optimal site selection, timely patient recruitment and efficient conduct of complex clinical trials with high-quality standards. CROs generally provide a comprehensive suite of services to assist us in the implementation and management of clinical trials, including trial preparation, day-to-day site management, clinical safety management, data management, and report preparation.

### SUMMARY HISTORICAL FINANCIAL INFORMATION

This summary of key financial information set forth below has been derived from, and should be read in conjunction with, our consolidated audited financial statements, including the accompanying notes, set forth in the Accountants’ Report set out in Appendix I to this document, as well as the information set forth in the section headed “Financial Information.”

#### Summary Consolidated Statements of Profit or Loss

We have never been profitable and have incurred operating losses during the Track Record Period, with RMB635.4 million, RMB1,461.8 million and RMB293.4 million for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, respectively. Substantially all of our operating losses resulted from research and development expenses, administrative expenses and fair value losses on preferred shares. In particular, the research and development expenses incurred for our Core Product amounted to RMB92.4 million, RMB118.0 million and RMB39.7 million, for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, respectively. The research and development expenses in relation to the services provided by third-party contract research organizations amounted to RMB67.3 million, RMB60.6 million and RMB38.9 million, for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, respectively. For more details, please refer to the paragraphs headed “Financial Information – Description of Certain Key Items of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Research and Development Expenses,” “Financial Information – Description of Certain Key Items of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Administrative Expenses” and “Financial Information – Description of Certain Key Items of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Fair Value Losses on Preferred Shares” in this document.

## SUMMARY

The following table summarizes our consolidated statements of profit or loss and other comprehensive income for the periods indicated:

	Year Ended December 31,		Five Months Ended May 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Revenue	–	60,260	–	161,062
Cost of sales	–	(4,277)	–	(11,458)
Gross profit	–	55,983	–	149,604
Other income and gains	2,337	19,637	1,494	21,480
Research and development expenses	(263,970)	(371,162)	(129,940)	(138,259)
Administrative expenses	(40,528)	(150,956)	(26,757)	(46,631)
Selling and marketing expenses	–	(42,834)	–	(103,567)
Royalty expenses	–	(7,153)	–	(17,364)
Other expenses	(5,929)	(8,940)	(1,371)	(14,224)
Finance costs	(8,058)	(1,528)	(365)	(740)
Fair value losses on preferred shares	(319,232)	(954,742)	(647,031)	(143,642)
Impairment losses on financial assets, net	–	(130)	–	(74)
<b>Loss before tax</b>	(635,380)	(1,461,825)	(803,970)	(293,417)
Income tax expenses	–	–	–	–
<b>Loss and total comprehensive loss for the year/period</b>	<u>(635,380)</u>	<u>(1,461,825)</u>	<u>(803,970)</u>	<u>(293,417)</u>
Attributable to:				
Owners of the parent	(635,380)	(1,434,092)	(803,970)	(280,379)
Non-controlling interests	–	(27,733)	–	(13,038)
	<u>(635,380)</u>	<u>(1,461,825)</u>	<u>(803,970)</u>	<u>(293,417)</u>

## SUMMARY

### Non-IFRS Measure

In order to supplement our consolidated statements of profit or loss and other comprehensive income which are presented in accordance with IFRS, we use adjusted loss and total comprehensive loss as an additional financial measure, which is not required by, or presented in accordance with IFRS. Our adjusted loss and total comprehensive loss represents our loss and total comprehensive loss for the year/period, adjusted to add back fair value losses on preferred shares and share-based payment expenses. We believe that such measure provides investors and other persons with useful information to understand and evaluate our consolidated results of operation in the same manner as it helps our management. However, adjusted net loss presented by us may not be comparable to the similar financial measure presented by other companies. There are limitations to the non-IFRS measure used as an analytical tool, and you should not consider it in isolation or regard it as a substitute for our results of operation or financial position analysis that is presented in accordance with IFRS.

The following table sets forth our loss and total comprehensive loss and adjusted loss and total comprehensive loss for the year/period, which is adjusted by adding back fair value losses on preferred shares and share-based payment expenses, for the periods indicated:

	<b>Year Ended December 31,</b>		<b>Five Months Ended May 31,</b>	
	<b>2020</b>	<b>2021</b>	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Loss and total comprehensive loss for the year/period	(635,380)	(1,461,825)	(803,970)	(293,417)
Add:				
Fair value losses on preferred shares <sup>(1)</sup>	319,232	954,742	647,031	143,642
Share-based payment expenses <sup>(2)</sup>	416	164,659	94	55,435
<b>Adjusted loss and total comprehensive loss for the year/period</b>	<b>(315,732)</b>	<b>(342,424)</b>	<b>(156,845)</b>	<b>(94,340)</b>

*Notes:*

- (1) Fair value losses on preferred shares consist of fair value losses on preferred shares we issued, during the Track Record Period. We will cease to recognize fair value losses on preferred shares upon the [REDACTED].
- (2) Share-based payment expenses mainly represent share award schemes and share incentive scheme adopted by our Group for the purpose of providing incentives to eligible participants. Share-based payment expenses are not expected to result in future cash payments (a non-cash item).

## SUMMARY

### Summary Consolidated Statements of Financial Position

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

	As of December 31,		As of May 31,
	2020	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
<b>Non-current assets</b>			
Property, plant and equipment	10,864	52,246	97,401
Intangible assets	–	929	887
Right-of-use assets	15,937	66,293	62,333
Other non-current assets	7,660	18,384	10,878
Amounts due from related parties	–	3,214	3,254
<b>Total non-current assets</b>	<b>34,461</b>	<b>141,066</b>	<b>174,753</b>
<b>Current assets</b>			
Trade receivables	–	65,004	101,889
Prepayments, other receivables and other assets	41,122	29,654	29,510
Amounts due from related parties	372	–	–
Financial assets at fair value through profit or loss (“FVTPL”)	–	50,178	50,021
Pledged deposits	6,000	–	–
Restricted bank balances	–	72	72
Cash and bank balances	414,261	774,306	660,231
Inventories	–	13	1,545
<b>Total current assets</b>	<b>461,755</b>	<b>919,227</b>	<b>843,268</b>
<b>Current liabilities</b>			
Trade payables	2,416	3,742	2,650
Other payables and accruals	88,340	137,431	193,404
Interest-bearing bank borrowings	3,522	–	–
Amounts due to a related party	1,702	150	150
Preferred shares	215,237	3,093,968	3,233,922
Lease liabilities	3,791	12,754	13,701
<b>Total current liabilities</b>	<b>315,008</b>	<b>3,248,045</b>	<b>3,443,827</b>

## SUMMARY

	As of December 31,		As of
	2020	2021	May 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>2022</i>
			<i>RMB'000</i>
<b>Net current assets/(liabilities)</b>	146,747	(2,328,818)	(2,600,559)
<b>Total assets less current liabilities</b>	181,208	(2,187,752)	(2,425,806)
<b>Non-current liabilities</b>			
Deferred income	7,579	–	–
Lease liabilities	13,061	45,987	41,512
Preferred shares	1,430,383	38,823	42,511
<b>Total non-current liabilities</b>	1,451,023	84,810	84,023
<b>Net liabilities</b>	(1,269,815)	(2,272,562)	(2,509,829)
<b>Equity</b>			
Equity attributable to owners			
of the parent			
Share capital	37	57	57
Treasury shares	–	(27)	(27)
Deficits	(1,269,852)	(2,238,041)	(2,467,519)
	(1,269,815)	(2,238,011)	(2,467,489)
Non-controlling interests	–	(34,551)	(42,340)
<b>Total deficit</b>	(1,269,815)	(2,272,562)	(2,509,829)

We incurred net current liabilities of RMB2,328.8 million as of December 31, 2021, compared to net current assets of RMB146.7 million as of December 31, 2020, primarily due to the significant increase in Preferred Shares classified as current liabilities of RMB2,878.7 million resulted from the occurrence of first and second trigger events in the redemption rights under the shareholders’ agreement, which enables the preferred shareholders (except for series seed preferred shareholders) to request the Company to redeem all or a portion of the outstanding Preferred Shares (except for Series Seed Preferred Shares) at any time and from time to time on or after such occurrence. Our net current liabilities increased from RMB2,328.8 million as of December 31, 2021 to RMB2,600.6 million as of May 31, 2022, primarily due to (i) an increase in Preferred Shares classified as current liabilities of RMB140.0 million resulted from the fair value increase of such Preferred Shares; and (ii) a decrease in cash and bank

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## SUMMARY

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balances of RMB114.1 million primarily because we did not have equity financing in 2022 but continuously incurred cash expenditures in relation to the operating activities. Upon the [REDACTED], our financial position will turnaround to net current assets with the automatic and irrevocable conversion of such Preferred Shares into Ordinary Shares. For details of the trigger events of the Redemption Rights, please refer to note 26 of the Appendix I to this document.

We recorded net liabilities of RMB1,269.8 million, RMB2,272.6 million and RMB2,509.8 million as of December 31, 2020 and 2021 and May 31, 2022, respectively, mainly attributable to our Preferred Shares we recorded as liabilities of RMB1,645.6 million, RMB3,132.8 million and RMB3,276.4 million as of December 31, 2020 and 2021 and May 31, 2022, respectively. We expect to turn from a net liability position to a net asset position upon the automatic and irrevocable conversion of the Preferred Shares into Ordinary Shares on the [REDACTED] or at such time prior to the [REDACTED] as may be required to give effect to the [REDACTED] pursuant to applicable listing rules of Hong Kong Stock Exchange. For more details, please refer to the paragraphs headed “Financial Information – Description of Certain Key Items of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Fair Value Losses on Preferred Shares” in this document and note 26 of the Appendix I to this document.

Our net liabilities increased from RMB1,269.8 million as of December 31, 2020 to RMB2,272.6 million as of December 31, 2021, mainly reflecting changes in equity comprising (i) total comprehensive loss of RMB1,461.8 million; (ii) capital contribution from a non-controlling shareholder of a subsidiary of RMB321.1 million; and (iii) recognition of equity-settled share-based payments of RMB164.7 million. Our net liabilities further increased to RMB2,509.8 million as of May 31, 2022, mainly reflecting changes in equity comprising total comprehensive loss for the period of RMB293.4 million. For more information, please refer to consolidated statements of changes in equity included in the Accountants’ Report in Appendix I to this document.

### Summary Consolidated Statements of Cash Flows

Our uses of cash primarily compose of pre-clinical research and development expenses, clinical development expenses, and license-in related expenses. During the Track Record Period, we primarily funded our working capital requirements through capital contributions from our shareholders, private equity financing and other borrowings. We monitor and maintain a level of cash and cash equivalents deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. Our net cash used in operating activities was RMB278.3 million, RMB377.1 million and RMB112.9 million for the years ended December 31, 2020 and 2021, and for the five months ended May 31, 2022, respectively. As our business develops and expands, we expect to generate net cash from our operating activities, through the sales revenue of our future commercialized products. Going forward, we believe our liquidity requirements will be satisfied by using funds from a combination of our cash equivalents and cash and net [REDACTED] from the [REDACTED]. For the five months ended May 31, 2022, we had cash and cash equivalents of RMB660.2 million.

## SUMMARY

The following table sets forth information regarding our cash flows as of the dates indicated:

	Year Ended December 31,		Five Months Ended May 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Cash flows from operating activities before movements in working capital	(300,140)	(337,200)	(152,972)	105,445
Changes in working capital	21,811	(39,879)	24,979	7,451
Net cash flows used in operating activities	(278,329)	(377,079)	(127,993)	(112,896)
Net cash flows used in investing activities	(20,480)	(98,871)	(16,711)	(13,166)
Net cash flows from/(used in) financing activities	607,387	840,082	104,380	(6,335)
Net increase in cash and cash equivalents	308,578	364,132	(40,324)	(132,397)
Cash and cash equivalents at beginning of year/period	112,156	414,261	414,261	774,306
Effect of foreign exchange rate changes, net	(6,473)	(4,087)	(1,370)	18,322
<b>Cash and cash equivalents at end of the year/period</b>	<b>414,261</b>	<b>774,306</b>	<b>372,567</b>	<b>660,231</b>

We expect our net operating cash outflows position to improve concurrently with our profitability, mainly through (i) further increasing our sales of envafolimab, by, for example, expanding our sales and marketing team and covering more pharmacy stores; (ii) putting more efforts in receivables collection management in order to reduce our receivables so as to improve our working capital condition; and (iii) further improving our operational efficiency to enhance our working capital position by reviewing regularly and updating our liquidity and funding policies to ensure that it is aligned with our business plan and financial position, and preparing cash flow and funding summaries on a regular basis to monitor our cash flow.



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## SUMMARY

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The Directors are of the opinion that, taking into account the financial resources available to our Group, including cash and cash equivalents, internally generated funds and the estimated net [REDACTED] from the [REDACTED], we have sufficient working capital to cover at least 125% of our costs, including research and development expenses, distribution costs, administrative expenses, and other operating costs, for at least the next 12 months from the date of this document.

Our cash burn rate refers to the average monthly aggregate amount of (i) net cash used in operating activities, including research and development expenses; (ii) payment for property, plant and equipment; (iii) interest paid; (iv) purchase amount of intangible assets; and (v) lease payment. Assuming that the average cash burn rate going forward of 1.9 times the level in 2021, which is primarily based on the difference between the average monthly burn rate in 2022 and the nine months ended September 30, 2023, we estimate that our cash and cash equivalents as of May 31, 2022 will be able to maintain our financial viability for approximately 9.6 months or, if we also take into account the estimated net [REDACTED] (based on the low-end of the indicative [REDACTED]) from the [REDACTED], for approximately 33.3 months. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development status. We expect to raise our next round of financing, if needed, with a minimum buffer of 12 months after the [REDACTED].

### KEY FINANCIAL RATIO

The following table sets forth the components of our key financial ratio as of the dates indicated:

	<u>As of December 31,</u>		<u>As of</u>
	<u>2020</u>	<u>2021</u>	<u>May 31,</u>
			<u>2022</u>
Current ratio <sup>(1)</sup>	1.5	0.3	0.2

*Note:*

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

The current ratio of the Company amounted to 1.5, 0.3 and 0.2 as of December 31, 2020 and 2021 and May 31, 2022, respectively. The decreasing trend of the current ratio during the Track Record Period was primarily because we reclassified large amount of Preferred Shares from non-current liabilities to current liabilities in 2021 and 2022. Upon the [REDACTED], such Preferred Shares will be converted into ordinary Shares, and our current liabilities are expected to decrease significantly. For more information on our key financial ratio, please refer to the paragraphs headed “Financial Information – Key Financial Ratio.”

## SUMMARY

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### SUMMARY OF MATERIAL RISK FACTORS

Our business faces risks including those set out in the section headed “Risk Factors.” As different investors 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 invest in the [REDACTED]. Some of the major risks that we face include:

- We face substantial competition in the entire oncology market and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do.
- The market opportunities for our Core Product may be small as it mainly targets late line treatment for most of its targeted indications and is limited to those patients who have failed prior treatments.
- Our business and financial prospects depend substantially on the success of our products, clinical-stage and pre-clinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain their regulatory approvals or achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.
- We have incurred net losses since inception, and expect to continue to incur significant net losses for the foreseeable future and we may not be able to generate sufficient revenue to achieve or maintain profitability.
- We have entered into collaborations with our partners and may form or seek additional collaborations or strategic alliances or enter into additional licensing arrangements in the future. We may not realize any or all benefits of such alliances or licensing arrangements, and disputes may arise between us and our collaboration partners.
- If our drug candidates or our collaborators’ data fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.
- If we are unable to obtain and maintain adequate patent protection for our product and 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 any of our future approved products or technologies would be materially adversely affected.

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## SUMMARY

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You should read the entire section headed “Risk Factors” in this document before you decide to invest in the [REDACTED].

### RECENT DEVELOPMENTS

Our Preferred Shares, classified as liabilities, affect and will continue to affect our financial performance until the automatic and irrevocable conversion of such Preferred Shares into Ordinary Shares on the [REDACTED] or at such time prior to the [REDACTED] as may be required to give effect to the [REDACTED] pursuant to applicable listing rules of Hong Kong Stock Exchange. The Company expects to incur net loss for the year ended December 31, 2022 due to the continuous research and development activities and recognition of fair value losses on Preferred Shares for the period before the [REDACTED] or at such time prior to the [REDACTED] as may be required to give effect to the [REDACTED] pursuant to applicable listing rules of Hong Kong Stock Exchange.

### OUTBREAK OF COVID-19

Since December 2019, the outbreak of a novel strain of coronavirus causing coronavirus disease 2019 (COVID-19) has materially and adversely affected the global economy. Since late July 2021, the COVID-19 has recurred in the form of the Delta variant in China and overseas, and since November 2021, another variant designated as Omicron (together with the Delta variant, the “COVID-19 Variants”) has also been discovered in many cases over the globe (the “Recurrences”). Recently, the Chinese government has implemented emergency measures in certain cities or regions, including Shanghai, in response to the Recurrence, including travel restrictions, mandatory cessations of business operations, mandatory quarantines, and limitations on social and public gathering and lockdowns.

While we experienced delays in the patient enrollment process and data entry for certain of our clinical trials in China (including the temporary delays in the patient enrollment in Shanghai since March 2022), the outbreak of COVID-19 and the Recurrences have not caused any early termination of our clinical trials or necessitated removal of any patients enrolled in our clinical trials. We have employed various measures to mitigate any impact the COVID-19 outbreak and the Recurrences may have on our ongoing clinical trials in China, including providing alternative methods for safety and efficacy assessment, continuing patient visit through remote access, supplying enrolled patients with study medication through monitored delivery process, and engaging necessary communications with our investigators to identify and address any issues that may arise. For our U.S. and Japan trials, we did not experience any material difficulties arising from the outbreak of COVID-19 and the Recurrences in our patient enrollment and trial management, and the progress of those trials is generally in line with our trial development plan despite minor delays. Based on the foregoing, we currently expect that our ongoing clinical trials will not be significantly affected by the outbreak of COVID-19 and the Recurrences. We may adjust our current clinical development plan covering multiple jurisdictions to the extent necessary depending on the status of the COVID-19 outbreak and the Recurrences worldwide. Currently, we do not expect it to have any material long-term impact on data quality of our clinical trials or our overall clinical development plans.

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## SUMMARY

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Our Directors have carried out a holistic review of the impact of the COVID-19 outbreak and the Recurrences on our operations, and confirmed that the COVID-19 outbreak and the Recurrences did not have any long-term material adverse impact on our business operation and financial performance as of the Latest Practicable Date, mainly because (i) the Recurrences are less severe in terms of its lower modality rate and higher curability rate than the early outbreak and (ii) the Chinese government authorities have responded quickly to the COVID-19 and the Recurrences and made controlling efforts timely. However, due to the prevalence of the Recurrences in Shanghai since March 2022, as of the Latest Practicable Date, we had experienced temporary delays in the patient enrollment in Shanghai and our sales activities in Shanghai had been temporarily affected. We have mobilized and will continue to mobilize internal and external resources and leveraged our operating capabilities to minimize the impact on our operations caused by the COVID-19 outbreak and the Recurrences.

The above analyses are made by our management based on currently available information concerning COVID-19 and the Recurrences. It is uncertain whether the continuance or future recurrence of the COVID-19 outbreak in China, the U.S., Japan or the rest of the world will have a material adverse effect on our results of operations, financial position or prospects. For example, with the ongoing COVID-19 outbreak and the Recurrences around the world, we cannot assure you that our clinical development plan covering multiple jurisdictions including the China, the U.S. and Japan will not be adversely affected. For more details, please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Operations – We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control, including the COVID-19 outbreak, which may have a material adverse effect on our business, financial condition and results of operations” in this document. We will continue to monitor and evaluate any impact of the COVID-19 outbreak and the Recurrences on us and adjust our precautionary measures according to the latest developments of the outbreak.

## REGULATORY DEVELOPMENT ON OVERSEAS LISTING

On December 24, 2021, the China Securities Regulatory Commission (中國證券監督管理委員會) (the “CSRC”) released the Administrative Provisions of the State Council on the Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (《國務院關於境內企業境外發行證券和上市的管理規定(草案徵求意見稿)》) and the Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for comments) (《境內企業境外發行證券和上市備案管理辦法(徵求意見稿)》) (collectively the “**Draft Regulations on Overseas Listing**”) for public comments until January 23, 2022.

The Draft Regulations on Overseas Listing, if adopted in their current form, will regulate both direct and indirect overseas offering and listing of PRC domestic companies by adopting a filing-based regulatory regime. Pursuant to the Draft Regulations on Overseas Listing, the issuers who meet the following criteria seeking to offer their securities or list overseas will be deemed as indirect overseas offering by PRC domestic companies: (a) whose PRC domestic operating entity generated more than 50% of the total assets, net assets, revenues or profits as shown in the issuer’s audited consolidated financial statements in the most recent accounting

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## SUMMARY

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year, and (b) whose senior management in charge of business operation and management are mostly Chinese citizens or have domicile in China, and whose main places of business are located in China or main business activities are conducted in China. PRC domestic companies that directly or indirectly seek to offer or list their securities overseas are required to file with the CSRC within 3 working days after submitting their application documents to the regulator in the place of intended listing or offering. In addition, according to the Draft Regulations on Overseas Listing, overseas offerings and listings (i) that are prohibited by specific laws and regulations, (ii) that constitute threat to or endanger national security as reviewed and determined by competent authorities, (iii) that involve material ownership disputes, (iv) where the PRC domestic companies, their controlling shareholder or actual controller are convicted of or investigated for certain criminal offences, or directors, supervisors and senior management of the issuer involved in certain criminal offences or severe administrative penalties (together the “**Forbidden Circumstances**”), among other circumstances, are explicitly forbidden.

As of the Latest Practicable Date, the Draft Regulations on Overseas Listing were released for public comments only and the final version and effective date of such regulations are subject to substantial uncertainties. Therefore, the [REDACTED] is currently not subject to any filing procedures with, or approval from, the CSRC. As of the Latest Practicable Date, we had not received any inquiries, notices, warnings, or sanctions regarding the [REDACTED] from the CSRC or any other PRC government authorities in terms of compliance with the proposed filing requirement under the new regulatory regime, if enacted. To our Directors’ best knowledge, we are not aware of the existence of any circumstances that would prohibit us from conducting overseas [REDACTED] and [REDACTED] under the Draft Regulations on Overseas Listing. Therefore, if the Draft Regulations on Overseas Listing become effective in their current form before the [REDACTED] is completed, other than the uncertainties of the filing procedures which may be further clarified in the final version of the Draft Regulations on Overseas Listing and/or their implementation rules, we do not foresee any impediment for us to comply with the Draft Regulations on Overseas Listing in any material respects.

### OUR SINGLE LARGEST SHAREHOLDER AND SHAREHOLDERS INFORMATION

Since the inception of our Group, Dr. Gong, our Key Founder and single largest shareholder, has been responsible for the strategic and operational management of our Group. As of the Latest Practicable Date, Dr. Gong is able to exercise [31.06]% voting rights in our Company through (i) Dragon Prosper Holdings Limited, his holding entity, and (ii) the share incentive platforms, namely Immunal Medixin US Limited, Immunal Medixin Cino L. Limited and Immunal Medixin Cino Limited, which are managed by a trustee who shall exercise voting rights in accordance with Dr. Gong’s instructions. Please refer to the paragraphs headed “History, Development and Corporate Structure – Share Incentive Scheme” for more details.

Immediately following the completion of the [REDACTED], Dr. Gong will be interested in approximately [REDACTED]% of our issued share capital, assuming the [REDACTED] is not exercised.

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## SUMMARY

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Our significant shareholders include sophisticated investors, such as dedicated healthcare funds and biotech funds, as well as long-term private equity funds with a focus on investments in the biopharmaceutical sector.

Our Company received several rounds of Pre-[REDACTED] Investments, including the 2019 Financing, the 2020 Financing and the 2021 Financing. We raised a total of approximately US\$229.9 million through the Pre-[REDACTED] Investments. Our Pre-[REDACTED] Investors will be subject to lockup arrangements at the time of the [REDACTED]. Generally, under these lock-up arrangements, each Pre-[REDACTED] Investor will not, at any time during the period commencing on the date of this document and ending on the last day of six (6) months from the [REDACTED], offer, pledge, sell, transfer or otherwise dispose of their Shares. Our Pre-[REDACTED] Investors includes sophisticated investors, such as dedicated healthcare funds and biotech funds as well as established funds with a focus on investments in the biopharmaceutical sector. [Five] of our Pre-[REDACTED] Investors, namely Tigermed, Simcere, Shenzhen Efung, Guofeng and Hillhouse, are sophisticated investors pursuant to Guidance Letter HKEX-GL92-18 issued by the Stock Exchange. Upon completion of the [REDACTED], assuming that the [REDACTED] is not exercised, Tigermed, Simcere, Shenzhen Efung, Guofeng and Hillhouse will hold approximately [REDACTED]%, [REDACTED]%, [REDACTED]%, [REDACTED]% and [REDACTED]% of the total share capital of our Company, respectively. For further details, please see “History, Development and Corporate Structure – Pre-[REDACTED] Investments – Information Regarding the Pre-[REDACTED] Investors” in this document.

### DIVIDEND POLICY

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 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 Articles of Association provide that dividends may be declared and paid out of the profits of our Company, realised or unrealised, or from any reserve set aside from profits which the Directors determine is no longer needed. With the sanction of an ordinary resolution dividends may also be declared and paid out of our share premium account or any other fund or account which can be authorised for this purpose in accordance with the Cayman Companies Act. No dividend may be paid out of our share premium account unless immediately following the date on which the dividend is proposed to be paid, our Company will be able to pay its debts as they fall due in the ordinary course of business. In light of our accumulated losses as disclosed in this document, it is unlikely that we will be eligible to pay a dividend out of our profits in the foreseeable future. We may, however, pay a dividend out of our share premium account provided that, immediately following the date on which the dividend is proposed to be paid, our Company will be able to pay its debts as they fall due in

## SUMMARY

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the ordinary course of business. There is no assurance that dividends of any amount will be declared to be distributed in any year. For more details, please refer to the paragraphs headed “Financial Information – Dividends” in this document.

### THE [REDACTED]

The [REDACTED] by us consists of:

- the offer by us of initially [REDACTED] Shares, or [REDACTED], for [REDACTED] in Hong Kong, referred to in this document as the [REDACTED]; and
- the offer by us of initially [REDACTED] Shares, or [REDACTED], outside the United States (including to professional, institutional and other investors within Hong Kong) in offshore transactions in reliance on [REDACTED] and in the United States to [REDACTED] in reliance on [REDACTED] or another exemption from the registration requirements under the U.S. Securities Act, referred to in this document as the [REDACTED].

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

### APPLICATION FOR [REDACTED] ON THE STOCK EXCHANGE

We have applied to the Listing Committee of the Hong Kong Stock Exchange for the granting of [REDACTED] of, and permission to [REDACTED] in, the Shares in issue and [REDACTED] pursuant to the [REDACTED] (including any additional Shares which may be issued pursuant to the exercise of the [REDACTED]).

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## SUMMARY

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### [REDACTED] STATISTICS

	Based on the [REDACTED] of HK\$[REDACTED]	Based on the [REDACTED] of HK\$[REDACTED]
Market [REDACTED] of our Shares <sup>(2)</sup>	HK\$[REDACTED]	HK\$[REDACTED]
Pro forma adjusted consolidated net tangible assets of the Group attributable to owners of the Company per Share <sup>(3)</sup>	HK\$[REDACTED]	HK\$[REDACTED]

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*Notes:*

- (1) All statistics in this table are on the assumption that the [REDACTED] are not exercised.
- (2) The calculation of market [REDACTED] is based on [REDACTED] Shares expected to be in issue immediately after completion of the [REDACTED].
- (3) The unaudited pro forma adjusted consolidated net tangible assets per Share is calculated on the basis that [REDACTED] Shares are in issue, assuming the [REDACTED] has been completed on [REDACTED]. The unaudited pro forma adjusted consolidated net tangible assets per Share is converted into HK\$ at an exchange rate of HK\$1.00 to RMB0.8592 prevailing on July 18, 2022.

### USE OF [REDACTED]

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

- (a) approximately 80%, or HK\$[REDACTED], will be used primarily for the research and development, regulatory filings and commercialization of our product and drug candidates:
  - (i) approximately 40%, or HK\$[REDACTED], will be used for our Core Product envafolimab, including:
    - (a) approximately 16.0% or HK\$[REDACTED], will be used for ongoing and planned clinical trials to evaluate envafolimab for the treatment of UC, TMB-H, EC and other solid tumors;



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## SUMMARY

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- (b) approximately 18.2% or HK\$[REDACTED], will be used for ongoing and planned clinical trials to evaluate envafolimab as combinational therapies for the treatment of HCC, RCC, NSCLC, BTC and other solid tumors;
  - (c) approximately 0.4% or HK\$[REDACTED], will be used for marketing business development (including employee salary, employee training, and procurement service), and the maintenance and management of envafolimab as its MAH holder; and
  - (d) approximately 5.4% or HK\$[REDACTED], will be used for expanding our production-lines, including procurement of production equipment, procurement of active pharmaceutical ingredients, procurement of pre-filled syringe, packing materials accessory ingredients, commissioning and production debugging, and setting up of personnel and quality management system.
- (ii) approximately 25%, or HK\$[REDACTED], will be used for our other drug candidates, including those in various clinical development stages, including 3D189, 3D229, 3D1001, 3D1002, 3D011, 3D185, 3D197 and other drug candidates; and those in early-stage drug discovery and development, pre-clinical studies; and
  - (iii) approximately 15%, or HK\$[REDACTED], will be used for (a) the construction of our in-house production facilities in Xuzhou, Jiangsu province (and for more information, please refer to the paragraphs headed “Business – Production and Quality Control” in this document); (b) the procurement of new machineries, instruments and equipment; and (c) the recruitment and training of manufacturing talents and the procurement of professional service;
- (b) approximately 10%, or HK\$[REDACTED], will be used to fund our business development activities, the expansion of our drug pipeline and portfolio, and the potential acquisition of high value and differentiated innovative assets and/or equities, if practicable; and
  - (c) approximately 10%, or HK\$[REDACTED], will be used for our general corporate and working capital purposes.

For more details, please refer to the section headed “Future Plan and Use of [REDACTED]” in this document.

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## SUMMARY

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### [REDACTED] EXPENSES

[REDACTED] expenses represent professional fees, [REDACTED] commissions and other fees incurred in connection with the [REDACTED]. [REDACTED] expenses to be borne by us are estimated to be approximately RMB[REDACTED] (HK\$[REDACTED]) (assuming the [REDACTED] is not exercised and based on the [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the [REDACTED] range), including (i) [REDACTED]-related expenses, including [REDACTED] commissions and fees of approximately RMB[REDACTED] (HK\$[REDACTED]), and (ii) non-[REDACTED]-related expenses of approximately RMB[REDACTED] (HK\$[REDACTED]), comprising (a) fees and expenses of legal advisors and reporting accountants of approximately RMB[REDACTED] (HK\$[REDACTED]) and (b) other fees and expenses of approximately RMB[REDACTED] (HK\$[REDACTED]).

Our [REDACTED] expenses as a percentage of gross [REDACTED] estimated to be received by us from the [REDACTED] is [REDACTED]%, assuming an [REDACTED] of HK\$[REDACTED] per Share (being the mid-point of the indicative [REDACTED] range stated in this document) and assuming that the [REDACTED] is not exercised. In 2020 and 2021 and for the five months ended May 31, 2022, the [REDACTED] expenses charged to profit or loss were RMB[REDACTED], RMB[REDACTED] and RMB[REDACTED], respectively. After May 31, 2022, we estimate that additional [REDACTED] expenses of approximately RMB[REDACTED] will be incurred by our Company, approximately RMB[REDACTED] of which is expected to be charged to our consolidated statements of profit or loss, and approximately RMB86.4 million of which is expected to be recognized directly as a deduction from equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

## DEFINITIONS

*In this document, the following expressions shall have the meanings set out below unless the context otherwise requires.*

- “2019 Investors” the holders of Series D Preferred Shares of our Company, namely Dragon Prosper Holdings Limited, Simcere Pharmaceutical Group Limited, Hangzhou Tigermed Equity Investment Partnership (Limited Partnership) (杭州泰格股權投資合夥企業(有限合夥)), Shanghai Zhenlu Enterprise Management Consulting Partnership (Limited Partnership) (上海甄路企業管理諮詢合夥企業(有限合夥)), China Securities (International) Finance Company Limited (中信建投(國際)財務有限公司), Smilegate Pathfinder Fund, Lucion VC 3 Limited, Powerful Kirin Limited, Golden Sail Ventures Limited, Tao Qiling, Grow Lighthouse Project Company Limited, Rui Xia Investment Holding Limited (上海瑞夏投資管理有限公司), Rainbow Beauty International Limited, Shenzhen Bo Rong Gong Ying No. 3 Investment Corporation (Limited Partnership) (深圳博榮共盈三號投資企業(有限合夥)), Gongqingcheng Hyde Dingchuang Investment Partnership (Limited Partnership) (共青城海德鼎創投資合夥企業(有限合夥)), Shanghai Xing Zhi Mang Information Technology Partners LP (上海星之芒信息科技合夥企業(有限合夥)) and Weifang Datron CNC Equipment Co., Ltd (濰坊達創數控設備有限公司)
- “2020 Investors” the holders of Series D+ Preferred Shares of our Company, namely Xuzhou Zhenxin Venture Capital Co., Ltd. (徐州臻心創業投資有限公司) and Zhuhai Hengqin Xingrui Yuanhang Investment Center (Limited Partnership) (珠海橫琴興銳遠航投資中心(有限合夥))
- “2021 Investors” the holders of Series E Preferred Shares of our Company, namely GSUM VIII Holdings Limited, U-Tiger Global Strategic International Placement Fund S.P., Hongkong Tigermed Co., Limited, JMC Capital HK LIMITED, Smilegate Global Unicorn 1st Venture Fund, Raderwo Limited, Chariot Spc Fund – Wanhai Balance Fund SP, Advantech Capital Investment XVIII Limited, Able Legend Development Limited and Coast Town Limited

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## DEFINITIONS

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“3DMed Beijing”	3D Medicines (Beijing) Co., Ltd.* (思路迪(北京)醫藥科技有限公司), a limited liability company incorporated under the laws of the PRC on December 22, 2014, being an indirect subsidiary of the Company
“3DMed Hong Kong”	3D Medicines (Hong Kong) Co., Limited (思路迪醫藥科技(香港)有限公司), a limited company incorporated under the laws of Hong Kong on February 8, 2018, being an indirect wholly-owned subsidiary of the Company
“3DMed Qingdao”	3D Medicines (Qingdao) Co., Ltd.* (思路迪醫藥(青島)有限公司), a limited liability company incorporated under the laws of the PRC on June 18, 2021, being an indirect wholly-owned subsidiary of the Company
“3DMed Shanghai”	3DMed Shanghai Pharmaceutical Technology Co., Ltd.* (思路迪(上海)醫藥科技有限公司), a limited liability company incorporated under the laws of the PRC on April 13, 2017, being an indirect subsidiary of the Company
“3DMed Sichuan”	Sichuan 3DMed-Alphamab Co., Ltd.* (四川思路康瑞藥業有限公司), a limited liability company incorporated under the laws of the PRC on March 16, 2016, being an indirect subsidiary of the Company
“3DMed Xuzhou”	Xuzhou 3D Medicines Pharmaceutical Co., Ltd.* (徐州思路迪藥業有限公司), a limited liability company incorporated under the laws of the PRC on November 26, 2020, being an indirect wholly-owned subsidiary of the Company
“3D Medicines”	3D Medicines Biotechnology (Shanghai) Co., Ltd.* (思路迪生物醫藥(上海)有限公司), a limited liability company incorporated under the laws of the PRC on September 10, 2015, formerly known as Zhaosi Biotechnology (Shanghai) Co., Ltd.* (兆思生物技術(上海)有限公司), which is owned as to 89.40%, 0.06% and 10.54% by 3DMed Hong Kong, Integral Lane and Qingdao Hainuo Investment Development Co., Ltd.* (青島海諾投資發展有限公司), respectively
“affiliate(s)”	any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person

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## DEFINITIONS

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“Alphamab Group” Alphamab Oncology (康寧傑瑞生物製藥), an exempted company with limited liability incorporated under the laws of the Cayman Islands on March 28, 2018 and listed on the Stock Exchange (stock code: 9966), and its subsidiaries, each of which is an Independent Third Party

[REDACTED]

“Aravive” Aravive Inc., a clinical-stage oncology company incorporated in the U.S. on December 10, 2008 and listed on the Nasdaq Stock Market (stock code: ARAV), which is an Independent Third Party

“Articles” or “Articles of Association” our articles of association, as conditionally adopted on [●] and which will come into effect on the [REDACTED] (as amended, supplemented or otherwise modified from time to time), a summary of which is set out in Appendix III to this document

“associate(s)” has the meaning ascribed thereto under the Listing Rules

“Board” or “Board of Directors” our board of Directors

“Business Day” a day that is not a Saturday, Sunday or public holiday in Hong Kong

“CAGR” compound annual growth rate

[REDACTED]

“Cayman Companies Act” the Companies Act (2022 Revision) of the Cayman Islands as amended, supplemented or otherwise modified from time to time

“CCASS” the Central Clearing and Settlement System established and operated by HKSCC

“CCASS Clearing Participant” a person admitted to participate in CCASS as a direct clearing participant or a general clearing participant

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## DEFINITIONS

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“CCASS Custodian Participant”	a person admitted to participate in CCASS as a custodian participant
“CCASS Investor Participant”	a person admitted to participate in CCASS as an investor participant, which may be an individual, joint individuals or a corporation
“CCASS Operational Procedures”	the Operational Procedures of HKSCC in relation to CCASS, containing the practices, procedures and administrative requirements relating to operations and functions of CCASS, as from time to time in force
“CCASS Participant”	a CCASS Clearing Participant, a CCASS Custodian Participant or a CCASS Investor Participant
“China” or “the PRC”	the People’s Republic of China excluding, for the purposes of this document, Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan region
“close associate(s)”	has the meaning ascribed thereto 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” or “our Company”	3D Medicines Inc., an exempted company incorporated with limited liability under the laws of the Cayman Islands on January 30, 2018
“connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“core connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“Core Product”	envafolimab, the designated “Core Product” as defined under Chapter 18A of the Listing Rules
“Director(s)”	the director(s) of our Company or any one of them

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## DEFINITIONS

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“Dr. Gong”	Dr. Gong Zhaolong (龔兆龍), the chairman of the Board, executive Director and chief executive officer of the Company and the Key Founder of the Group
“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the government of Hong Kong
“FRC”	the Financial Reporting Council, the full-fledged independent auditor regulator of Hong Kong established under the Financial Reporting Council Ordinance (Chapter 588 of the Laws of Hong Kong)
“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent market research and consulting company
“Frost & Sullivan Report”	the industry report commissioned by us and independently prepared by Frost & Sullivan, summary of which is set forth in the section headed “Industry Overview” in this document
“Full Goal”	Full Goal Trading Limited, a business company incorporated under the laws of the British Virgin Islands on January 30, 2018, being a direct wholly-owned subsidiary of the Company
“General Rules of CCASS”	General Rules of CCASS published by the Stock Exchange and as amended from time to time

[REDACTED]

“Group”, “our Group”, “our”, “we”, or “us”	the Company and all of its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
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## DEFINITIONS

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“Haihe Biopharma”	Haihe Biopharma Research and Development Co., Ltd.* (上海海和藥物研究開發股份有限公司) (formerly known as Haihe Biopharma Research and Development Limited.* (上海海和藥物研究開發有限公司)), a limited liability company incorporated in the PRC on March 11, 2011, which is an Independent Third Party
“Haihe Biopharma Group”	Haihe Biopharma and its subsidiaries, each of which is an Independent Third Party

[REDACTED]

“HKSCC”	the Hong Kong Securities Clearing Company Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited
“HKSCC Nominees”	HKSCC Nominees Limited, a wholly owned subsidiary of the HKSCC
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong dollars” or “HK dollars” or “HK\$”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong

[REDACTED]



## DEFINITIONS

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

[REDACTED]

“Independent Third Party” or “Independent Third Parties”      a person or entity who is not a connected person of the Company under the Listing Rules

“Integral Lane”      Integral Lane Holdings Limited, a business company incorporated under the laws of the British Virgin Islands on April 17, 2018, being an indirect wholly-owned subsidiary of the Company

[REDACTED]

## DEFINITIONS

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[REDACTED]

“ImmuneOncia”

ImmuneOncia Therapeutics, Inc., an immuno-oncology-centric biopharmaceutical company incorporated in South Korea on March 2, 2016, which is an Independent Third Party

[REDACTED]

“Joint Sponsors”

the joint sponsors as named in the section headed “Directors and Parties Involved in the [REDACTED]” of this document

“Key Founder”

Dr. Gong, the chairman of our Board, an executive Director and our chief executive officer, who founded our biotechnology business

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## DEFINITIONS

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“Latest Practicable Date” July 18, 2022, being the latest practicable date for the purpose of ascertaining certain information contained in this document prior to its publication

[REDACTED]

“Listing Committee” the listing committee of the Stock Exchange

[REDACTED]

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

“Longteng Medicines” Longteng Medicines (Jiangsu) Co., Ltd.\* (龍騰藥業(江蘇)有限公司), a limited liability company incorporated in the PRC on March 30, 2021, being an indirect wholly-owned subsidiary of the Company

“Main Board” the stock market (excluding the option market) operated by the Hong Kong Stock Exchange which is independent from and operated in parallel with the Growth Enterprise Market of the Stock Exchange

“Memorandum” or  
“Memorandum of Association” our memorandum of association, as conditionally adopted on [●] and which will come into effect on the [REDACTED] (as amended, supplemented or otherwise modified from time to time), a summary of which is set out in Appendix III to this document

“NMPA” China National Medical Products Administration (國家藥品監督管理局), successor to the China Food and Drug Administration (國家食品藥品監督管理總局) (the “CFDA”)

## DEFINITIONS

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[REDACTED]

“PMDA”	Pharmaceuticals and Medical Devices Agency of Japan
“Preferred Shares”	Series Seed Preferred Shares, Series A Preferred Shares, Series A+ Preferred Shares, Series B Preferred Shares, Series B+ Preferred Shares, Series C Preferred Shares, Series D Preferred Shares, Series D+ Preferred Shares and Series E Preferred Shares of our Company and/or any one of them as the context may require
“Pre-[REDACTED] Investments”	the 2019 Financing, the 2020 Financing and the 2021 Financing of our Company, details of which are set out in the paragraph headed “History, Development and Corporate Structure – Pre-[REDACTED] Investments” in this document

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## DEFINITIONS

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“Pre-[REDACTED] Investors”	the 2019 Investors, the 2020 Investors, the 2021 Investors and CNCB (Hong Kong) Investment Limited
“Qualified Institutional Buyers” or “QIBs”	qualified institutional buyers within the meaning of Rule 144A under the U.S. Securities Act
“Regulation S”	Regulation S under the U.S. Securities Act
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“Rule 144A”	Rule 144A under the U.S. Securities Act
“SELLAS Group”	SELLAS Life Sciences Group, Inc., a late-stage clinical biopharmaceutical company incorporated in the U.S. on April 3, 2006 and listed on the Nasdaq Stock Market (stock code: SLS), and its subsidiaries, each of which is an Independent Third Party
“SFC”	the Securities and Futures Commission of Hong Kong
“SFO”	the Securities and Futures Ordinance, Chapter 571 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
“Share(s)” or “Ordinary Share(s)”	ordinary share(s) in the capital of our Company with a nominal or par value of HK\$0.001 each
“Shareholder(s)”	holder(s) of the Share(s)
“Share Subdivision”	the subdivision of each issued and unissued shares of our Company of par value HK\$0.01 into 10 shares of par value of HK\$0.001, which was completed in June 2021
“Sincere”	Sincere Pharmaceutical Group Limited (先聲藥業集團有限公司) (formerly known as Sincere Pharmaceutical (Hong Kong) Limited (先聲藥業(香港)有限公司) and Sound & Sincere Investment Limited (興聲投資有限公司)), a private company limited by shares incorporated under the laws of Hong Kong on November 30, 2015 and listed on the Stock Exchange (stock code: 2096), an Independent Third Party
“Sincere Group”	Sincere and its subsidiaries, each of which is an Independent Third Party

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## DEFINITIONS

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“SIMM” Shanghai Institute of Materia Medica, Chinese Academy of Sciences (中國科學院上海藥物研究所)

[REDACTED]

“subsidiary” has the meaning ascribed thereto under the Listing Rules

“substantial shareholder(s)” has the meaning ascribed thereto under the Listing Rules

“Takeovers Code” the Code on Takeovers and Mergers and Share Buy-backs, as published by the SFC (as amended, supplemented or otherwise modified from time to time)

“Track Record Period” the two years ended December 31, 2020 and 2021 and the five months ended May 31, 2022

“TRACON” TRACON Pharmaceuticals, Inc., a leading biopharmaceutical company incorporated in the U.S. on October 28, 2004 and listed on the Nasdaq Stock Market (stock code: TCON), which is an Independent Third Party

[REDACTED]

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

“U.S. dollars”, “US\$” or “USD” United States dollars, the lawful currency of the United States

“U.S. Securities Act” the U.S. Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder

“Y-Biologics” Y-Biologics Inc., a biotech company focusing on the discovery and development of novel antibody therapeutics incorporated in South Korea in 2007, which is an Independent Third Party

“Zhaosi Technology” Zhaosi Biotechnology (Shanghai) Co., Ltd.\* (兆思生物技術(上海)有限公司), the former name of 3D Medicines

\* For identification purpose only

## DEFINITIONS

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In this document, the terms “associate,” “close associate,” “connected person,” “core connected person,” “connected transaction,” “subsidiaries” and “substantial shareholder” shall have the meanings given to such terms in the Listing Rules, unless the context otherwise requires.

Certain amounts and percentage figures included in this document have been subject to rounding. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them. Any discrepancies in any table or chart between the total shown and the sum of the amounts listed are due to rounding.

For ease of reference, the names of the PRC established companies or entities, laws or regulations have been included in this document in both the Chinese and English languages; in the event of any inconsistency, the Chinese versions shall prevail.

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## GLOSSARY

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*In this document, in addition to terms defined elsewhere and unless the context otherwise requires, the following technical terms have the following meanings.*

“ADCC”	antibody-dependent cell-mediated cytotoxicity
“ADP”	adenosine diphosphate
“AEs”	adverse events, any untoward medical occurrences in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
“Ags”	antigens
“ALL”	acute lymphoblastic leukemia, a type of cancer of the lymphoid line of blood cells characterized by the development of large numbers of immature lymphocytes
“allo-HSCT”	allogeneic hematopoietic stem cell transplantation, a procedure in which a portion of a healthy donor’s stem cell or bone marrow is obtained and prepared for intravenous infusion
“alanine aminotransferase”	a liver enzyme that is released in the blood where liver cells are damaged; the blood test for ALT is used to diagnose liver disorders
“AML”	acute myeloid leukemia, a type of cancer that progresses rapidly and aggressively, and affects the bone marrow and blood
“anemia”	a condition characterized by a deficiency of red cells or haemoglobin in the blood, resulting in pallor, weariness and even more serious conditions such as multiple organ failure
“angiogenesis”	the growth of blood vessels, which involves the migration, growth, and differentiation of endothelial cells, which line the inside wall of blood vessels.



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## GLOSSARY

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“ankylosing spondylitis”	a type of arthritis in which there is long term inflammation of the joints of the spine. Typically the joints where the spine joins the pelvis are also affected. Occasionally other joints such as the shoulders or hips are involved. Eye and bowel problems may also occur. Back pain is a characteristic symptom of AS, and it often comes and goes. Stiffness of the affected joints generally worsens over time
“antibody”	also known as an immunoglobulin, a Y-shaped protein produced mainly by plasma cells to neutralize pathogens such as bacteria and viruses
“anti-PD-1 mAb”	monoclonal antibody targeting PD-1
“anti-tumor activity”	preventing or inhibiting the formation or growth of tumors
“APC”	Antigen-presenting cells
“ASCO”	The American Society of Clinical Oncology
“ASCT”	autologous stem cell transplantation
“assay”	an analysis done to determine (1) the presence of a substance and the amount of that substance and (2) the biological or pharmacological potency of a drug
“ATP”	adenosine triphosphate
“AUC”	area under curve, a parameter of systemic exposure
“AXL”	AXL is a receptor tyrosine kinase that transduces signals from the extracellular matrix into the cytoplasm <sup>28</sup> and regulates many physiological processes, including cell survival, proliferation, differentiation and immune responses
“BAT”	best available treatment
“BCR”	B-cell receptor, a specialized receptor protein that allows a B-cell to bind to specific antigens
“BID”	“ <i>bis in die</i> ”, Latin for twice daily

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## GLOSSARY

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“biliary tract”	an anatomical term for the path by which bile is secreted by the liver, then transported to the duodenum, or small intestine
“Bilirubin”	yellow compound that occurs in the normal catabolic pathway that breaks down heme in vertebrates
“biologic(s)”	any pharmaceutical drug product manufactured in, extracted from, or semi-synthesized from biological sources
“biomarker”	a naturally occurring molecule, gene, or characteristic by which a particular pathological or physiological process, disease, etc. can be identified
“biochemical”	relating to chemical composition of a particular living system or biological substance
“biopharmaceutical”	relating to medicines created by means of biotechnology
“biosimilar”	also known as follow-on biologic or subsequent entry biologic. It is a biologic medical product that is almost an identical copy of an original product that is manufactured by a different company. Biosimilars are officially approved versions of original “innovator” products and can be manufactured when the original product’s patent expires. A biosimilar product is similar in terms of quality, safety and efficacy to a reference medicinal product, which has been granted a marketing authorisation on the basis of a complete dossier in the community
“BIRC”	blinded independent radiology review
“bispecific antibody”	antibody that combines two antigen-recognizing elements into a single construct, able to bind to two different antigens at the same time
“BLA”	biologic license application
“BRAF”	B-Raf proto-oncogene, a gene that encodes a protein called B-Raf
“BTC”	biliary tract cancer

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## GLOSSARY

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“c-Met”	tyrosine-protein kinase Met or hepatocyte growth factor receptor, a protein that in humans is encoded by the MET gene
“capsules”	very small containers that are filled with medicine and swallowed whole
“carcinoma”	a type of cancer that develops from epithelial cells. Specifically, a carcinoma is a cancer that begins in a tissue that lines the inner or outer surfaces of the body, and that arises from cells originating in the endodermal, mesodermal or ectodermal germ layer during embryogenesis
“cardiovascular”	pertaining to the heart and blood vessels
“CBR”	clinical benefit rate
“ccRCC”	clear cell renal cell carcinoma
“CD20”	cluster of differentiation 20, a protein that is expressed on the surface of B cells, starting at the pre-B cell stage and also on mature B cells in the bone marrow and in the periphery
“CD3”	cluster of differentiation 3, a protein complex (enzyme) and T-cell co-receptor that is involved in activating both the cytotoxic T-cell and T helper cells
“CD4”	cluster of differentiation 4, a glycoprotein found on the surface of immune cells such as T helper cells
“CD47”	cluster of differentiation 47, a broadly expressed protein that costimulates T cells, facilitates leukocyte migration, and inhibits macrophage scavenger function
“CD8”	cluster of differentiation 8, a transmembrane glycoprotein that serves as a co-receptor for the T-cell receptor
“cell line”	a cell culture developed from a single cell and therefore consisting of cells with a uniform genetic makeup
“cGMP”	current Good Manufacturing Practice

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## GLOSSARY

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“chemotherapy” or “chemo”	a category of cancer treatment that uses one or more anti-cancer chemotherapeutic agents as part of its standardized regimen
“CI”	confidence interval
“clinical trial”	a research study for validating or finding the therapeutic effects and side effects of test drugs in order to determine the therapeutic value and safety of such drugs
“CMC”	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
“CMO(s)”	a contract manufacturing organization, which provides support to the pharmaceutical industry in the form of manufacturing services outsourced on a contract basis
“cohort”	a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time
“colon cancer”	a cancer of the colon or rectum, located at the digestive tract’s lower end
“combination therapy” or “combo”	treatment in which a patient is given two or more drugs (or other therapeutic agents) for a single disease
“compounds”	a substance consisting of two or more elements in union
“COX-1”	cyclooxygenases-1
“COX-2”	cyclooxygenases-2
“CSF-1R”	colony stimulating factor 1 receptor
“CR”	complete response or complete response rate, the disappearance of all signs of cancer in response to treatment
“CR1”	first complete remission
“CR2/CR2p”	second morphological complete remission, with or without adequate platelet recovery

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## GLOSSARY

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“CRC”	colorectal cancer, a type of cancer arising from the colon or rectum
“CREB”	cAMP-response element binding protein
“CRO(s)”	contract research organization, a company provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research and development services outsourced on a contract basis
“CTCAE”	Common Terminology Criteria for Adverse Events, a set of criteria, published by the National Cancer Institute, for the standardized classification of adverse effects of drugs used in cancer therapy
“CTL”	cytotoxic T lymphocytes, a T lymphocyte that kills cancer cells, cells that are infected (particularly with viruses), or cells that are damaged in other ways
“CYP”	cytochrome P-450
“cytokine”	a broad and loose category of small proteins that are important in cell signaling. Their release has an effect on the behavior of target cells
“cytotoxic”	toxic to living cells
“DCR”	disease control rate, the total proportion of patients who demonstrate a response to treatment, equal to the sum of complete responses, partial responses and stable disease
“DLT”	dose-limiting toxicity, side effects of a drug or other treatment that are serious enough to prevent an increase in dose of that treatment in clinical trial
“dMMR”	Mismatch repair deficiency
“DNA”	deoxyribonucleic acid
“DOR”	duration of response
“dose-escalation trial” or “dose-escalation study”	trials involving dose ranging to determine the best dose of the treatment

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## GLOSSARY

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“dose expansion trial” or “dose expansion study”	trials enrolling additional participants to typically further evaluate efficacy, safety, tolerability, PK, and pharmacodynamics
“doxorubicin”	a medicine developed in the 1950’s and used as a chemotherapy treatment of various cancers. It belongs to the anthracycline family, a class of medicine derived from Streptomyces bacteria
“EC”	endometrial cancer
“ECG”	electrocardiogram
“ECOG PS”	Eastern Cooperative Oncology Group Performance Status, a scale used to assess how a patient’s disease is progressing, assess how the disease affects the daily living abilities of the patient, and determine appropriate treatment and prognosis
“EGF”	epidermal growth factor
“EGFR”	epidermal growth factor receptor
“ELISA”	Enzyme-Linked Immunosorbent Assay
“endothelial”	cells that line the interior surface of blood vessels and lymphatic vessels, forming an interface between circulating blood or lymph in the lumen and the rest of the vessel wall
“EP”	E prostanoid receptor, including E prostanoid receptors 1–4
“EPRAP”	E receptor 4-associated protein
“ESMO”	the European Society for Medical Oncology
“Fc” or “Fc region”	fragment crystallizable region, which is the tail region of an antibody that interacts with cell surface receptors called Fc receptors and some proteins of the complement system
“FDA”	U.S. Food and Drug Administration

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## GLOSSARY

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“FGF”	fibroblast growth factor
“FGFR”	fibroblast growth factor receptor
“first-line” or “1L”	with respect to any disease, the first line therapy, which is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment. It is also called primary treatment or therapy
“FOLFOX”	fluorouracil plus oxaliplatin
“GAS”	growth arrest specific
“GAS6”	growth arrest specific 6
“gastrointestinal”	a subspecialty of internal medicine concerned with the study of the physiology and diseases of the digestive system
“gastrointestinal tract”	an organ system within humans and other animals which takes in food, digests it to extract and absorb energy and nutrients, and expels the remaining waste as feces
“G/GEJ”	gastric or gastroesophageal junction cancer
“GLP”	good laboratory practice
“GCP”	good clinic practice
“GC”	gastric cancer
“GEMOX”	gemcitabine plus oxaliplatin
“glioblastoma”	tumors that arise from astrocytes
“GMP”	good manufacturing practice, guidelines and regulations issued from time to time pursuant to the PRC Law on the Administration of Pharmaceuticals (《中華人民共和國藥品管理法》) as part of quality assurance which ensures that pharmaceutical products subject to these guidelines and regulations are consistently produced and controlled in conformity to the quality and standards appropriate for their intended use

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## GLOSSARY

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“GM-CSF”	granulocyte macrophage colony-stimulating factor
“GPS”	galinpepimut-S
“grade” or “G”	term used to refer to the severity of adverse events, using Grade 1, Grade 2, Grade 3, etc.
“granulocytes”	a white blood cell with secretory granules in its cytoplasm
“Hatch-Waxman”	the Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act, which is a 1984 U.S. federal law
“HCC”	hepatocellular carcinoma, a type of cancer arising from hepatocytes
“HLA”	human leukocyte antigen
“HM”	hematological malignancies
“HNSCC”	head and neck squamous cell carcinoma, a type of cancer arising from the mucous membranes of the mouth, nose, and throat and can spread to other parts of the body
“host cell”	an animal or plant cell on or in which a parasite or commensal organism lives
“HR”	hazard ratio
“hypertension”	a long-term medical condition in which blood pressure is persistently elevated
“ICAM-1”	intercellular adhesion molecule 1, also known as CD54 (cluster of differentiation 54). ICAM-1 is a protein that in humans is encoded by the ICAM1 gene. This gene encodes a cell surface glycoprotein which is typically expressed on endothelial cells and cells of the immune system. It binds to integrins of type CD11a/CD18, or CD11b/CD18 and is also exploited by rhinovirus as a receptor
“ICH”	the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use



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## GLOSSARY

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“IDMC”	Independent Data Monitoring Committee
“IHC”	immunohistochemistry, a test that uses a chemical dye to stain and measure specific proteins
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China
“indication”	a valid reason to use a certain test, medication, procedure or surgery
“infusion”	the therapeutic introduction of fluid other than blood into a vein
“IgG”	human immunoglobulin G, the most common antibody type found in blood circulation that plays an important role in antibody-based immunity against invading pathogens, which includes IgG1, IgG2, IgG3 and IgG4
“IMiDs”	immunomodulatory imide drugs, a class of immunomodulatory drugs that adjust immune responses, containing an imide group
“immune checkpoint inhibitor(s)” or “ICI(s)”	a type of drugs that block certain proteins made by some types of immune system cells, and some cancer cells, which help keep immune responses in check and allow immune cells to kill cancer cells
“immuno-oncology”	a type of immunotherapy that is specifically targeted to fight cancer
“immunogenicity”	the capability of being immunogenic
“immunoglobulin” or “Ig”	an antibody, also known as an immunoglobulin (Ig). It is a large, Y-shaped protein produced mainly by plasma cells that is used by the immune system to neutralize pathogens such as pathogenic bacteria and viruses. The antibody recognizes a unique molecule of the pathogen, called an antigen, via the Fab’s variable region
“immunotherapy”	a type of therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer, infection, and other diseases

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## GLOSSARY

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“IMWG”	International Myeloma Working Group
“injection”	sterile solution injection, emulsion injection or suspension injection which can be applied by way of intramuscular injection, intravenous injection or intravenous drip
“inhibitor”	a chemical or substance added or applied to another substance to slow down a reaction or to prevent an unwanted chemical change
“ <i>in vitro</i> ”	Latin for “within the glass”, studies <i>in vitro</i> are conducted using components of an organism that have been isolated from their usual biological surroundings, such a microorganisms, cells or biological molecules
“ <i>in vivo</i> ”	Latin for “within the living”, studies <i>in vivo</i> are those in which the effects of various biological or chemical substances are tested on whole, living organisms as opposed to a partial or dead organism, or those done <i>in vitro</i>
“IR-”	immune-related-
“irinotecan”	a DNA topoisomerase inhibitor used as the hydrochloride salt as an antineoplastic in the treatment of colorectal carcinoma
“ITIM”	immunoreceptor tyrosine-based inhibitory motifs, a conserved sequence of amino acids that is found intracellularly in the cytoplasmic domains of many inhibitory receptors of the non-catalytic tyrosine-phosphorylated receptor family found on immune cells
“ITT”	intention-to-treat
“intravenous” or “IV”	a route of administration of injecting drugs directly into a vein
“kDa”	kilodalton

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## GLOSSARY

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“kinase”	a type of enzyme that catalyzes the transfer of phosphate groups from high-energy, phosphate-donating molecules to specific substrates. The protein kinases make up the majority of all kinases. Protein kinases act on proteins, phosphorylating them on their serine, threonine, tyrosine, or histidine residues. These kinases play a major role in protein and enzyme regulation as well as signaling in the cell
“leukemia”	cancer that starts in blood-forming tissue, such as the bone marrow, and causes large numbers of abnormal blood cells to be produced and enter the bloodstream
“liposarcoma”	a cancer that arises in fat cells in deep soft tissue, such as that inside the thigh or in the retroperitoneum
“LH”	luteinizing hormone
“LOCF”	last observation carried forward
“lung cancer”	cancer that forms in tissues of the lung, usually in the cells lining air passages
“lung SCC”	squamous cell carcinoma of the lungs, a type of non-small cell lung cancer that typically develops in one of the air passages, or bronchi, of the lungs
“lymphocytes”	a sub-type of white blood cells, such as T cells, B cells and NK cells
“MAH”	Marketing Authorization Holder
“MSK”	Memorial Sloan Kettering Cancer Center
“MDACC”	The University of Texas MD Anderson Cancer Center
“melanoma”	a type of cancer that develops from the pigment-containing cells known as melanocytes
“metabolism”	the sum of all the physical and chemical processes by which living organized substance is produced and maintained (anabolism), and also the transformation by which energy is made available for the uses of the organism (catabolism)

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## GLOSSARY

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“metastasis”	the spread of cancer from one part of the body to another
“metastatic”	in reference to any disease, including cancer, disease producing organisms or of malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
“MFS”	myxofibrosarcoma
“MHC”	major histocompatibility complex
“MM”	multiple myeloma, cancer of plasma cells, a type of white blood cell normally responsible for producing antibodies
“monotherapy”	therapy that uses a single drug to treat a disease or condition
“monoclonal antibody”	antibodies capable of binding to specific antigens and inducing immunological responses against the target antigens. Monoclonal antibodies when used as a cancer treatment have the ability to bind only to cancer cell-specific antigens and interrupt the growth of cancer cells to achieve efficient treatment with low dosages and less toxic side effects than traditional chemotherapy
“mPFS”	median PFS
“MPM”	malignant pleural mesothelioma
“MRCT”	multi-regional clinical trial
“MRD”	minimal residual disease
“MSI-H”	microsatellite instability-high
“MTD”	maximum tolerated dose
“mutation”	permanent alteration in the DNA sequence that makes up a gene
“myelofibrosis”	one of a collection of progressive blood cancers known as myeloproliferative neoplasms
“NCI”	the U.S. National Cancer Institute

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## GLOSSARY

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“NE”	not evaluable
“NDA”	new drug application or biologics license application, as applicable
“NK cells”	natural killer cells, a type of cytotoxic lymphocyte
“NSAID”	nonsteroidal anti-inflammatory drug
“NSCLC”	non-small-cell lung cancer
“OC”	ovarian cancer, a cancerous growth arising from the ovary
“oncology”	the branch of medicine dealing with the physical, chemical, and biological properties of tumors, including study of their development, diagnosis, treatment, and prevention
“ORR”	overall response rate
“OS”	overall survival
“osteosarcoma”	cancer that starts in the bone
“oxaliplatin”	An injectable platinum chemotherapy medicine used in the treatment of gastric cancer, colorectal cancer and other cancers
“PAC”	paclitaxel, an anticancer drug derived from the bark of the Pacific yew tree and used to treat ovarian and breast cancer that has not responded to prior therapy
“PBMCs”	peripheral blood mononuclear cells
“PC”	prostate cancer
“PCR”	polymerase chain reaction
“PD”	progressive disease

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## GLOSSARY

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“PDGF”	platelet-derived growth factor, a family of growth factors with mitogenic activity for connective tissue cells, such as fibroblasts and smooth muscle cells, as well as for certain other cell types. The PDGF family consists of including PDGF-A, -B, -C and -D, which form either homo- or heterodimers (PDGF-AA, -AB, -BB, -CC, -DD)
“PDX”	patient-derived xenograft
“PD-1”	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages. The normal function of PD-1 is to turn off the T cell mediated immune response as part of the process that stops a healthy immune system from attacking other pathogenic cells in the body. When PD-1 on the surface of a T cell attaches to certain proteins on the surface of a normal cell or a cancer cell, the T cell turns off its ability to kill the cell
“PD-L1”	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
“pegylated”	the process of forming chemical attachment of polyethylene glycol polymer chains to another molecule
“PFS”	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse. In a clinical trial, measuring the progression free survival is one way to see how well a new treatment works
“PGE2”	prostaglandin E2
“pharmacodynamics” or “PD”	the study of how a drug affects an organism, which, together with pharmacokinetic, influences dosing, benefit, and adverse effects of the drug
“pharmacokinetics” or “PK”	the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit, and adverse effects of the drug

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## GLOSSARY

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“Phase I clinical trials”	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 II clinical trials”	study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage
“Phase III clinical trials”	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 labeling of the product
“pivotal trial” or “registrational trial”	a clinical trial or study intended to provide evidence for a drug marketing approval
“placebo”	any dummy medical treatment; originally, a medicinal preparation having no specific pharmacological activity against the patient’s illness or complaint given solely for the psychophysiological effects of the treatment; more recently, a dummy treatment administered to the control group in a controlled clinical trial in order that the specific and non-specific effects of the experimental treatment can be distinguished
“placebo-controlled”	a term used to describe a method of research in which an inactive substance (a placebo) is given to one group of participants, while the treatment (usually a drug or vaccine) being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective than the placebo
“PLD”	pegylated liposomal doxorubicin
“PR”	partial response or partial response rate

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## GLOSSARY

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“pre-clinical”	studies or programs testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials
“primary efficacy endpoints”	the most important outcomes evaluating drug effectiveness
“PROC”	platinum resistant ovarian cancer
“production capacity”	the maximum amount of biologics that can be produced in a bioreactor system, which is typically measured by the maximum reaction volume of bioreactor system, e.g. 3* 1,500L, 3*7,500L and 2*18,000L, referred to in this document. Specifically, “3*1,500L” refers to three bioreactors, each with a maximum reaction volume of 1,500L; “3*7,500L” refers to three bioreactors, each with a maximum reaction volume of 7,500L; and “2*18,000L” refers to two bioreactors, each with a maximum reaction volume of 18,000L
“protein”	large biological molecules or macromolecules, consisting of one or more long chains of amino acid residues
“PSMA”	prostate-specific membrane antigen
“QW”	once every week
“Q2W”	once every two weeks
“Q3”	third quarter
“Q4W”	once every four weeks
“Q4”	fourth quarter
“QD”	once daily
“R&D”	research and development
“RCC”	renal cell carcinoma, a kidney cancer that originates in the lining (epithelial cells) of the proximal convoluted tubule, a part of the very small tubes in the kidney that transport waste molecules from the blood to the urine



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## GLOSSARY

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“RD”	repeat-dose
“RECIST”	Response Evaluation Criteria In Solid Tumors, a set of published rules that define when tumors in cancer patients improve, stay the same, or worsen during treatment
“recombinant”	the formation by the processes of crossing-over and independent assortment of new combination of genes in progeny that did not occur in the parents
“reference drugs”	a standardised substance or approved drug which is used as a measurement base for biosimilar drug candidates
“refractory”	when used in reference to any type of cancer that does not respond to treatment. The cancer may be resistant at the beginning of treatment or become resistant during treatment
“regression”	a decrease in the size of a tumor or in the extent of cancer in the body
“respiratory”	relating to the system that includes airways, lungs, and the respiratory muscles
“rheumatoid arthritis”	a chronic, systemic inflammatory disorder that may affect many tissues and organs, but principally attacks synovial joints
“relapsed”	when used in reference to any disease, including cancer, the return of a disease or the signs and symptoms of a disease after a period of improvement
“RP2D”	recommended Phase II dose
“RTK”	receptor tyrosine kinase
“SAD”	single ascending-dose

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## GLOSSARY

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“SAEs”	serious adverse events, any untoward medical occurrence in a patient during clinical trials that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or results in a congenital anomaly/birth defect
“sarcoma” or “SC”	a malignant type of tumor of connective or other non-epithelial tissue
“sAXL”	soluble AXL
“SCLC”	small cell lung cancer
“SCT”	stem cell transplant, a procedure in which a patient receives healthy blood-forming cells (stem cells) to replace their own that have been destroyed by disease or by the radiation or high doses of anticancer drugs that are given as part of the procedure. A SCT may be autologous (using a patient’s own stem cells that were collected and saved before treatment), allogeneic (using stem cells donated by someone who is not an identical twin), or syngeneic (using stem cells donated by an identical twin)
“SD”	stable disease, cancer that is neither obviously decreasing nor increasing in extent or severity
“sdAb”, or “single-domain antibody”	an antibody composed of and formed only by a single heavy chain domain
“second-line” or “2L”	with respect to any disease, the therapy or therapies that are tried when the first-line treatments do not work adequately
“SHP-1”	Src homology phosphatase 1, a negative regulator of signalling in immune cells
“SHP-2”	Src homology phosphatase 2, a ubiquitous tyrosine phosphatase containing Src homology 2 domains which plays major biological functions in response to various growth factors, hormones or cytokines
“single agent”	treatment using a single pharmaceutical product

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## GLOSSARY

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“SIRP $\alpha$ ”	signal regulatory protein $\alpha$ , a regulatory membrane glycoprotein from SIRP family expressed mainly by myeloid cells and also by stem cells or neurons
“small molecule” or “small molecule drug(s)”	a kind of drug that is a low molecular weight organic compound with a size in the order of $10^{-9}$ m, which helps regulate a biological process
“solid tumor”	an abnormal mass of tissue that usually does 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.
“subcutaneous”	situated or applied under the skin
“T-cell(s)”	cells that originate in the thymus, mature in the periphery, become activated in the spleen/nodes if their T-cell receptors bind to an antigen presented by an MHC molecule and they receive additional co-stimulation signals driving them to acquire killing (mainly CD8+ T cells) or supporting (mainly CD4+ T cells) functions
“tablets”	a medicinal formulation made of a compressed powdered substance containing an active drug and excipients
“TAMs”	Tyro3, AXL, and Mer
“TCR”	T-cell receptor
“TEAEs”	treatment emergent adverse events
“TGI”	tumor growth inhibition
“TKIs”	tyrosine kinase inhibitors, a type of pharmaceutical drug that inhibits tyrosine kinases
“TMB-H”	tumor mutational burden-high
“TNF $\alpha$ ”	tumor necrosis factor- $\alpha$ ; a cell signaling protein (cytokine) involved in systemic inflammation and is one of the cytokines that make up the acute phase reaction

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## GLOSSARY

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“TNBC”	triple-negative breast cancer, a breast cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2 protein
“tolerability”	degree to which overt adverse effects of a drug can be tolerated by a patient
“TOTPAR(6)”	total pain relief through 6 hours
“toxicity”	the degree to which a substance or a mixture of substances can harm humans or animals. It is expressed generally as a dose response
“toxicokinetics” or “TK”	evaluate drug exposure for adverse effects and therapeutic index during preclinical development
“TRAEs”	treatment-related adverse events
“Tregs”	T-regulatory cells, a subpopulation of T cells that modulate the immune system, maintain tolerance to self-antigens, and prevent autoimmune disease
“tumors”	an abnormal growth of tissue resulting from uncontrolled, progressive multiplication of cells
“tyrosine kinase”	an enzyme that can transfer a phosphate group from ATP to tyrosine residues of a protein in a cell
“UC”	urothelial carcinoma
“ulcerative colitis”	a chronic, inflammatory bowel disease that causes inflammation in the digestive tract
“UPS”	undifferentiated pleomorphic sarcoma
“USPTO”	U.S. Patent and Trademark Office
“VAS”	visual analogue scale
“VCAM-1”	vascular cell adhesion protein 1, also known as vascular cell adhesion molecule 1 (VCAM-1) or cluster of differentiation 106 (CD106). VCAM-1 is a protein that in humans is encoded by the VCAM1 gene. VCAM-1 functions as a cell adhesion molecule

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## GLOSSARY

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“VEGF”	vascular endothelial growth factor, a gene critical for the growth and development of cancer cells
“VEGFA”	vascular endothelial growth factor A
“VEGFR”	vascular endothelial growth factor receptor. There are three main subtypes of VEGF receptors, including VEGFR1, VEGFR2 and VEGFR3
“Wilms Tumor 1” or “WT1”	a protein that in humans is encoded by the WT1 gene on chromosome 11p.
“WOMAC”	Western Ontario and McMaster Universities Arthritis Index
“xenograft tumor model”	animals with transplanted human tumors or other tissues
“5-FU”	5-Fluorouracil, a chemical medication used to treat cancers
“1H”	first half
“2H”	second half

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## FORWARD-LOOKING STATEMENTS

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### FORWARD-LOOKING STATEMENTS CONTAINED IN THIS DOCUMENT ARE SUBJECT TO RISKS AND UNCERTAINTIES

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

- our business strategies and plans to achieve these strategies;
- our ability to complete the development and obtain the relevant requisite regulatory approvals of our drug candidates;
- our ability to successfully commercialize our approved drugs in a timely manner;
- our future debt levels and capital needs;
- changes to the political and regulatory environment in the industry and markets in which we operate;
- our expectations with respect to our ability to acquire and maintain regulatory licenses or permits;
- changes in competitive conditions and our ability to compete under these conditions;
- future developments, trends and conditions in the industry and markets in which we operate;
- general economic, political and business conditions in the markets in which we operate;
- effects of the global financial markets and economic crisis;
- our financial conditions and performance;
- our dividend policy; and
- change or volatility in interest rates, foreign exchange rates, equity prices, volumes, operations, margins, risk management and overall market trends.

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## FORWARD-LOOKING STATEMENTS

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

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

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

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

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## RISK FACTORS

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*An investment in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an investment in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In any such case, the market price of our Shares could decline, and you may lose all or part of your investment.*

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

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) key risks relating to our business, business operations, intellectual property rights and financial prospects; (ii) other risks relating to our financial position and need for additional capital; (iii) other risks relating to our business, comprising (a) risks relating to the development of our drug candidates, (b) risks relating to extensive government regulations, (c) risks relating to manufacturing of our products, (d) risks relating to commercialization of our products, (e) risks relating to our intellectual property rights; and (f) risks relating to our reliance on third parties; (iv) risks relating to our operations; (v) risks relating to our doing business in China; and (vi) risks relating to the [REDACTED].

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

### **KEY RISKS RELATING TO OUR BUSINESS, BUSINESS OPERATIONS, INTELLECTUAL PROPERTY RIGHTS AND FINANCIAL PROSPECTS**

**We face substantial competition in the entire oncology market and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do.**

The pharmaceutical industries are subject to intense competition and rapid and significant technological change. We face fierce competition from existing products and product candidates under development in the entire oncology market, in addition to approved oncology therapy options including surgery, radiotherapy and chemotherapy, and we will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future. Our competitors include major pharmaceutical companies, specialty



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## RISK FACTORS

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pharmaceutical companies and biotechnology companies worldwide. We are developing our drug candidates in competition with a number of pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for the same target indications as ours. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial, technical and human resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Competition may increase further as a result of advances in the commercial applicability of new or disruptive technologies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drugs that we may develop or commercialize. Our competitors also may obtain approval from the NMPA, FDA, PMDA or other comparable regulatory authorities for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. They may render our drug candidates obsolete or non-competitive before we can recover expenses of developing and commercializing any of our drug candidates.

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

**The market opportunities for our Core Product may be small as it mainly targets late line treatment for most of its targeted indications and is limited to those patients who have failed prior treatments.**

The field of cancer treatment has advanced rapidly in recent decades, progressing from surgery and radiotherapy, to chemotherapy and, more recently, to targeted drugs and immune-oncology therapies including cell therapies. Medication treatment with chemotherapy, targeted drugs and immune-oncology therapies can be characterized as first-line, second-line or third-line based on the timing of the treatment. First-line treatment or therapy simply refers to the initial, or first treatment recommended for the cancer, which, for most people, is

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## RISK FACTORS

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expected to provide the best results with the fewest number of side effects. In contrast, second-line treatments are used when the first-line treatment failed to improve a cancer, or if the first-line worked initially before and then the cancer progressed. Third-line treatment may be adopted if previous treatments failed.

Our Core Product is primarily developed to target second line or later stage of treatment for cancer patients. Consequently, it is only approved for treatment of patients who have failed prior treatments, limiting its target patients group in nature. According to J Clin Oncol. 2016 Sep 20;34(27):3300-7., J Anus Rectum Colon. 2021; 5(1): 11–24., Gastroenterology Report, Volume 9, Issue 4, August 2021, Pages 279–289., KEYNOTE-177., KEYNOTE-158., TUMOR, 2015, 35(3): 322-332, the second line progression percentage for MSI-H/dMMR solid tumors, the approved target indication of our Core Product, is only over 50% in advanced MSI-H/dMMR solid tumors. These numbers have been derived from a variety of sources, such as scientific literature or surveys of clinics, and they may prove to be incorrect. Regulatory authorities also may establish narrower definitions around when a patient is ineligible for other treatments than we have used in our projections, and that would reduce the size of the patient population eligible for our drug candidates. Furthermore, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our Core Product may be limited or may not be amenable to treatment with our Core Product.

Our market opportunities may also be limited by competitor treatments that may enter the market. See the risk factor above “Risk Factors – Key Risks Relating to Our Business, Business Operations, Intellectual Property Rights and Financial Prospects – We face substantial competition in the entire oncology market and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do.”

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

Our ability to generate revenue and realize profitability is dependent on our ability to successfully complete the development of our products and drug candidates, obtain necessary regulatory approvals, and manufacture and commercialize our products and drug candidates. We have invested a significant portion of our efforts and financial resources in the development of our existing product and drug candidates, and we expect to continue to incur substantial and increasing expenditures for the development and commercialization of our products and drug candidates.

The majority of our drug candidates are still in pre-clinical and clinical development. We have obtained investigational new drug, or IND, approvals from the NMPA, PMDA, FDA or other regulatory authorities for the relevant indications of our drug candidates in clinical development. However, we cannot guarantee that we will be able to obtain additional

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## RISK FACTORS

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regulatory approvals for our products and drug candidates in a timely manner, or at all, which could be subject to various factors, including without limitation, the ongoing conflicts between the U.S. and China. Significant delays in our ability to obtain approval for and/or to successfully commercialize our products and drug candidates would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

Most of our product and drug candidates will require additional clinical development, regulatory approvals, development of manufacturing supply and capacity, substantial investment and significant marketing efforts before we generate any revenue from product sales. Further, our licensors are concurrently conducting clinical trials for some of our in-licensed drug candidates in the U.S. or other countries. We are not in control of such clinical trials or their strategies for obtaining regulatory clearance and our licensors may be driven by strategic goals or concerns that do not align with ours. If our licensors fail to obtain regulatory approval for those drug candidates in the U.S. or other countries, it would be more difficult for us to obtain regulatory approval from the regulatory authorities in other jurisdictions where we have exclusive rights to develop the drug candidates for regulatory approval. We may need to conduct additional clinical trials to obtain more clinical data than we have originally planned, which may result in increased costs or affect the timing or outcome of our planned clinical trials, adversely affecting our ability to advance the development of our products and drug candidates.

The success of our products and drug candidates will depend on several factors, including but not limited to:

- successful enrollment of patients in, and completion of, clinical trials, as well as completion of pre-clinical studies;
- favorable safety and efficacy data from our pre-clinical studies, clinical trials and other studies;
- obtaining sufficient resources to acquire or discover additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- obtaining sufficient supplies of any drug products that are used in combination with our products and drug candidates, competitor drugs or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials;

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## RISK FACTORS

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- capabilities and competence of our collaborators to perform their duties under their agreements with us, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process and to assist with our commercialization effort;
- establishing sufficient commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- the performance by CROs or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our products and drug candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- successfully launching commercial sales of our products and drug candidates, if and when approved;
- obtaining and maintaining favorable reimbursement from third-party payers for drugs, if and when approved;
- competition with other drug candidates and drugs; and
- continued acceptable safety profile of our products and drug candidates following regulatory approval.

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

Some of our product and drug candidates represent a novel approach to therapeutic needs compared with more commonly used medical methods, which carries inherent development risks and could result in delays in clinical development, regulatory approval or commercialization. Our future approved product and drug candidates may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these

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## RISK FACTORS

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treatments to the exclusion of our drug candidates that are in clinical trials for the same or similar cancer indications. In addition, physicians, patients and third-party payors may prefer other novel products to ours. The degree of market acceptance of our product and drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product and drug candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product and drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our product and drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our product and drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities; and
- the effectiveness of our sales and marketing efforts.

If any approved product and drug candidates that we commercialize fail to achieve market acceptance in the medical community, we will not be able to generate significant revenue. Even if our future approved product and drug candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our product and drug candidates, are more cost-effective or render our product and drug candidates obsolete.

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**We have incurred net losses since inception, and expect to continue to incur significant net losses for the foreseeable future and we may not be able to generate sufficient revenue to achieve or maintain profitability.**

Investment in pharmaceutical drug companies is highly speculative. We have incurred substantial R&D expenses to date, and expect to continue to incur significant expenses related to clinical trials and pre-clinical studies. However, we cannot assure you that our drug candidates will obtain regulatory approvals and/or become commercially viable. Our ability to generate significant revenue from our drug candidates will depend primarily on the success of the regulatory approval, manufacturing and commercialization of the drug candidates, which is subject to significant uncertainty. Even if we obtain regulatory approval to market our drug candidates, our future revenue will depend upon other factors such as the market size for the proposed indications of our drug candidates, and our ability to achieve sufficient market acceptance.

Substantially all of our operating losses have resulted from costs and expenses incurred by our research and development programs and in relation to our operations. The amount of our future net losses will depend, in part, on our future expenditures resulted from costs and expenses incurred by our research and development programs and in relation to our operations, the cost of commercializing any approved products, our ability to generate revenues, and the timing and amount of milestone and other payments we make or receive with or through arrangements with third parties. We expect to continue to incur significant expenses and losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- continue to advance the clinical trials and pre-clinical studies of our product pipeline;
- initiate pre-clinical, clinical or other studies for new drug candidates;
- seek regulatory approvals for our drug candidates to complete clinical development and commence commercialization;
- manufacture our drug candidates for clinical trials and for commercial sale;
- develop and expand our commercialization team to commercialize any drug candidates in our pipeline for which we may obtain regulatory approval;
- acquire or in-license other drug candidates, intellectual property assets and technologies;
- incur costs to develop or manufacture drug candidates under any collaboration or in-license agreements;
- maintain, protect, expand and enforce our intellectual property portfolio;

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- attract and retain skilled personnel, and grant share options to our employees under our share incentive schemes; and
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

In addition, considering the numerous risks and uncertainties associated with regulatory approval, we are unable to accurately predict the timing or amount of additional expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the NMPA, FDA or other similar authorities to perform studies in addition to those that we currently anticipate. Even if our drug candidates are approved for commercial sale, we expect to continue incurring significant costs associated with the manufacturing and the commercial launch of the drug candidates.

Even if we are able to generate revenue from the sale of our approved drug candidates, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or obtain sufficient equity or debt financings, we may be unable to continue our operations according to our plans and be forced to scale back our operations. Moreover, even if we manage to achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. Our failure to become and remain profitable may also impact investors’ perception of the potential value of our company and could impair our ability to raise additional capital, expand our business or continue our operations. Failure to become and remain profitable may also adversely affect the market price of our Shares. A decline in the market price of our Shares could cause potential investors to lose all or part of their investment in our business.

**We have entered into collaborations with our partners and may form or seek additional collaborations or strategic alliances or enter into additional licensing or sub-licensing arrangements in the future. We may not realize any or all benefits of such alliances or licensing or sub-licensing arrangements, and disputes may arise between us and our collaboration partners.**

We have in the past entered into licensing arrangement and may in the future seek and form further collaborations or strategic alliances, or enter into additional licensing arrangement, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Certain of our collaboration agreements are sub-licensing arrangements that involve our collaborator sub-licensing us intellectual property developed by third parties. For more details of our collaboration agreements, please refer to the paragraphs headed “Business – Our Research and Development – Collaboration Agreements” in this document. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business.

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## RISK FACTORS

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Our strategic collaboration with partners involves numerous risks, which may include the following:

- collaboration partners have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaboration partners may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, or change their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaboration partners may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new design of a drug candidate for clinical testing;
- collaboration partners could independently develop, or develop with third parties, products that compete directly or indirectly with our future drug products or drug candidates;
- collaboration partners may renew the existing collaboration agreements with us on less favorable terms to us;
- collaboration partners with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- disputes may arise between a collaboration partner and its sub-licensor or between us and a collaboration partner that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaboration partners or their sub-licensors may own or co-own intellectual property covering our drug candidates that results from our collaborating with them, and in such cases, we may not have the exclusive right to commercialize such intellectual property;
- collaboration partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; and



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- collaborations may be terminated and, if terminated, may result in our inability to generate revenue in the foreseeable future and a need for additional capital to pursue further development or commercialization of the applicable drug candidates.

Under the Co-Development Agreements with Alphamab Group, the worst case scenario in the event of termination is that the non-breaching party would have unilateral decision-making power over envafolimab and the licensing of the Patent Rights. For further details on the Co-Development Agreements, please refer to the paragraph headed “Business – Collaboration Agreements – Collaboration with Alphamab Group for Envafolimab.”

Under the SELLAS Agreement, in the event of termination, depending on the reason for the termination, the consequences could be that (i) all licenses and other rights granted by SELLAS Group to us shall terminate, and all of our rights under the intellectual property with respect to the SELLAS Licensed Products shall revert to SELLAS Group; (ii) we shall cease any and all development, manufacture and commercialization activities relating to the SELLAS Licensed Products; and (iii) we shall, at our own cost, wind down any of our ongoing clinical trials of the SELLAS Licensed Products or transfer such clinical trials to SELLAS Group. For further details on the SELLAS Agreement, please refer to the paragraph headed “Business – Collaboration Agreements – Collaboration with SELLAS Group for 3D189 and 3D059.”

Under the Aravive Sub-Licensing Agreement, in the event of termination, the consequences could be that (i) all licenses and other rights granted by Aravive to us would terminate, and all of our rights under the licensed intellectual property in relation to 3D229 shall revert to Aravive; and (ii) we would, at our own cost, wind down any ongoing clinical trials for 3D229 or and transfer such clinical trials to Aravive, unless the Aravive Sub-Licensing Agreement is terminated by us due to Aravive’s material breach or bankruptcy, at Aravive’s reasonable request. For further details on the Aravive Sub-Licensing Agreement, please refer to the paragraph headed “Business – Collaboration Agreements – Collaboration with Aravive for 3D229.”

Under the ImmuneOncia Agreement, in the event of termination, the consequences could be that (i) the license granted by ImmuneOncia to us would terminate; and (ii) we would terminate our ongoing clinical trial for 3D197 or, if ImmuneOncia agrees, transfer such clinical trial to ImmuneOncia. For further details on the ImmuneOncia Agreement, please refer to the paragraph headed “Business – Collaboration Agreements – Collaboration with ImmuneOncia for 3D197.”

Under the Y-Biologics Agreement, in the event of termination, the consequences could be that (i) the license granted by the Y-Biologics to us would terminate and revert to Y-Biologics; (ii) unless our activities, rights and benefits under the Y-Biologics Agreement have been adversely affected by Y-Biologics’s breach, we would still pay the 50% development costs, upfront payment, milestone payments and royalty payments; and (iii) we would terminate the ongoing clinical trial of 3D057 or transfer such clinical trial to Y-Biologics or its designee. For further details on the Y-Biologics Agreement, please refer to the paragraph headed “Business – Collaboration Agreements – Collaboration with Y-Biologics for 3D057.”

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Furthermore, a number of our collaboration partners are listed companies in various jurisdictions and subject to the compliance with securities laws and regulations in such jurisdictions. However, there is a risk that, if our collaboration partners fail to comply and were subject to securities litigations, they would be adversely impacted and our existing relationship with them would be jeopardized. In addition, we may not achieve the revenue and cost synergies expected from the transaction. These synergies 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. If we achieve the expected benefits, they may not be achieved within the anticipated time frame. Also, the synergies from our collaboration with partners may be offset by other costs incurred in the collaboration, increases in other expenses, operating losses or problems in the business unrelated to our collaboration. As a result, there can be no assurance that these synergies will be achieved.

Moreover, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early 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 can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits.

Furthermore, disputes may arise between us and our current or future collaboration partners. Such disputes may cause delay or termination of the research, development or commercialization of our drug candidates, or may result in costly litigation or arbitration that diverts management attention and resources. Global markets are an important component of our growth strategy. If we fail to obtain licenses or enter into collaboration arrangements with third parties in other markets, or if third-party collaborator is not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- third parties obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;

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- difficulty of ensuring that third-party partners do not infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of others;
- unexpected changes in or imposition of trade restrictions, such as tariffs, sanctions or other trade controls, and similar regulatory requirements;
- economic weakness, including inflation;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest;
- failure of our employees and contracted third parties to comply with United States Department of the Treasury’s Office of Foreign Assets Control rules and regulations and the United States Foreign Corrupt Practices Act of 1977, as amended (“FCPA”); and
- business interruptions resulting from geopolitical actions, including war and acts of terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

**If our drug candidates or our collaborators’ data fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.**

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. If our drug candidates or our collaborators’ data fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in future clinical trials, we would have expended a significant amount of capital to progress the relevant drug candidates to that stage, and would not realize any revenue on such drug candidate if it then ultimately failed to receive regulatory approval due to unsatisfactory clinical trial results. In addition, if we terminate our studies or cease further development of certain of our drug candidates due to the change of our strategy, we would also have expended

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a significant amount of capital and would not realize any revenue on such drug candidate. Such an uncompensated expenditure could materially adversely affect our business, financial condition, results of operations and prospects.

The International Multi-Regional Clinical Trial Guidelines (Trial) (《國際多中心藥物臨床試驗指南(試行)》) (the “**Multi-Regional Clinical Trial Guidelines**”), promulgated by the CFDA in January 2015 and came into effect in March 2015, provided guidance on the implementation of international MRCT in China. According to the Multi-Regional Clinical Trial Guidelines, international MRCT applicants may simultaneously perform clinical trials in different regions using the same clinical trial protocol. Please refer to the paragraphs headed “Regulatory Overview – Regulations in relation to the Registration of New Drugs – Regulations relating to International Multi-Center Clinical Trials and Acceptance of Overseas Clinical Trial Data” in this document. As we plan to join and use data derived from the international MRCTs for approval of some of our drug candidates, if the international MRCTs conducted by our partners fail to demonstrate satisfactory safety and efficacy profiles, we may not be able to complete the development of such drug candidates. Moreover, if competing drugs conducted by others fail to demonstrate satisfactory safety and efficacy profiles during the development process, it might also adversely impact the development of our related drug candidates.

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

Our drug candidates are considered as emerging and relatively novel cancer therapeutics. The adverse events or side effects of some of our drug candidates in connection with their usage in patients are yet to be thoroughly tested and understood, and may only arise after a longer period of observation. Undesirable adverse events caused by our drug candidates, or caused by our drug candidates when used in combination with other drugs, could potentially cause significant negative consequences, including but not limited to:

- regulatory authorities could interrupt, delay or halt pending clinical trials;
- we may suspend, delay or alter development or marketing of our drug candidates;
- regulatory authorities may order us to cease further development of, or delay or even deny approval of, our drug candidates for any or all targeted indications if results of our trials reveal a high and unacceptable severity or prevalence of certain adverse events;
- regulatory authorities may withdraw approvals or revoke licenses of an approved drug candidate, or we may determine to do so even if not required;

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- regulatory authorities may require additional warnings on the label of an approved drug, issue safety alerts or other communications containing warnings or other safety information of such approved drug, or impose other limitations on such approved drug;
- we may be required to develop a risk evaluation mitigation strategy for the drug candidate, or, if one is already in place, to incorporate additional requirements under the risk evaluation mitigation strategy, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to change the way the drug candidate is administered, or conduct post-market studies;
- we could be subject to litigation proceedings and held liable for harm caused to patients exposed to or taking our drug candidates may suffer from adverse events related to the treatment and patients;
- the patient enrolment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated;
- the product may become less competitive;
- we could be required to recall our drug candidates and be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

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

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

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

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

- severity of the disease under investigation;
- total size and nature of the relevant patient population;
- design and eligibility criteria for the trial in question;
- the size of the study population required for analysis of the trial's primary endpoints;
- our resources to facilitate timely enrollment in trials;
- patient referral practices of physicians;
- the proximity of prospective patients to available trial sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our investigator's or clinical trial site's efforts to screen and recruit eligible patients;
- clinicians' and patients' perceptions of the potential advantages and side effects of the drug candidate being studied compared to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will not complete a clinical trial;
- the availability of approved therapies that are similar in mechanism to our drug candidates; and
- the negative impact of COVID-19 on patient enrolment and clinical progress.

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

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patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

**We may not be able to identify, discover, develop or in-license new drug candidates, or to identify additional therapeutic opportunities, to expand our product pipeline.**

Although our R&D capabilities enable us to design, evaluate and select optimal candidates and continue to enrich our pipeline, we cannot guarantee that we will be successful in identifying potential new drug candidates. Drug candidates that we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. Some drug candidates are technically challenging to develop and manufacture. We may also pursue collaboration with third parties in the discovery, development and in-licensing of potential drug candidates, but we cannot assure you that such collaboration will be able to deliver the intended results. We may not realize the benefits of our existing and future collaborations, strategic alliances or licensing arrangements. Please refer the paragraph headed “– Other Risks Relating to Our Business – Risks Relating to Our Intellectual Property Rights – If we fail to comply with our obligations in the agreements under which we license intellectual property rights to or from third parties or otherwise experience disruptions to our business relationships with our licensees or licensors, we could be required to pay monetary damages or could lose license rights that are important to our business” in this section.

Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and drug targets require substantial technical, financial and human resources. Our research programs may initially show promising results in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including but not limited to the following factors:

- the research methodology used may not be successful in identifying potential indications and/or new drug candidates;
- potential drug candidates may, after further study, be shown to have adverse effects or other characteristics that indicate they are unlikely to achieve desired efficacy; and
- may take greater resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates, thereby limiting our ability to diversify and expand our drug portfolio.

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

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

We have worked with and plan to continue to work with third-party collaborators, such as CROs, to monitor and manage data for our ongoing pre-clinical and clinical programs. We work with these parties to execute our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our collaboration with the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCP, which are regulations and guidelines enforced by the NMPA, FDA, PMDA and other comparable regulatory authorities for all of our drug candidates in clinical development. If we or any of our CROs or clinical investigators fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, FDA, PMDA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing pre-clinical studies, and clinical and non-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

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

Our future revenues are dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approval. Our arrangements with such collaborators will be critical to successfully bringing our drug candidates to market and



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commercializing them. We rely on third-party collaborators in various respects, including but not limited to undertaking research and development programs, conducting clinical trials, managing or assisting with the regulatory filings and approval process, and assisting with our commercialization efforts. We do not control our collaborators; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaborators and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed product, which could materially and adversely affect our business, financial condition, cash flows and results of operations.

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

**We have no track record and limited experience in commercialization of drugs. Although we have entered into marketing agreements with third party CSOs, if we are unable to build or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our products or sell our products, which will materially affect our ability to generate product sales revenue.**

We have not yet demonstrated an ability to launch and commercialize any of our drug candidates when approved. As a result, our ability to successfully commercialize our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience launching and marketing drug candidates.

We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities for any or all of our future approved drugs, we will likely continue to rely on collaborative arrangements regarding the sales and marketing of our drug candidates. We entered into a tripartite collaboration agreement with Alphamab Group and Simcere Group, together with a separate marketing and promotion agreement with Simcere Group, pursuant to which Simcere Group is responsible for the exclusive commercial promotion of the future approved product in mainland China. Please refer to the paragraphs headed “Business – Our Collaboration Arrangements – Collaboration with Alphamab Group and Simcere Group for Envafolimab” in this document for more details. However, there can be no assurance that we are or will be able to establish or maintain such collaborative arrangements with third party CSOs such as Simcere Group, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales

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may be lower than if we had commercialized our drug candidates ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates when approved.

In particular, given the limited experience generally in marketing recently approved innovative drugs in China, there can be no assurance that we will be able to further develop and successfully maintain in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaboration partners to successfully commercialize any product. As a result, we may not be able to generate product sales revenue.

**If we are unable to obtain and maintain adequate patent protection for our product and 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 any of our future approved products or technologies would be materially adversely affected.**

Our success depends in large part on our ability to protect our proprietary technologies and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect our product, drug candidates and technologies that we consider commercially important by filing patent applications in China, the U.S. and other jurisdictions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. In particular, we have sought patents in China, the U.S., Japan and various other jurisdictions for our Core Products. For further information on our patent portfolio, please refer to the paragraphs headed “Business – Intellectual Property” in this document. Certain of our collaboration partners or their sub-licensors are responsible for or have the first right to prosecute, maintain and/or enforce the certain patents relevant to our product, drug candidates and technologies. For example, we and Alphamab Group are jointly responsible for the prosecution and maintenance of the patents we co-own. Further, with respect to any patents and/or patent applications in-licensed from Alphamab Group to us, Alphamab Group as the patentee is legally responsible for the prosecution, maintenance and enforcement of such licensed patents and/or patent applications according to patent laws and regulations. For details, please refer to the paragraphs headed “Business – Collaboration Agreement” in this document. If we or any of our collaboration partners or sub-licensors fail to obtain or maintain patent protection, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to our product and drug candidates in the worst case scenario. Even if we or any of our collaboration partners or sub-licensors are successful in defending against any claims challenging the inventorship of our owned or in-licensed patents, patent applications or other intellectual property, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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Any failure by us or our collaboration partners or sub-licensors to obtain or maintain patent protection with respect to our product, drug candidates and technologies could materially adversely affect our business, financial condition, results of operations and prospects.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patents at a reasonable cost or in a timely manner in all desirable jurisdictions. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive drugs in all such fields and jurisdictions.

The requirements for patentability differ in certain jurisdictions, particularly developing countries. For example, China has a heightened requirement for patentability and, specifically, requires a detailed description of medical uses of a claimed drug. Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be materially impaired and our business, financial condition, results of operations, and prospects may be adversely affected.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. Our pending and future patent applications may not be granted with approvals, while not being granted with such approvals may effectively prevent third parties from commercializing competitive technologies and biosimilar drug candidates. For more details, please refer to the paragraphs headed “Business – Intellectual Property” in this document. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we generally enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaboration partners, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we or our licensors were the first to file for patent protection of such inventions. Furthermore, China and, recently, the U.S. have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, even after reasonable investigation we may be unable to determine with certainty whether any of our drug candidates, processes, technologies, inventions, improvement and other related matters have infringed upon the intellectual

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property rights of others, because such third party may have filed a patent application without our knowledge while we are still developing that product, and the term of patent protection starts from the date the patent was filed, instead of the date it was issued. Therefore, the validity of issued patents, patentability of pending patent applications and applicability of any of them to our programs may be lower in priority than third-party patents issued on a later date if the application for such patents was filed prior to ours and the technologies underlying such patents are the same or substantially similar to ours. If such a third party can establish that we or our licensors were not the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable, and third parties may be granted a patent relating to a technology which we invented.

We are primarily focused on protecting our intellectual property rights in our target markets, which are China, the U.S., Japan and other jurisdictions. Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights with respect to our drug candidates in all other jurisdictions throughout the world would be prohibitively expensive for us. Besides, the actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular jurisdiction and the validity and enforceability of the patent. Our intellectual property rights in certain jurisdictions may have a less or different scope and strength compared to those in our target markets. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of our target markets. Consequently, in some cases, we may not be able to obtain issued patents or other intellectual property rights covering our drug candidates in jurisdictions outside our target markets and, as a result, we may not be able to prevent third parties from using our inventions in all jurisdictions outside our target markets, or from selling or importing drugs made using our inventions in and into our target markets or other jurisdictions. Competitors and other third parties may use our technologies in jurisdictions where we have not pursued and obtained patent and other intellectual property protection to develop their own drugs and further, may export otherwise infringing drugs to jurisdictions where we have patent or other intellectual property protection, but where enforcement rights are not as strong as those in markets such as the U.S. 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.

Many companies have encountered significant problems in protecting and defending intellectual property rights in jurisdictions such as China. The legal system in these jurisdictions, particularly those in certain developing countries, does not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights in these jurisdictions. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our

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business, could put our patents and other intellectual property rights at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a commercial advantage from the intellectual property that we develop or license. In addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the NIPA, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

**We will need to obtain additional financing to fund our operations, and if we are unable to obtain sufficient financing, we may be unable to complete the development and commercialization of our drug candidates.**

Our drug candidates require substantial investments for the completion of clinical development, regulatory review, drug manufacturing, marketing and launch before they can generate product sales revenue. Our operations have consumed substantial amounts of cash since our inception. We will need to expend substantial resources on the research and development and commercialization of our product pipelines. Our future funding requirements will depend on many factors, including but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely identify and enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our drug candidates;
- the progress, timing, scope and costs related to discovery and early development of additional drug candidates;
- the preparation required for anticipated commercialization of our drug candidates, and if regulatory approvals are obtained, to fund the product launch;
- the manufacturing requirements and capabilities related to clinical development and future commercialization for any approved drug candidates;
- selling and marketing costs associated with any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the amount and timing of any profit sharing, milestone and royalty payments we receive from our current or future collaboration partners;

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- cash requirements of any future development of other pipeline drug candidates; and
- our headcount growth and associated costs.

We expect to continue to spend substantial amounts on drug discovery, advancing the clinical development of our drug candidates, and launching and commercializing any approved drug candidates for which we receive regulatory approvals. However, if the commercialization of our drug candidates is delayed or terminated, or if the expenses associated with drug development and commercialization increase substantially, we may need to obtain additional financing to fund our operations. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. Our ability to raise funds will depend on financial, economic and market conditions and other factors, many of which are beyond our control. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate pre-clinical studies, clinical trials or other research and development activities or commercialization for one or more of our drug candidates, and in turn will adversely affect our business prospects.

**We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control, including the COVID-19 outbreak, which may have a material adverse effect on our business, financial condition and results of operations.**

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, or other events, 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. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of operations.

The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments in China or elsewhere in the world could materially disrupt our business and operations. For example, the recent outbreak of COVID-19 has affected many people globally, caused temporary suspension of productions and shortage of labor and raw materials in affected regions, and disrupted local and international travel and economy. The exacerbation, continuance or reoccurrence of COVID-19 has already caused and may continue to cause an adverse and prolonged impact on the economy, geopolitical and social conditions in China and other affected countries. Since late July 2021, the COVID-19 has recurred in the form of the Delta variant in China and overseas, and since November 2021, another variant designated as Omicron (together with the Delta variant, the “**COVID-19 Variants**”) has also

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been discovered in many cases over the globe (the “**Recurrences**”). Recently, the Chinese government has implemented emergency measures in certain cities or regions, including Shanghai, in response to the Recurrence, including travel restrictions, mandatory cessations of business operations, mandatory quarantines, and limitations on social and public gathering and lockdowns. The exacerbation, continuance or reoccurrence of COVID-19 has already caused, and may continue to cause, an adverse and prolonged impact on the economy and social conditions in China and other affected countries. The existing clinical trials and the commencement of new clinical trials could also be substantially delayed or prevented by any delay or failure in patient recruitment or enrollment in our or our collaborators’ trials as a result of the outbreak of COVID-19 and the Recurrences. These factors could cause delay of clinical trials, regulatory submissions, and required approvals of our drug candidates, and could cause us to incur additional costs. If our employees or employees of our business partners are suspected of being infected with an epidemic disease, our operations may be disrupted because we or our business partners must quarantine some or all of the affected employees or disinfect the operating facilities. If we are not able to effectively develop and commercialize our drug candidates as a result of protracted clinical trials of enrolled patients, elevated public health safety measures, and/or failure to recruit and conduct patient follow-up, we may not be able to generate revenue from sales of our drug candidates as planned.

### **OTHER RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL**

#### **We had net liabilities and net cash outflows in operating activities during the Track Record Period.**

We had net liabilities of RMB1,269.8 million, RMB2,272.6 million and RMB2,509.8 million as of December 31, 2020 and 2021 and May 31, 2022, respectively. We had net current assets of RMB146.7 million as of December 31, 2020 and net current liabilities of RMB2,328.8 million and RMB2,600.6 million as of December 31, 2021 and May 31, 2022, respectively. We had net cash flows used in operating activities of RMB278.3 million, RMB377.1 million and RMB112.9 million for the years ended December 31, 2020, 2021 and the five months ended May 31, 2022, respectively. While we believe we have sufficient capital to fund our current operations, we expect that we may have net liabilities and experience net cash outflows from operating activities for the foreseeable future. A net current liabilities or net liabilities position can expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources such as equity or equity-linked instruments and external debt, which may not be available on terms favorable or commercially reasonable to us or at all. If we are unable to maintain adequate working capital or obtain sufficient equity or debt financings to meet our capital needs, we may be unable to continue our operations according to our plans and be forced to scale down our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

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**We have a limited operating history and have only recently begun commercializing our drug candidates, which may make it difficult to evaluate our current business and predict our future performance.**

We are a development-stage biotechnology company with a relatively short operating history as a standalone company. Please refer to the section headed “History, Development and Corporate Structure” in this document. Our operations have focused on the pre-clinical studies and clinical trials of oncology-focused drug candidates. We also have limited experience in commercial-scale manufacturing and sales of drugs. For these reasons, particularly in light of the rapidly evolving pharmaceutical industry, it may be difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer.

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

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through equity or convertible equity-linked securities, the value of your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. Incurring additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, the issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline.

In the event we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party our rights to technologies or drug candidates on unfavorable terms, which we would have otherwise sought to develop or commercialize ourselves or reserve for future potential arrangements when we are more likely to achieve more favorable terms.

**Fair value changes in our financial instruments issued to investors and related valuation uncertainty may materially affect our financial condition and results of operations.**

The financial instruments with preferred rights, which mainly includes our preferred shares during the Track Record Period, were not traded in an active market and the fair value is determined by using valuation techniques. The discounted cash flow method and back-solve method were used to determine the underlying share value and the equity allocation model was adopted to determine the fair value of the financial instruments with preferred rights as of each date of issuance and as of December 31, 2020 and 2021 and May 31, 2022. Key valuation assumptions used to determine the fair value of the preferred shares include risk-free interest



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rate, volatility and discount for lack of marketability. Any change in the assumptions may lead to different valuation results and, in turn, changes in the fair value of these financial instruments with preferred rights. To the extent we need to revalue the financial instruments with preferred rights prior to the closing of the [REDACTED], any change in fair value of the financial instruments with preferred rights and related valuation uncertainty, for example, resulted from the use of unobservable inputs, could materially affect our financial position and performance. As of December 31, 2020 and 2021 and May 31, 2022, we recorded financial instruments with preferred rights as our non-current liabilities of RMB1,430.4 million, RMB38.8 million and RMB42.5 million, respectively. We also recorded fair value losses on preferred shares of RMB319.2 million, RMB954.7 million and RMB143.6 million as of December 31, 2020 and 2021 and May 31, 2022, respectively. We expect that we will recognize significant additional losses on the fair value changes of the financial instruments with preferred rights from December 31, 2020 to the [REDACTED] because of the significant increase in the fair value of such financial instruments during such period. After the automatic conversion of all preferred shares into Shares upon the closing of the [REDACTED], we do not expect to recognize any further gains or losses on fair value changes from the financial instruments with preferred rights in the future.

### **We are exposed to risks in connection with the wealth management products we purchased.**

We had financial assets at FVTPL of nil, RMB50.2 million and RMB50.0 million, as of December 31, 2020 and 2021 and May 31, 2022, respectively, which were wealth management products we purchased from banks in China. Pursuant to the Guidance on Regulating Financial Institution’s Asset Management Business (《關於規範金融機構資產管理業務的指導意見》) promulgated by the People’s Bank of China, the China Banking and Insurance Regulatory Commission, the China Security Regulatory Commission and the State Administration of Foreign Exchange on April 27, 2019, financial institutions selling wealth management products shall not guarantee the returns of principal and interest of such products. As a result, the returns of our investments on the wealth management products were not guaranteed, and therefore were measured at fair value through profit or loss. We are exposed to credit risks in relation to these financial assets, which may adversely affect their fair value.

Net changes in their fair value are recorded as our other income and gains, and therefore directly affect our results of operations. We may continue to invest in wealth management products in the future when we believe that we have surplus cash on-hand and the potential investment returns are attractive. However, there can be no assurance that our internal management and investment strategy will be effective and adequate with respect to our purchased wealth management products. We cannot guarantee that we will not experience losses with respect to such investments in the future or that such losses or other potentially negative consequences due to such investments will not have material adverse effects on our business, results of operations and prospects.

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

We adopted share incentive scheme for the benefit of our employees as remuneration for their services provided to us to incentivize and reward the eligible persons who have contributed to the success of our Company. For details, please refer to the paragraphs headed “History, Development and Corporate Structure – Share Incentive Scheme” in this document. During 2020, 2021 and for the five months ended May 31, 2022, we incurred share-based payments of nil, RMB105.1 million and RMB55.4 million, respectively. To further incentivize our employees to contribute to us, we may grant additional share-based payments in the future. Issuance of additional Shares with respect to such share-based payments may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payments may also increase our operating expenses and therefore have a material and adverse effect on our financial performance.

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

The change in the value of RMB against the Hong Kong dollar and other currencies may fluctuate and is affected by, among other things, the policies of the PRC Government and changes in China’s international, political and economic conditions, as well as supply and demand in the local market. It is difficult to predict how market forces or government policies may impact the exchange rate between RMB and the Hong Kong dollar, the U.S. dollar or other currencies in the future. In addition, the PBOC regularly intervenes in the foreign exchange market to limit fluctuations in RMB exchange rates and achieve policies goals.

There remains significant international pressure on the PRC Government to adopt a more flexible currency policy, which, together with domestic policy considerations, could result in a significant appreciation of RMB against the Hong Kong dollar, the U.S. dollar or other foreign currencies.

Substantially all of our costs are denominated in RMB and U.S. dollars, most of our assets are cash and bank balances primarily denominated in RMB and U.S. dollars, and our [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. Any significant change in the exchange rates of the Hong Kong dollar against RMB or U.S. dollars against RMB may materially and adversely affect the value of and any dividends payable on, our Shares in Hong Kong dollars.

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### OTHER RISKS RELATING TO OUR BUSINESS

#### Risks Relating to the Development of Our Drug Candidates

**Clinical drug development involves a lengthy and expensive process with an uncertain outcome.**

Clinical trials are expensive, difficult to design and implement, and can take years to complete with inherent uncertainty as to outcome. Failure can occur at any time during the clinical trial process.

We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approvals for the development and commercialization of our drug candidates, including but not limited to situations whereby:

- regulators may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;
- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate;
- our drug candidates may lack meaningful clinical responses or the participants may be exposed to unacceptable health and safety risks;
- regulators may require that we or our investigators suspend or terminate clinical research for various reasons such as non-compliance with regulatory requirements;
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and

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

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates or not obtain regulatory approval at all;
- obtain approval for proposed indications that are not as broad as intended;
- have the drug removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the drug is distributed or used; or
- be unable to obtain reimbursement for use of the drug.

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

### **Results of earlier studies and trials may not be predictive of future trial results.**

The results of pre-clinical studies and early clinical trials may not be predictive of the success of later phase clinical trials, and successful initial or interim results of a clinical trial do not necessarily predict successful final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the pharmaceutical and biopharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. As drug candidates are developed through pre-clinical and clinical trials towards approval and commercialization, it is customary that various aspects of the development programs, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the inherent risks that they may not necessarily achieve the intended objectives.

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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, but not limited to, changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including ethnical and genetic differences, patient adherence to the dosing regimen and other trial protocol elements, the rate of dropout among clinical trial participants, and other compounding factors, such as other medications or pre-existing medical conditions. In the case of any trials we conduct, results may differ from earlier trials due to, among other things, the larger number of clinical trial sites, additional countries and languages involved in such trials, the different conductors of our conducting the trials, different clinical trial standards required in different jurisdictions, different patient population, and different standard of care and pretreatment of patients before enrolling in such trials. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our drug candidates to perform differently, which could delay completion of clinical trials, delay approval of our drug candidates and/or jeopardize our ability to commence commercialization of our drug candidates.

**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 our product pipeline on research programs and in-licensed drug candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain development and commercialization rights to such drug candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

### **Risks Relating to Extensive Government Regulations**

**All material aspects of the research, development, manufacturing and commercialization of our drug candidates are heavily regulated.**

All jurisdictions in which we intend to develop and commercialize our drug candidates regulate these activities in great depth and detail. We intend to focus our activities in China while pursuing international opportunities, such as in the U.S. and Japan. These jurisdictions all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of the development, approval, manufacturing,

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marketing, sales and distribution of products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in these regions.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the investment of substantial time and financial resources. Any recently enacted and future legislation may increase the difficulty and cost of us to obtain regulatory approval of, and commercialize, our drug candidates, and affect the prices we may obtain. Changes in government regulations or in practices relating to the pharmaceutical industry, such as a relaxation in regulatory requirements, or the introduction of simplified approval procedures, which would lower the entry barrier for potential competitors, or an increase in regulatory requirements, which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations, and prospects.

Failure to comply with the applicable requirements at any time during the product development process or approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include but are not limited to a regulator's refusal to approve pending applications, withdrawal of an approval, revocation of a license, a holding off of clinical trials, voluntary or mandatory recalls of products, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal penalties. Any occurrence of the foregoing could therefore materially adversely affect our business, financial condition, results of operations and prospects.

**The regulatory approval processes of the NMPA, FDA, PMDA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are unable to obtain without undue delay any regulatory approval for our drug candidates in our targeted countries, our business may be substantially harmed.**

The time required to obtain approval by the NMPA, FDA, PMDA, and other comparable regulatory authorities is inherently unpredictable but typically takes 10-15 years following the commencement of pre-clinical studies and clinical trials and depends on numerous factors in recent years, including the substantial discretion of the regulatory authorities. 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. We cannot guarantee that we will be able to obtain regulatory approvals for our existing drug candidates or any drug candidates we may discover, in-license or acquire and seek to develop in the future.

Our drug candidates could fail to receive regulatory approval of the NMPA, FDA, PMDA or a comparable regulatory authority for many reasons, including but not limited to:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities in the design or implementation of our clinical trials;

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- failure to demonstrate that our drug candidate is safe, pure and potent for its proposed indications;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- failure of our clinical trial process to pass relevant good clinical practice, or GCP, inspections;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- insufficient data collected from the clinical trials of our drug candidates or disagreement with our interpretation of data from pre-clinical studies or clinical trials that result in failure to support the submission and filing of a new drug application, or NDA, or other submissions or to obtain regulatory approval;
- failure of our drug candidates to pass current Good Manufacturing Practice, or GMP, 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, FDA, PMDA or comparable regulatory authorities, resulting in a potential invalidation of our research data;
- findings by the NMPA, FDA, PMDA or comparable regulatory authorities of deficiencies related to our manufacturing processes or the facilities of third-party manufacturers with whom we contract for clinical and commercial supplies;
- changes in approval policies or regulations that render our pre-clinical and clinical data insufficient for approval;
- failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations;
- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from pre-clinical studies or clinical trials; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

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The NMPA, FDA, PMDA or comparable regulatory authorities may require more information, including additional analyses, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development programs. 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.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Resubmission may impact the costs, timing or successful completion of a clinical trial. The policies of the NMPA, FDA, PMDA and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. For example, 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》) (No. 46[2021], the “**Guiding Principles**”) issued by NMPA’s Center for Drug Evaluation came into force in November 2021. The Guiding Principles call for a patient-oriented approach to the R&D of oncology drugs and require drug innovators to use the standard-of-care treatment as control in late-stage clinical trials, rather than comparing to treatments that have already been replaced in clinical practice. Consequently, it may increase the cost of conducting oncology drug trials and raise the bar for regulatory approval. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

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

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

- regulatory authorities could interrupt, delay or halt pending clinical trials;
- we may suspend, delay or alter development or marketing of our drug candidates;
- regulatory authorities may order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications if results of our trials reveal a high and unacceptable severity or prevalence of certain adverse events;



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- regulatory authorities may delay or deny approval of our drug candidates;
- regulatory authorities may withdraw approvals or revoke licenses of an approved drug candidate, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label of an approved drug candidate or impose other limitations on an approved drug candidate;
- we may be required to develop a risk evaluation mitigation strategy for the drug candidate, or, if one is already in place, to incorporate additional requirements under the risk evaluation mitigation strategy, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to conduct post-market studies;
- we could be subject to litigation proceedings and held liable for harm caused to patients exposed to or taking our drug candidates, who may suffer from adverse events related to the treatment;
- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated; and
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated.

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

**We believe that our drug candidates’ Category 1 designation in China should confer certain regulatory advantages on us. These advantages may not result in commercial benefits to us as we have expected, and these advantages may change in the future in a manner adverse to us.**

In China, prior to seeking approval from the NMPA, a pharmaceutical company needs to determine the drug’s registration category, which will determine the requirements for its clinical trial and marketing application. Among our pipeline of 12 drug candidates, eight are in clinical development in China, all of which are designated as Category 1 drug candidates.

The NMPA has adopted several mechanisms for expedited review and approval for drug candidates that apply to Category 1 drug candidates. While we believe that the Category 1 designation of our internally developed clinical stage drug candidates should provide us with a significant regulatory, and therefore commercial, advantage over non-Chinese companies seeking to market products in China, we cannot be sure that this will be the case. The

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pharmaceutical regulatory environment is evolving quickly, and changes in laws, regulations, enforcement and internal policies could result in the “favored” status of Category 1 products changed, or being eliminated altogether or our products classification in Category 1 changed. We cannot be certain that the advantages we believe will be conferred by our Category 1 classifications will be realized or result in any material development or commercial advantage.

**We may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials.**

We 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 sensitive information. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the 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. Failure to comply with any of these laws could result in enforcement action against us, including 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 adverse effect on our business, financial condition, results of operations and prospects.

Such data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects’ private or medical records without their consent, they will be held liable for damages caused thereby. We have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected, including encrypting such information in our information technology system so that it cannot be viewed without proper authorization, and setting internal rules requiring our employees to maintain the confidentiality of our subjects’ medical records. However, these measures may not always be effective. For example, our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence. In addition, our clinical trials frequently also involve professionals from third party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. Please refer to the paragraphs headed “– Risks Relating to Our Operations – Our internal information technology and other infrastructure, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches” in this section. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure to protect the confidentiality of subjects’ medical records and personal data, or any restriction on or liability as a result of, our use of medical data, could have a material adverse effect on our business, financial condition and results of operations.

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The Data Security Law of the PRC (《中華人民共和國數據安全法》), which took effect on September 1, 2021, provides that the relevant authorities will promulgate measures for cross-border transfers of important data. If any company violates the Data Security Law of the PRC to provide important data outside China, it may be subject to penalties, fines, suspension of business operation and/or revocation of business license. However, as of the Latest Practicable Date, the Chinese government has not promulgated the important data catalogs.

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

Additionally, the Gramm-Leach-Bliley Act of 1999 (along with its implementing regulations) (the “**GLBA**”) restricts certain collection, processing, storage, use and disclosure by covered companies of certain personal information, requires notice to individuals of privacy practices and provides individuals with certain rights to prevent the use and disclosure of certain non-public or otherwise legally protected information. The GLBA also imposes requirements regarding the safeguarding and proper destruction of personal information through the issuance of data security standards or guidelines. In addition, many U.S. states have laws that protect the privacy and security of sensitive and personal information. Certain U.S. state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the California Consumer Privacy Act of 2018 (the “**CCPA**”), which went into effect on January 1, 2020, imposes stringent data privacy and security requirements and obligations with respect to the personal information of California residents and households. Among other things, it requires covered companies to provide new disclosures to California consumers and

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provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information that may increase the likelihood of, and risks associated with, data breach litigation. The CCPA was amended in September 2018 and November 2019, and it is possible that further amendments will be enacted. It remains unclear how various provisions of the CCPA will be interpreted and enforced, and multiple states have enacted or are expected to enact similar laws. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we may be subject.

In Europe, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, in the European Economic Area (the “EEA”) and the United Kingdom, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation (the “GDPR”). The GDPR came into effect in May 2018, superseding the European Union Data Protection Directive, and imposing more stringent data privacy and security requirements on companies in relation to the processing of personal data of EU data subjects. The GDPR, together with national legislation, regulations and guidelines of the EU member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, use, retain, protect, disclose, transfer and otherwise process personal data. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal data relates, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications and the security and confidentiality of personal data. The GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater. Such fines are in addition to any civil litigation claims by customers and data subjects. European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which contribute to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices is often updated or otherwise revised. Further, while the United Kingdom enacted the Data Protection Act 2018 in May 2018 that supplements the GDPR and has publicly announced that it will continue to regulate the protection of personal data in the same way post-Brexit, Brexit has created uncertainty with regard to the future of regulation of data protection in the United Kingdom. Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services.

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security, and transfers may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant awards, fines, penalties, judgments and negative publicity, and may otherwise materially and adversely affect our business, financial condition and results of operations. We may not be able to respond quickly or effectively to regulatory, legislative and other

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developments, and these changes may in turn impair our ability to offer our existing or planned drug candidates or increase our cost of doing business. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

**Even after we obtain regulatory approval for the marketing and distribution of our drug candidates, our products will continue to remain subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our future approved drugs.**

If the NMPA, FDA, PMDA or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping 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, or CMC, specifications, continued compliance with current GMPs, and GCPs and potential post-approval studies for the purposes of license renewal.

Any approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug’s commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug candidates. The NMPA, FDA, PMDA or a comparable regulatory authority may also require a risk evaluation mitigation strategy program as a condition of approval of our drug candidates or following approval. In addition, if the NMPA, FDA, PMDA or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements, including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and good clinical practice (“GCP”), for any clinical trials that we conduct post-approval.

Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could significantly harm our business, financial condition and prospects.

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The NMPA, FDA, PMDA and other regulatory authorities strictly regulate the marketing, labelling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA, FDA, PMDA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

**If we are able to commercialize our drug candidates, we may face uncertainties from national, provincial or other third party drug reimbursement practices and unfavorable drug pricing policies or regulations, which could harm our business.**

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from jurisdiction to jurisdiction. We intend to seek approval to market our drug candidates in China, the U.S., and in other jurisdictions. In both China and the U.S., the pricing of pharmaceutical products 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 or provincial or local human resources and social security authorities, 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”), or provincial or local medical insurance catalogues for the National Medical Insurance Program, 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 drugs will be included in the NRDL or relevant provincial or local medical insurance catalogs. Products included in the NRDL or relevant provincial or local medical insurance catalogs are typically generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in the NRDL or relevant provincial or local medical insurance catalogs due to the affordability of the government’s Basis Medical Insurance. In particular, the PRC government has implemented significant reforms of the pharmaceutical industry in recent years and may enforce additional measures in the future which may adversely affect our pricing strategy drugs. Even if our drug candidates have already obtained regulatory approval, any adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates.

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

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

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the NMPA, FDA, PMDA 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. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved drugs and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

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

Healthcare providers, physicians and others play a primary role in recommending and prescribing any products for which we obtain regulatory approval. If we obtain the NMPA, FDA, PMDA or other comparable regulatory authorities' approval for any of our drug candidates and begin commercializing those drugs in China, the U.S. or other applicable jurisdictions, our operations may be subject to various fraud and abuse laws of such jurisdictions, including, without limitation, the PRC Anti-Unfair Competition Law (《反不正當競爭法》), the PRC Criminal Law (《刑法》), the Federal Anti-Kickback Statute and the Federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs.

In addition, we are subject to similar healthcare laws in other jurisdictions, some of which may be broader in scope than others and may apply to healthcare services reimbursed by any source, which may include not only governmental payers, but also private insurers. There are ambiguities as to what is required to comply with any of these requirements, and if we fail to comply with any such requirement, we could be subject to penalties.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the Federal False Claims Act as well as under the false claims laws of several states.

Neither the PRC government nor the PRC courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations. Furthermore, if any of the physicians or



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other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which may also adversely affect our business.

**Changes in U.S. and international trade policies, particularly with regard to China, may adversely impact our business and operating results.**

Any tensions and political concerns between China and the relevant foreign countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. The U.S. government has made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs affecting certain products manufactured in China. It is unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry. While we have not started commercialization of drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our future approved drugs, the competitive position of our future approved drugs, 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 future approved drugs in certain countries. If any new tariffs, legislation and/or regulations are implemented, or in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition and results of operations. It also remains unclear what actions, if any, the U.S. government will take with respect to other existing international trade agreements. If the U.S. were to withdraw from or materially modify certain international trade agreements to which it is a party, especially with respect to intellectual properties transfer, our business, financial condition and results of operations could be negatively impacted.

### **Risks Relating to Manufacturing of Our Products**

**We have limited experience in manufacturing pharmaceutical drug products on a large commercial scale, which is a highly exacting and complex process, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.**

We have limited experience in large-scale manufacturing of our products for commercial use. Moreover, the manufacturing of pharmaceutical drug products is highly complex. Problems may arise during manufacturing for a variety of reasons, including but not limited to:

- equipment malfunction;
- failure to follow specific protocols and procedures;
- changes in product specification;

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

Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred. We face additional manufacturing risks in relation to the CMOs we engage from time to time. Please refer to the paragraphs headed “– Other Risks Relating to Our Business – Risks Relating to Our Reliance on Third Parties – We may rely on third parties to manufacture a portion of our drug candidates for clinical development and commercial sales. Our business could be harmed if those third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality levels or prices” in this section.

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

We may also encounter problems with achieving adequate or clinical-grade products that meet the NMPA, FDA, PMDA or other comparable regulatory authority standards or specifications, and maintaining consistent and acceptable production costs. We may also experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to our facilities or the equipment in them. In such events, we may be required to delay or suspend our manufacturing activities. We may be unable to secure temporary, alternative manufacturers for our drugs with the terms, quality and costs acceptable

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to us, or at all. It could delay our clinical trials and/or the availability of our future approved products for commercial sale. Moreover, we may spend significant time and costs to remedy these deficiencies before we can continue production at our manufacturing facilities.

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

**Any delays in completing and receiving regulatory approvals for our manufacturing facilities, or any disruption of our current facilities or in the development of new facilities, could reduce or restrict our production capacity or our ability to develop or sell products, which could have a material and adverse effect on our business, financial condition and results of operations.**

We currently cooperate with third-party collaboration partners to manufacture our existing drug candidates for research and development purposes, and we have been building our in-house production facilities in Xuzhou, Jiangsu province, with cGMP-compliant manufacturing system and facilities to meet stringent global standards. In anticipation of large needs of our drugs upon commercialization, we purchased the use right to land in Xuzhou with an aggregate area of 65,637.97 square meters. We have obtained the construction permit and started construction of new manufacturing facilities in Xuzhou. We expect to complete building the facilities and commence operation by 2024. These facilities may encounter unanticipated delays and expenses due to a number of factors, including regulatory requirements. If construction, regulatory evaluation and/or approval of our new facilities is delayed, we may not be able to manufacture sufficient quantities of our drug candidates and our drugs, if approved, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from various sources.

Our future manufacturing facilities will be required to obtain and maintain regulatory approvals, including being subject to ongoing, periodic inspection by the NMPA, FDA, PMDA or other comparable regulatory authorities to ensure compliance with GMP regulations. Further, we will be subject to continual review and inspections to assess compliance with

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cGMP and adherence to commitments made in any NDA, other marketing application, and previous responses to any inspection observations if we are to build manufacturing facilities in the future. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We cannot guarantee that we will be able to adequately follow and document our adherence to such GMP regulations or other regulatory requirements. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to follow and document our adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the construction of our manufacturing facilities and the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or their commercialization, if approved. Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of our drug candidates, operating restrictions and criminal prosecutions, any of which could harm our business. We cannot assure you that we will not experience any disruptions to the construction of our manufacturing facility, and there could be delays in completing and receiving regulatory approvals for our new manufacturing facility.

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

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

If our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new

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

**If we are unable to meet the increasing demand for our existing drug candidates and future drug products by ensuring that we have adequate manufacturing capacity, or if we are unable to successfully manage our anticipated growth or to precisely anticipate market demand, our business could suffer.**

Manufacturers of drug products oftentimes encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process, including the absence of contamination. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel and compliance with strictly-enforced regulations. If our manufacturing facilities encounter unanticipated delays and expenses as a result of any of these difficulties, or if construction, regulatory evaluation and/or approval of our new facilities is delayed, we may not be able to manufacture sufficient quantities of our drug candidates, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could also require us to raise additional funds from other sources.

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

In anticipation of commercialization of our drug candidates, we aim to significantly expand our manufacturing capacity, mainly through the construction of new manufacturing facilities. However, the timing and success of these plans are subject to significant uncertainty.

Furthermore, given the size of our new facility, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence operation. During the construction and ramp-up period, there may be significant changes in the macroeconomics of the pharmaceutical and biopharmaceutical industry, including, among other things, market

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demand, product and supply pricing trends and customer preferences. Any adverse trends in these respects could result in operational inefficiency and unused capacity in our facility. We may also experience various unfavorable events in the course of developing our new manufacturing facility, such as:

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

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

### **Risks Relating to Commercialization of Our Products**

**Our drug and drug candidates (once approved) may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community that would be necessary for their commercial success.**

Our drug and drug candidates (once approved), may fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community, who may prefer other drugs to ours. If our drug or future approved drugs do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our drug and drug candidates, if approved for commercial sale, will depend on a number of factors, including, but not limited to:

- physicians, hospitals, medical treatment centers and patients considering our drug to be safe and effective;
- product labeling or package insert requirements of the NMPA, FDA, PMDA or other comparable regulatory authorities, including the clinical indications for which our drug and drug candidates are approved and limitations or warnings contained in the labeling;
- whether our drug and drug candidates have achieved first-in-class or best-in-class status and the potential and perceived advantages of our drug candidates over alternative treatments;

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- the prevalence and severity of any side effects;
- product labelling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labelling approved by regulatory authorities;
- the timing of market introduction of our drug and drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- availability of adequate coverage and reimbursement under the NRDL and provincial reimbursement drug lists in China, or from third-party payers and government authorities in other applicable jurisdictions;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities;
- relative convenience and ease of administration, including as compared with alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

Even if our drug and future approved drug candidates achieve market acceptance, we may not be able to maintain such market acceptance over time if new products or technologies are introduced that are more favorably received than our drug and drug candidates, more cost-effective or render our drug and drug candidates obsolete. Our failure to achieve or maintain market acceptance for our drug and future approved drug candidates would materially adversely affect our business, financial condition, results of operations and prospects.

**We are exposed to credit risk of our customers and we may experience delays or defaults in our trade and other receivables.**

Our trade receivables as of December 31, 2020 and 2021 and May 31, 2022, were nil, RMB65.1 million and RMB101.9 million, respectively. Our loss allowance for impairment of trade receivables in 2020, 2021 and the five months ended May 31, 2022 were nil, RMB130,000 and RMB204,000, respectively. In the event that Simcere Group, or a significant number of our customers fail to settle the trade receivables in full for any reason, our cashflow level may be adversely affected, and we may have to make provision for impairment, write-off the receivables and/or incur legal costs to recover the outstanding sum from Simcere Group or our customers, which may in turn have a material and adverse impact on our business, financial conditions and results of operations.

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### Risks Relating to Our Intellectual Property Rights

**The scope of our patent protection may be uncertain. Our current or any future patents may not be successful and any patent rights we or our licensing partners have may be challenged and invalidated even after issuance, which would materially adversely affect our ability to successfully commercialize any product or technology.**

The patent position of pharmaceutical and biopharmaceutical companies is generally highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future owned and licensed patent applications may not issue as patents at all, and even if such patent applications do issue as patents, they may not issue in a form, or with a scope of claims, that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance and changes in either the patent laws or interpretation of the patent laws in China, the U.S. and other jurisdictions. Any patents that we own or in-license may be challenged, narrowed, circumvented or invalidated by third parties. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patent rights may be challenged in the courts or patent offices in China, the U.S. and other jurisdictions. We may be subject to a third-party submission of prior art to the United States Patent and Trademark Office (the “USPTO”) challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a patent’s issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. We or our licensors may become involved in opposition, derivation, revocation, re-examination, post-grant review, *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. In addition, a third party may claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. An adverse determination in any such submission, proceeding or litigation could put one or more of our owned or licensed patents at risk of being interpreted narrowly, invalidated, or ruled unenforceable and could allow third parties to commercialize products similar or identical to our technology or drug candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize drug candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we or our licensors may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges and proceedings may result in loss of patent rights or freedom to operate, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, any of



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which could limit our ability to stop others from using or commercializing similar or identical technology and products, or could limit the duration of the patent protection of our technology and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we cannot predict whether any of our technology or drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Despite the measures we or our licensing partners have taken to obtain patent protection with respect to our major drug candidates and technologies, any of such issued patents could be challenged or invalidated. For example, if we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the U.S., for example, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the relevant patent office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in China, the U.S. or in other jurisdictions, even outside the context of litigation. Such mechanisms include *ex parte* re-examination, *inter partes* review, post-grant review, interference proceedings, derivation, invalidation, revocation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer adequately cover and protect our drug candidates.

Additionally, patent rights we may own or license currently or in the future may be subject to a reservation of rights by one or more third parties. These rights may also permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology that was developed using U.S. government funding. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the U.S. government-funded technology, or if it determines that action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the U.S. Any exercise by the government or other third parties of such rights could harm our competitive position, business, financial condition, results of operations, and prospects. Furthermore, the recipient of such U.S. government funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. If we are unable to meet these

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obligations, it may lead to a loss of rights or the unenforceability of relevant patents or patent applications. 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 are able to obtain patent protection for our drug candidates, the life of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially adversely affected.**

Although various adjustments and extensions may be available, the life of a patent, and the protection it affords, is limited. For example, in the U.S., the expiration of a patent is 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., a patent’s term may be extended or adjusted to account for administrative delays during prosecution by the USPTO, in excess of a patent applicant’s own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly owned patent having an earlier expiration date. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights. As a result, we 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. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates as described in “Business – Intellectual Property” of this document. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our owned and licensed patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing 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.

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**The implementation of patent linkage, patent term extension and data and market exclusivity for pharmaceutical products in China and the United States, as applicable, remain uncertain and could increase the risk of early generic competition for our products in China.**

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

Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Moreover, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the U.S. to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the U.S. Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where FDA designates the drug candidate as an orphan drug and the drug is approved for the designated orphan indication. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after the FDA grants marketing approval for the innovative product.

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In China, the fourth Amendments to the PRC Patent Law (《中華人民共和國專利法》), which was adopted on October 17, 2020 and was put into effect on June 1, 2021, provides a drug-patent linkage system, as well as Patent Term Extension for drug patents.

According to the drug-patent linkage system, “During the review and approval of marketing authorization of a drug, when the applicant of drug marketing authorization and the patentee or interested party have dispute regarding patent rights of the drug under application, relevant parties may file a lawsuit with the people’s court and pursue judgement for whether the relevant technical solution of the drug under application falls within the scope of protection of the relevant patent rights. The drug regulatory authority of the State Council may make a decision on whether to suspend the drug marketing authorization according to effective judgment of the people’s court within specified period. The applicant of drug marketing authorization and the patentee or interested party may also apply for an administrative ruling to the patent administration department of the State Council regarding patent right dispute related to the drug under application of marketing authorization.”

As to the Patent Term Extension for drug patents, the fourth Amendments provides that, “In order to compensate for the time occupied by review and approval for marketing the new drugs, the patent administration department of the State Council may extend the period of the patent right for an invention patent of new drug that obtains the marketing authorization in China upon the patentee’s request. The compensation period shall not exceed 5 years, and the total effective term of the patent right of the innovative drug after being put into the market shall not exceed 14 years.”, which is in line with corresponding provisions in the Economic and Trade Agreement Between the Government of the People’s Republic of China and the Government of the United States of America (中華人民共和國政府和美利堅合眾國政府經濟貿易協議) with the U.S. government entered into in January 2020.

Certain detailed implementation rules and interpretation rules for drug-patent linkage are published for solicitation of public comments, including Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial) (《藥品專利糾紛早期解決機制實施辦法(試行)》) published by the NMPA and the China National Intellectual Property Administration the “CNIPA”) on July 4, 2021, and Provisions on Several Issues Concerning the Application of Law in the Trial of Patent Civil Cases Involving Drug Marketing Review and Approval of Patent (Draft for Solicitation of Comments) (《關於審理涉藥品上市審評審批專利民事案件適用法律若干問題的規定(徵求意見稿)》) published by Supreme People’s Court on October 29, 2020. However, the implementing rules for the drug-patent linkage system have not yet been adopted and therefore the implementation, interpretation and enforcement of laws and regulations regarding the drug-patent linkage system remain uncertain in China.

In view of the uncertainty in the implementation rules in patent term extension and patent linkage, and also in view of the lack of effective law or regulation providing regulatory data protection, a lower-cost generic drug can emerge onto the market much more quickly. These factors result in weaker protection for us against generic competition in China than could be available to us in the United States. For instance, it remains unclear whether the patents we have in China would be eligible to be extended for patent term lost during clinical trials and

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the regulatory review process, and currently no regulatory data protection is available to us to extend exclusivity of our drug products. If we are unable to obtain patent term extension, or the term of any such extension is less than that we request, our competitors or other third parties may obtain approval of competing products following our patent expiration. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

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

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

Although we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we

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

Moreover, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our drug candidates.

Additionally, while we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaboration partners or other third parties have an interest in our owned, out-licensed or in-licensed patents, patent applications, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, collaboration partners, consultants or others who are involved in developing our drug candidates or technology. Litigation may be necessary to defend against these and other claims challenging inventorship of our owned, out-licensed or in-licensed patents, patent applications, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to our drug candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

**Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.**

Application fees, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and patent applications are due to be paid to the NIPA, the USPTO and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The NIPA, the USPTO and other patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We rely on our in-house and outside counsel and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to

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comply with these requirements with respect to our licensed intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors or other third parties might be able to enter the market, which would have a materially adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

**We may be subject to substantial costs and liability, or be prevented from using technologies incorporated in our drug candidates or future drugs, as a result of litigation or other proceedings relating to patent or other intellectual property rights.**

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields in which we are developing our drug candidates. We may also be unaware of third-party patents or patent applications, and given the dynamic area in which we operate, additional patents are likely to be issued that relate to aspects of our business. There are a substantial amount of litigations and other claims and proceedings involving patent and other intellectual property rights in the pharmaceutical industry generally. As the pharmaceutical industry expands and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are using technology in violation of their patents or other proprietary rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from their normal responsibilities. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalty and other fees and expenses on us.

If third parties bring successful claims against us for infringement of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would substantially divert diversion of employee resources from our business. In the event of a successful claim against us of infringement or misappropriation, or a settlement by us of any such claims, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, pay royalties or redesign our infringing drug candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. Any such license might not be available on reasonable terms or at all. In the event

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that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the market price of our Shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

**Changes in patent laws of China, the U.S. or other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates and future drugs.**

As is the case with other pharmaceutical companies, our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves technological and legal complexity, and obtaining and enforcing pharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in China, the U.S. or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

In China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in China. For example, the fourth Amendments to the PRC Patent Law was put into effect on June 1, 2021, provides a patent term extension and patent term adjustment. Patent term extension of up to five years is available to invention patents claiming new drugs, to compensate for the time occupied by review and approval for marketing the new drugs. Patent term adjustment is available to all invention patents, to compensate unreasonable delays caused by CNIPA during the patent examination procedures. The Proposed Amendments to Implementing Rules of the Patent Law of the People’s Republic of China (Draft) (《專利法實施細則修改建議(徵求意見稿)》) was published by the CNIPA on November 27, 2020, and proposed detailed implementation rules for patent term extension and adjustment, including for example, the eligible type of patents, requirements for the application for patent term extension and adjustment, how to calculate the extension, and limitations during the extended patent term. However, the implementing rules for the drug patent extension



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system have not yet been finalized or adopted, and therefore the implementation, interpretation and enforcement of laws and regulations regarding the patent extension system remain uncertain. As a result, patents owned by third parties eligible for submitting applications for a patent term extension may be extended, which may in turn affect our ability to commercialize our drug candidates without facing infringement risks. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may in turn render our drug candidates non-competitive. We cannot guarantee that any other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

Recently enacted U.S. laws have changed the procedures through which patents may be obtained and by which the validity of patents may be challenged. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications in the U.S. and the enforcement or defense of our issued patents, each of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Recent U.S. Supreme Court rulings have also changed the law surrounding patent eligibility and narrowed the scope of patent protection available in certain circumstances and weakened 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, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights. Any of the foregoing could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial condition, results of operations and prospects.

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**If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers, and we may be subject to 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 secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to trade secrets or confidential information, such as our employees, collaboration partners, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties that have access to them. However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Any of the parties with whom we enter into confidentiality agreements may breach or violate the terms of any such agreements and may disclose our proprietary information, and we may not be able to obtain adequate remedies for any such breach or violation. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our drug candidates and technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, consultants, and advisors, including our senior management, may currently be, or were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisors, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. An inability to incorporate such intellectual property

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rights would harm our business and may prevent us from successfully commercializing our drug candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates and technology, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our employees and management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Furthermore, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Moreover, our trade secrets and other proprietary or confidential information may become known or be independently developed by a third party, or misused by any collaborator or other third party to whom we disclose such information. Although we seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, confidential or proprietary information and other intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

Finally, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar drug candidates or technology, without payment to us, or could limit the duration of the patent protection covering our drug candidates and technology. Such challenges may also result in our inability to develop, manufacture or commercialize our drug candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened,

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it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

**If we fail to comply with our obligations in the agreements under which we license intellectual property rights to or from third parties or otherwise experience disruptions to our business relationships with our licensees or licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.**

We may in the future enter into license agreements with third parties providing us or such third parties with rights to various intellectual property, including rights in patents, patent applications and copyrights. These license agreements may impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us or the third party. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements and, upon the effective date of such termination, may have the right to terminate our exclusive rights or all of our rights and acquire rights to certain of our intellectual property. If any of our licensors terminate any license we rely upon, we might not be able to develop, manufacture or market any drug candidate related to the intellectual property licensed under these agreements and we may face other additional penalties. Such an occurrence could diminish the value of these products and our business. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under such agreements to important intellectual property or technology or our rights to develop and commercialize our drug candidates. In addition, such an event may cause us to experience significant delays in the development and commercialization of our drug candidates or incur liability for damages. If any such license is terminated, our competitors or other third parties could have the freedom to seek regulatory approval of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain of our drug candidates.

In addition, we may need to obtain additional licenses from licensors and others to advance our research or allow commercialization of drug candidates we may develop. In connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our drug candidates and technology. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our drug candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected drug candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

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Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our or our licensors' obligation to obtain, maintain and defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, drug candidates and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other intellectual property rights under our license agreements;
- our diligence, financial or other obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are, and any such future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our diligence, financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed or any other dispute described above related to our license agreements prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

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

We currently own issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. We cannot assure you that any

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currently pending trademark applications or any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature in the future, upon regulatory approval, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may be unsuccessful to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

### **Intellectual property rights do not necessarily protects us from all potential threats.**

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 or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any drug candidates or any potential drug candidates we may develop or utilize similar technology that are not covered by the claims of the patents that we own or license now or in the future;
- we, our licensors or current or future collaboration partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we may license in or own in the future;

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- we, our licensors or current or future collaboration partners might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we hold rights to may not provide us with a competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in jurisdictions where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not be able to successfully maintain our intellectual property rights in compliance with various procedural, document submission, fee payment and other requirements in each jurisdiction;
- we may not successfully continue to apply for, obtain or maintain related intellectual properties to further develop our product pipeline;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business;
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property; and
- the success of licensed-in products depends upon our and our current or future collaboration partners' ability to obtain and maintain intellectual property protection for our products and technologies, and it is difficult and costly to protect our proprietary rights and technology, and we and our current or future collaboration partners may not be able to ensure such protections.

Should any of these events occur, they could materially adversely affect our competitive position, business, financial condition, results of operations and prospects.

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### Risks Relating to Our Reliance on Third Parties

**We may rely on third parties to manufacture a portion of our drug candidates for clinical development and commercial sales. Our business could be harmed if those third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality levels or prices.**

We currently rely on and may continue to rely on third parties such as CMOs for our manufacturing process and for the clinical supply and commercial sales of our drug candidates in the future. Reliance on third-party CMOs would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the NMPA, FDA, PMDA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates. This evaluation would require new testing and cGMP-compliance inspections by the NMPA, FDA, PMDA or other comparable regulatory authorities;
- our third-party CMOs might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- third-party CMOs are subject to ongoing periodic unannounced inspection and other government regulations by the NMPA, FDA, PMDA or other comparable regulatory authorities to ensure strict compliance with cGMP. We do not have control over third-party CMOs' compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party CMOs in the manufacturing process for our drug candidates;
- third-party CMOs 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;
- third-party CMOs may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;



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- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- we may lose or fail to maintain our relationship with our third-party CMOs and may incur additional costs in identifying and engaging qualified replacement in a timely manner.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs or adversely impact commercialization of our future approved drugs.

Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or because of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide any future approved drugs for commercial sale and our drug candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the provision of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs, and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

**We depend on a stable and adequate supply of quality materials, including reagents and consumables and R&D and manufacturing equipment, from our suppliers, and price increases or interruptions of such supply could have an adverse impact on our business.**

Our business operations require a substantial amount of raw materials, such as reagents and consumables, as well as equipment and other materials needed for research and development as well as manufacturing purposes. During the Track Record Period, we relied on third parties to supply certain materials. We expect to continue to rely on third parties to supply such materials and equipment for the research, development, manufacturing and commercialization of our drug candidates. Please refer to the paragraphs headed “Business – Raw Materials and Suppliers” in this document.

Currently, the materials and equipment are supplied by a limited number of major source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist and we have developed alternative sourcing strategies for these supplies. We will establish necessary relationship with alternative sources based on supply continuity risk assessment. However, since we have a limited number of major source suppliers during the Track Record Period, there is a risk that, if supplies were interrupted, our business and results of operations would be materially harmed. Any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the research and development of our drug candidates.

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Moreover, we require a stable supply of materials for our drug candidates in the course of our research and development activities, and such needs are expected to increase significantly once we enter commercial production of drugs upon receipt of regulatory approval, but there is no assurance that current suppliers have the capacity to meet our demand. Any significant delay in receiving such materials in the quantity and quality that we need could delay the completion of our clinical studies, regulatory approval of our drug candidates or our ability to timely meet market demand for our commercialized products, as applicable. Our suppliers may not be able to cater to our growing demands or may reduce or cease their supply of materials to us or alter the commercial terms in an unfavorable way to us at any time.

We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers and as a result, lower our profitability. In the event of significant price increases for such materials, we cannot assure you that we will be able to raise the prices of our future approved drugs and services sufficiently to cover the increased costs. As a result, any significant price increase for our needed materials may have an adverse effect on our profitability. Additionally, although we have implemented quality inspection on the materials before using them in the manufacturing process, we cannot assure you that we will be able to identify all of the quality issues.

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

### RISKS RELATING TO OUR OPERATIONS

#### **We operate in a competitive industry and may fail to compete effectively.**

The pharmaceutical industry in which we operate is highly competitive and rapidly changing. Large multinational pharmaceutical companies, established biopharmaceutical companies, specialty pharmaceutical companies, universities and other research institutions have commercialized or are commercializing or pursuing the development of drugs for the treatment of cancer or other indications for which we are developing our drug candidates.

Many of our competitors have substantially more developed commercial infrastructure, greater financial, technical and human resources as well as more drug candidates in late-stage clinical development than we do. Even if successfully developed and subsequently approved by the NMPA, FDA, PMDA or other comparable regulatory authorities, our drug candidates will still face competition based on safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price, patent

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position and other factors. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or gain better acceptance for the same target markets as ours, which will undermine our competitive position. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome price competition and to be commercially successful. Disruptive technologies and medical breakthroughs may further intensify the competition and render our drug candidates obsolete or non-competitive. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

**Any failure to obtain or renew certain approvals, licenses, permits and certificates required for our business may materially and adversely affect our business, financial condition and results of operations.**

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. Some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or bear fines and penalties which could materially and adversely affect our business, financial condition and results of operations. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and we cannot assure that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and in turn, adversely affect results of operations and prospects.

**Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.**

Our operations, and those of our third-party research institution collaborators, suppliers and other contractors and consultants, could be subject to natural or man-made disasters or business interruptions. In addition, we rely on our third-party research institution collaborators for conducting research and development of our drug candidates, and they may be affected by government shutdowns or funding withdrawals. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and could increase our costs and expenses. Moreover, we rely on third-party manufacturers to produce and process supplies of our future approved drugs and drug candidates. Our collaborations with CMOs, our operation of our new manufacturing facility (upon construction completed) and our ability to obtain supplies for manufacturing our drug candidates or future approved drugs could be disrupted if the operations of these collaborators, suppliers or our new manufacturing facility are affected by a man-made or natural disaster or other business interruption. Damage or

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extended periods of interruption to our corporate, development, research or manufacturing facility due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our drug candidates. Our insurance might not cover all losses under such circumstances and our business and financial condition may be seriously harmed by such delays and interruption.

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as other key clinical and scientific personnel, and other employees and consultants. The loss of services of any of these individuals or one or more of our senior management could delay or prevent the successful development of our drug candidates.

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

**Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, and insider trading.**

We are subject to the anti-bribery laws of various jurisdictions, particularly in China and the U.S. As our business expands, the applicability of the anti-bribery laws to our operations will increase. We may be exposed to fraud, bribery or other misconduct committed by our employees, principal investigators, consultants and commercial partners that could subject us to financial losses and sanctions imposed by government authorities, which may adversely affect our reputation. Our procedures and controls to monitor compliance with anti-bribery law may fail to protect us from reckless or criminal acts committed by our employees or other commercial partners. We could be liable for actions taken by them that violate anti-bribery, anti-corruption and other related laws and regulations in China, the U.S. or other jurisdictions. The government authorities may limit the sales of the products involved in any illegal or improper conduct engaged in by our employees or commercial partners. We may be subject to claims, fines or suspension of our operations. Our reputation, our sales activities or the price

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of our Shares could be adversely affected if we are associated with any negative publicity as a result of illegal or improper actions, or allegations of illegal or improper actions, taken by our employees or commercial partners.

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. Any such misconduct committed against our interests, including past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

### **We are subject to the risks of doing business globally.**

Because we operate in China and other jurisdictions, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the occurrence of economic weakness, including inflation or political instability;
- the burden of complying with a variety of foreign laws including difficulties in effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in certain jurisdictions;
- enforcement of anti-corruption and anti-bribery laws;
- trade-protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment;

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- the effects of applicable local tax regimes and potentially adverse tax consequences; and
- significant adverse changes in local currency exchange rates.

In addition, we are subject to general geopolitical risks in foreign countries where we operate, such as political and economic instability and changes in diplomatic and trade relationships, which could cause our results to fluctuate and our revenue to decline. The occurrence of any one or more of these risks of doing business internationally, individually or in the aggregate, could materially adversely affect our business and results of operations.

**Product and professional liability claims or lawsuits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.**

We face an inherent risk of product and professional liability as a result of the clinical testing and any future commercialization of our drug candidates in China, the U.S., and any of our targeted markets. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our drug candidates; injury to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labelling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; significant increase in insurance premium; the inability to commercialize any approved drug candidate; and a decline in the market price of our Shares.

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

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**If we use hazardous materials in a manner that causes injury, we could be liable for damages.**

We are subject to laws and regulations governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials. Our operation involves the use of hazardous materials, including chemicals, and may produce hazardous waste products. We cannot eliminate the risks of contamination or personal injury from these materials.

We do not maintain insurance for environmental liability claims that may be asserted against us in connection with our storage or disposal of hazardous materials. In the event of contamination or personal injury resulting from our use of hazardous materials or our or third parties' disposal 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 may incur substantial costs in order to comply with current or future laws and regulations on use of hazardous materials. These current or future laws and regulations may have significant adverse impact on our research our research, development or production activities. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

**Our internal information technology and other infrastructure, or those used by our CROs 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 current or future CROs, consultants and other service providers are vulnerable to damage from cyber-attacks, computer viruses, malicious codes, unauthorized access, employee theft or misuse, natural disasters, fire, power loss, terrorism, war, and telecommunication and electrical failures, among other things. 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 may 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. In addition, a security breach may result in the loss of, damage to, or public disclosure of personally identifiable information, and such an event could have serious negative consequences, including disputes, regulatory action, investigation, litigation, fines, penalties and damages, and time-consuming and expensive litigation, any of which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

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In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our Company or vendors that provide information systems, networks or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have a material adverse impact on us and our business, including loss of data and damage to equipment, among other things. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, system malfunction or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including but not limited to personal information of our employees and patients, and companies, vendors and the other users of our vendors' confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data or systems. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or those of our third-party vendors and other contractors and consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, results of operations, financial condition or prospects. If we experienced any such material system failure or security breach and interruptions in our operations, it could result in a material disruption of our development programs and our business operations, a breach of sensitive personal information or a loss or corruption of critical data assets including trade secrets or other proprietary information. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.



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Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing and other cyber-attacks. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be adversely influenced. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we engage in more electronic transactions with payers and patients and collect and store an increasing volume of data, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

We may not have adequate insurance coverage to compensate for any losses associated with a system failure, any breach of our computer systems or other cybersecurity attack or any violation of any privacy laws or other obligations. Any breach or failure of our or our vendors' computer systems, information technology and other infrastructure could materially adversely affect our business, financial condition, results of operations and prospects.

**If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, cause dilution to our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.**

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

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;

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- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

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.

PRC regulations and rules concerning mergers and acquisitions, including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (《關於外國投資者併購境內企業的規定》) (the “**M&A Rules**”), and other recently adopted regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. For example, the M&A Rules require that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on national economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. Moreover, according to the Anti-Monopoly Law of PRC (《反壟斷法》) and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings (《關於經營者集中申報標準的規定》) (the “**Prior Notification Rules**”) issued by the State Council, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the MOFCOM when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors (《實施外國投資者併購境內企業安全審查制度的規定》) (the “**Security Review Rules**”), issued by the MOFCOM, specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns, and mergers and acquisitions through which foreign investors may acquire the *de facto* control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval and filing processes, including obtaining approval or filings from the MOFCOM or its local counterparts, may delay or inhibit our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises “national defense and security” or “national security” concerns. However, the MOFCOM or other

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government agencies may publish explanations in the future determining that our business is in an industry subject to security review, in which case our future acquisitions in China, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

Further, we may also discover deficiencies in internal controls, data adequacy and integrity, product quality and regulatory compliance, and product liabilities in businesses we acquire which we did not uncover prior to such acquisition. As a consequence, we may become subject to penalties, lawsuits or other liabilities. Further, any difficulties in the integration of acquired businesses, product or technologies or unexpected penalties, lawsuits or liabilities in connection with such businesses, product or technologies could have a material adverse effect on our business, financial condition and results of operation. 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.

**If we or our CROs/CDMOs/CMOs fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could materially adversely affect the success of our business.**

We are subject to numerous environmental, health and safety laws and regulations, including but not limited to the treatment and discharge of pollutants into the environment and the use of toxic and hazardous chemicals in the process of our business operations. In addition, our new manufacturing facility construction project can only be put into operation after the relevant administrative authorities in charge of environmental protection and health and safety have examined and approved the facility. We cannot assure you that we will be able to obtain all the regulatory approvals for our construction projects in a timely manner, or at all. Delays or failures in obtaining all the requisite regulatory approvals for our construction projects may affect our abilities to develop, manufacture and commercialize our drug candidates as we plan. As requirements imposed by such laws and regulations may change and more stringent laws or regulations may be adopted, we may not be able to comply with, or accurately predict any potential substantial cost of complying with, these laws and regulations. If we fail to comply with environmental protection, and health and safety laws and regulations, we may be subject to rectification orders, substantial fines, potentially significant monetary damages, or production suspensions in our business operations. As a result, any failure by us to control the use or discharge of hazardous substances could have a material and adverse impact on our business, financial condition, results of operations and prospects.

In addition, we cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our facility during the process of discovery, testing, development and manufacturing of our drug candidates. In the event of such accident, we could be held liable for damages and clean-up costs which, to the extent not covered by existing insurance or indemnification, could harm our business. Other adverse effects could result from

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such liability, including reputational damage. We may also be forced to close or suspend operations at certain of our affected facility temporarily, or permanently. As a result, any accidental contamination, biological or chemical hazards or personal injury could have a material and adverse impact on our business, financial condition, results of operations and prospects.

We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

**We have historically received government grants and subsidies for our research and development activities. Expiration of, or changes to, these incentives or policies or our failure to satisfy any condition for these incentives would have an adverse effect on our results of operations.**

We have historically benefited from government grants, subsidies and other preferential policies as incentives for our research and development activities. We recorded government grants of RMB0.6 million, RMB8.4 million and RMB0.7 million, for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, respectively. Apart from the government grants, our subsidiary in China, 3DMed Beijing, was recognized as a High and New Technology Enterprise in 2019 and therefore is entitled to a preferential income tax rate of 15% for a three-year period. These government grants were generally in support of our research and development activities of our drugs on oncology. Please refer to the paragraphs headed “Financial Information – Description of Certain Key Items of Consolidated Statements of Profit or Loss and Other Comprehensive Income – Other Income and Gains” in this document and note 5 to the Accountants’ Report set out in Appendix I to this document for further details. Our government grants may vary from period to period going forward and our results of operations may be affected as a result. Our eligibility for government grants and the preferential income tax treatment is dependent on a variety of factors, including the assessment of our improvement on existing technologies, relevant government policies, the availability of funding at different granting authorities and the research and development progress made by other peer companies. The incentives are subject to the discretion of the central government or relevant local government authorities, which could determine at any time to eliminate, suspend or reduce these financial incentives, generally with prospective effect. In addition, the policies according to which we historically received government grants may be halted by the relevant government entities at their sole discretion. Since our receipt of the government grants and eligibility for the preferential income tax treatment are subject to periodic time lags and inconsistent government practice, as long as we continue to receive these government grants and enjoy the preferential income tax treatment, our net income in a particular period may be higher or lower relative to other periods depending on the potential changes in these government grants or preferential income tax policies in addition to any business or operational

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factors that we may otherwise experience. There is no assurance that we will continue to receive such government grants, receive similar level of government grants, or at all, or be eligible to enjoy the preferential income tax treatment in the future. The discontinuation of government grants, subsidies and our eligibility for the preferential income tax treatment currently available to us could have a material adverse effect on our business, financial condition and results of operations.

**We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which we may not be able to do successfully.**

The global pharmaceutical drug market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, our research and development costs were RMB264.0 million, RMB371.2 million and RMB138.3 million, respectively. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our clinical trials. We intend to continue to enhance our technical capabilities in drug discovery, development and manufacturing, which are capital-and-time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may make our techniques obsolete, which could harm our business and prospects.

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

As our development and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent and any future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- continuing to innovate and develop advanced technology in the highly competitive pharmaceutical market;
- managing our relationships with third parties, including suppliers and partners;

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- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our drug candidates will depend, in part, on our ability to effectively manage our recent growth and any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

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

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

Since our operations are labor-intensive and our operations, to a certain extent, require the use of technical skills and know-how of our employees, our success depends in part on our ability to attract, retain and motivate a sufficient number of qualified employees. We have implemented a number of initiatives in an effort to attract, retain and motivate our qualified and competent staff. There is no assurance that these measures will be effective or that supply of skilled labor in local markets will be sufficient to fulfil our needs. Competition for competent and skilled labor is intensive in the industry. Our failure to hire and retain enough skilled employees could delay the anticipated pre-clinical studies or clinical trials timeframe or receipt of regulatory approvals to commercialize our drug candidates, or result in our expenses exceeding our initial budget. Any of the foregoing changes could have a material adverse effect on our business, profitability and prospects.

Further, substantially our entire workforce is employed in China. The average labor cost in China has been steadily increasing over the past years as a result of government- mandated wage increases and other changes in the PRC labor laws. Further changes in the labor laws, rules and regulations may be promulgated by the Chinese government in the future and our operations may be materially adversely affected if such laws, rules or regulations impose additional burden on the employers. The labor cost will continue to increase in the future which is in line with the economic growth in China. Competition for employees would require us to pay higher wages, which would result in higher labor costs.

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

We maintain insurance policies that are required under the PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. In line with industry practice in China, we have elected not to maintain certain types of insurance, such as insurance for environmental liability. Our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our facility or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may negatively impact our drug development and overall operations.

**Any failure to comply with the PRC regulations regarding mandatory social insurance and housing fund contributions may subject us to fines and other legal or administrative sanctions.**

According to the Social Insurance Law (《中華人民共和國社會保險法》) which was last amended on December 29, 2018 and other applicable PRC regulations, any employer operating in China must open social insurance registration accounts and contribute social insurance premium for its employees. Any failure to open social insurance registration account may trigger an order of correction where correction is not made within a specified period of time, the competent authority may further impose fines. Any failure to make timely and adequate contribution of social insurance premium for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such overdue social insurance premium within a specified period of time, and the competent authority may further impose fines or penalties. According to the Regulation on the Administration of Housing Accumulation Funds (《住房公積金管理條例》), as amended in 2002 and 2019, the relevant housing fund authority may order an enterprise to pay outstanding contributions within a prescribed time limit.

During the Track Record Period, we have engaged a third party human resources company to pay, on behalf of the Company, the relevant contribution for certain offsite employees. As a result, we may be required by competent authorities to rectify the non-compliance and could be subject to a fine or penalty. As of the Latest Practicable Date, no competent government authorities had imposed administrative action, fine or penalty to us with respect to this non-compliance incident. We cannot assure you that we will not be subject to any penalty, or order to rectify non-compliance in the future. We may incur additional expenses to comply with such laws and regulations.

**We have been building our in-house production facilities in Xuzhou and any disruptions to the future operation of our in-house production facilities could materially adversely affect our business, financial condition and results of operations.**

As of the Latest Practicable Date, we owned land use rights to one parcel of land in Xuzhou Economic and Development Area with an area of 65,637.97 square meters and we have been building our in-house production facilities on this parcel of land. We have obtained the

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construction permit and started construction of new manufacturing facilities in Xuzhou. Please refer to the paragraphs headed “Business – Production and Quality Control – In-house Production Facilities and Future Expansions” in this document for more details. The future operation of our in-house production facilities might be substantially interrupted due to a number of factors, many of which are outside of our control, including but not limited to fires, floods, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks and wars, loss of licenses, certifications and permits, changes in governmental planning for the land underlying these facilities, and regulatory changes.

If the future operation of any of our in-house production facilities is substantially disrupted, we might not be able to replace the equipment at such facilities, or use a different facility to continue production in a timely and cost-effective manner. As a result, we might fail to fulfill contract obligations or meet market demand for our products, and our business, revenue and profitability could be materially adversely affected.

### **We are subject to risks associated with leasing space.**

We lease our some of our offices in China. The lessors of the leased properties may not have valid title or have the legal rights to such leased properties or may not have complied with all the necessary procedures. In addition, as our leases expire, we may fail to negotiate renewals, either on commercially acceptable terms or at all, which could require us to close such offices. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially adversely affect our business, results of operations and financial condition.

Under 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 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. However, as of the Latest Practicable Date, because the lessors failed or are reluctant to provide necessary documents for us to register the leases, a few of the lease agreements for the premises under which we operated our branch offices had not obtained such registrations. We may be required by relevant government authorities to file these lease agreements for registration within a time limit, and may be subject to a fine for non-registration exceeding such time limit, which may range from RMB1,000 to RMB10,000 for each lease agreement.

### **Negative publicity and allegations involving us, our Shareholders, Directors, officers, employees and business partners may affect our reputation and may, as a result, negatively affect our business, financial condition and results of operations.**

We, our Shareholders, Directors, officers, employees and business partners may be subject to negative media coverage and publicity from time to time. Any negative publicity concerning us, our affiliates or any entity that entitled the “3DMed” name, our Shareholders, Directors, officers, employees and business partners, management, even if untrue, could



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adversely affect our reputation and business prospects. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, Directors, officers, employees and business partners were incompliant with any laws or regulations or became involved in lawsuits, disputes, or other legal proceedings or became subject to administrative measures, penalties or investigations by regulatory authorities, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity. In addition, referrals and word of mouth have significantly contributed to our ability to establishing new partnerships. As a result, any negative publicity about us could adversely affect our ability to maintain our existing collaboration arrangements or attract new collaboration partners, and we may not be able to diffuse such negative publicity to the satisfaction of our investors and customers.

### **RISKS RELATING TO OUR DOING BUSINESS IN CHINA**

**The pharmaceutical industry in China is highly regulated and such regulations are subject to change, which may affect approval and commercialization of our drug candidates.**

We conduct almost all of our operations in China, which we believe confers clinical, commercial and regulatory advantages. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. Please refer to the section headed “Regulatory Overview” in this document for a discussion of regulatory requirements that are applicable to our current and planned business activities in China. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China, which would materially adversely affect our business, financial condition, results of operations and prospects. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach are consistent with the Chinese government’s policies, but we cannot ensure that our strategy and approach will continue to be consistent.

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**Changes in the political and economic policies of the Chinese government may materially and adversely affect our business, financial condition, results of operations and prospects and may result in our inability to sustain our growth and expansion strategies.**

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China’s economy differs from the economies of developed countries in many respects, including with respect to the extent of government involvement, level of development, growth rate, control of foreign exchange, allocation of resources, an evolving regulatory system, and the level of transparency in the regulatory process. While China’s economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. There is no assurance that future growth will be sustained at similar rates or at all.

The Chinese government implements various measures intended to encourage economic growth and guide the allocation of resources. These measures may include differential policies towards specific groups of pharmaceutical companies, such as promotion of traditional medicines or state-owned companies, or investments in pharmaceutical companies competing with us, which may have an adverse effect on us. Our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are applicable to us. Further, any adverse change in the economic conditions or government policies in China could have a material adverse effect on overall economic growth and the level of healthcare investments and expenditures in China, which in turn could lead to a reduction in demand for our products and consequently have a material adverse effect on our business.

The Chinese economy has been transitioning from a planned economy to a more market-oriented economy. Although the Chinese government has implemented reform measures allowing for an increasingly market-based economy, reduced state ownership of productive assets and established sound corporate governance practices in business enterprises, a substantial portion of the productive assets in China is owned by the Chinese government. The continued control of these assets and other aspects of the national economy by the Chinese government could materially and adversely affect our business. The Chinese government also exercises significant control over Chinese economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies.

Changes and developments in China’s economic, political and social conditions could adversely affect our financial condition and results of operations. For example, the pharmaceutical market may grow at a slower pace than expected, which could adversely affect our business, financial condition or results of operations.

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In addition, in the past the Chinese government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

**There are uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations.**

Substantially all of our operations are conducted in China, and are governed by PRC laws, rules and regulations. The Chinese legal system is a civil law system based on written codes and statutes. Unlike the common law system, prior court decisions may be cited as persuasive authority with limited precedential value, but do not have legally binding force.

In 1979, the Chinese government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investment in China. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to significant degrees of interpretation by Chinese regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and the non-binding nature of such decisions, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the Chinese legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Additionally, the NMPA's recent reform of the drug-approval system may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our drug candidates in a timely manner.

Moreover, Chinese administrative and court authorities also have significant discretion in interpreting and enforcing statutory and contractual terms. Depending on the government agency or how an application or a case is presented to such agency or other factors, we may receive less favorable application of law.

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since Chinese administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than we

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## RISK FACTORS

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would in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

Finally, we cannot predict the effect of future legal developments in China, including promulgation of new laws, changes to existing laws or the interpretation or enforcement thereof, the preemption of local rules and regulations by national law, the overturn or modification of the lower-level authority’s decisions at the higher level, or the changes in judiciary and administrative practices. As a result, there is substantial uncertainty as to the legal protection available to us or to our investors.

### **We may be restricted from transferring our scientific data abroad or from overseas to China.**

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 provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, where scientific data involving state secrets needs to be provided to foreign parties during the relevant foreign contacts and cooperation, corporate entities shall provide the type, scope and usage of the scientific data, and submit the information to the competent authorities for approval according to the specified procedures for confidentiality management. Upon approval by the competent authorities, corporate entities shall undergo the required procedures, and enter into the confidentiality agreements with the users of the scientific data. Further, any researcher conducting research funded at least in part by the Chinese 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 our R&D of medical drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals or comply with the regulatory requirements in a timely manner, or at all, our R&D of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

In addition, some foreign jurisdictions have stringent laws and regulations on collection, use, security, disclosure and transfer of personal information and privacy data. Non-compliance could result in proceedings against us by data protection authorities, which might subject us to fines, penalties, judgments and negative publicity, and may otherwise materially and adversely affect our business, financial condition and results of operations. Please refer to the paragraphs

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## RISK FACTORS

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headed “Other Risk Relating to Our Business – Risks Relating to Our Intellectual Property Rights – We may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials” in this section for more details.

### **The relationships between China and other countries may affect our business operations.**

We may pursue partnerships with entities in foreign countries and regions, in particular in the U.S. and Japan, and establishing new collaboration partnerships is key to our future growth. We may also sell a portion of our products to certain foreign countries in the future. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. As a result, China’s political relationships with those foreign countries and regions may affect our development of drug candidates and our commercialization of our drug candidates, upon approval, in foreign countries.

It is notably that the U.S. government has recently made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs which have led to other countries, including China and members of EU, imposing tariffs against the U.S. in response. Please refer to the paragraphs headed “Other Risks Relating to Our Business – Risks Relating to Extensive Government Regulations – Changes in U.S. and international trade policies, particularly with regard to China, may adversely impact our business and operating results” in this section. These trade disputes may escalate going forward and may result in certain types of goods, such as advanced R&D equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even becoming illegal to export.

Tensions and political concerns between China and the relevant foreign countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. China’s political relationships with those foreign countries and regions may also affect the prospects of our relationship with third parties. There can be no assurance that our existing or potential service providers, collaboration partners, or customers 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, and such alteration may cause a decline in the demand for our products and adversely affect our business, financial condition, results of operations, cash flows and prospects.

Furthermore, in the event that China and/or the countries from which we import raw materials impose import tariffs, trade restrictions or other trade barriers affecting the importation of raw materials, we may not be able to obtain a steady supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected.

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**We and our shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributed to a PRC establishment of a non-PRC company. Gains on the sales of Shares and dividends on the Shares may be subject to PRC income taxes.**

The indirect transfer of equity interests in PRC resident enterprises by a non-PRC resident enterprise is potentially subject to income tax in China at a rate of 10% on the gain if such transfer is considered as not having a commercial purpose and is carried out for tax avoidance. On February 3, 2015, the SAT issued the Public Announcement on Several Issues Concerning Enterprise Income Tax for Indirect Transfer of Assets by Non-Resident Enterprises (the “**Circular 7**”) (《國家稅務總局關於非居民企業間接轉讓財產企業所得稅若干問題的公告》), which supersedes certain provisions in the Notice on Strengthening the Administration of Enterprise Income Tax on Non-Resident Enterprises (the “**Circular 698**”) (《國家稅務總局關於加強非居民企業股權轉讓所得企業所得稅管理的通知》), which was previously issued by the SAT on December 10, 2009, as well as certain other rules providing clarification on Circular 698. Circular 7 provides comprehensive guidelines relating to, and also heightened the PRC tax authorities’ scrutiny over, indirect transfers by a non-resident enterprise of assets (including equity interests) of a PRC resident enterprise (“**PRC Taxable Assets**”).

For example, Circular 7 specifies that when a non-resident enterprise transfers PRC Taxable Assets indirectly by disposing of equity interests in an overseas holding company which directly or indirectly holds such PRC Taxable Assets, the PRC tax authorities are entitled to reclassify the nature of an indirect transfer of PRC Taxable Assets by disregarding the existence of such overseas holding company and considering the transaction to be a direct transfer of PRC Taxable Assets, if such transfer is deemed to have been conducted for the purposes of avoiding PRC enterprise income taxes and without any other reasonable commercial purpose.

Except as provided in Circular 7, transfers of PRC Taxable Assets under the following circumstances shall be automatically deemed as having no reasonable commercial purpose, and are subject to PRC enterprise income tax: (i) more than 75% of the value of the equity interest of the overseas enterprise is directly or indirectly attributable to PRC Taxable Assets; (ii) more than 90% of the total assets (cash excluded) of the overseas enterprise are directly or indirectly composed of investment in China at any time during the year prior to the indirect transfer of PRC Taxable Assets, or more than 90% of the income of the overseas enterprise is directly or indirectly from China during the year prior to the indirect transfer of PRC Taxable Assets; (iii) the overseas enterprise and its subsidiaries directly or indirectly hold PRC Taxable Assets and have registered with the relevant authorities in the host countries (regions) in order to meet the local legal requirements in relation to organization forms, yet prove to be inadequate in their ability to perform their intended functions and withstand risks as their alleged organization forms suggest; or (iv) the income tax from the indirect transfer of PRC Taxable Assets payable abroad is lower than the income tax in China that may be imposed on the direct transfer of such PRC Taxable Assets.

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Circular 7 contains certain exemptions, including (i) the Public Market Safe Harbor described below; and (ii) where there is an indirect transfer of PRC Taxable Assets, but if the non-resident enterprise had directly held and disposed of such PRC Taxable Assets, the income from the transfer would have been exempted from enterprise income tax in the PRC under an applicable tax treaty or arrangement. Provisions of Circular 7, which impose PRC tax liabilities and reporting obligations, do not apply to “non-resident enterprise acquiring and disposing of the equity interests of the same offshore listed company in a public market” (the “**Public Market Safe Harbor**”), which is determined by whether the parties, number and price of the shares acquired and disposed are not previously agreed upon, but determined in accordance with general trading rules in the public securities markets, according to one implementing rule for Circular 698. In general, transfers of the Shares by Shareholders on the Stock Exchange or other public market would not be subject to the PRC tax liabilities and reporting obligations imposed under the Circular 7 if the transfers fall under the Public Market Safe Harbor. However, it remains unclear whether any exemptions under Circular 7 will be applicable to the transfer of our Shares that do not qualify for the Public Market Safe Harbor or to any future acquisition by us outside of the PRC involving PRC Taxable Assets, or whether the PRC tax authorities will reclassify such transactions by applying Circular 7. Therefore, the PRC tax authorities may deem any transfer of our Shares that do not qualify for the Public Market Safe Harbor by our Shareholders that are non-resident enterprises, or any future acquisition by us outside of the PRC involving PRC Taxable Assets, to be subject to the foregoing regulations, which may subject our Shareholders or us to additional PRC tax reporting obligations or tax liabilities.

**Governmental control of currency conversion, and restrictions on the remittance of Renminbi into and out of China, may adversely affect the value of your investment.**

The RMB is not currently a freely convertible currency, as the Chinese Government imposes controls on the convertibility of the RMB into foreign currencies and in certain cases, the remittance of currency out of China. A substantial majority of our revenue is denominated in the RMB and we will need to convert the RMB into foreign currencies for the payment of dividends, if any, to holders of our Shares. Shortages in the availability of foreign currency may then restrict our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency denominated obligations.

The RMB is currently convertible under the “current account,” which includes dividends, trade and service-related foreign exchange transactions, but not under the “capital account,” which includes foreign direct investment and foreign currency debt. Approval from appropriate government authorities is required where the RMB 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. Foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from SAFE, but we are required to present relevant documentary evidence of such transactions and conduct such

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transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. However, the relevant Chinese government authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions.

The Chinese Government may also at its discretion restrict access in the future to foreign currencies for current account transactions. Since 2015, in response to China’s declining foreign currency reserves, the Chinese Government has placed increasingly stringent restrictions on the convertibility of the RMB into foreign currencies. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our Shareholders. Further, there is no assurance that new regulations will not be promulgated in the future that would have the effect of further restricting the remittance of the RMB into or out of China.

**You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing original actions in China against us or our management named in the documents based on Hong Kong or other foreign laws.**

Majority of our operational subsidiaries are incorporated under the laws of China, and substantially all of our assets are located in China. A majority of our Directors, Supervisors and senior management personnel also reside in China, and substantially all of their assets are located in China. As a result, it may not be possible for investors to effect service of process upon us or our Directors, Supervisors and senior management personnel in China.

On July 14, 2006, the Supreme People’s Court of PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《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》) (the “Arrangement”). Under the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a PRC court is expressly designated as the court having sole jurisdiction for the dispute. Therefore, it is not possible to enforce a judgment rendered by a Hong Kong court in PRC if the parties in dispute have not agreed to enter into a choice of court agreement in writing. Although the Arrangement became effective on August 1, 2008, the outcome and effectiveness of any action brought under the Arrangement remain uncertain.



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On January 18, 2019, the Supreme People’s Court of PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (《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》) (the “**New Arrangement**”), which seeks to establish a mechanism with further clarification on and certainty for recognition and enforcement of judgments in a wider range of civil and commercial matters between Hong Kong Special Administrative Region and PRC. The New Arrangement discontinued the requirements for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court of PRC and the completion of the relevant legislative procedures in Hong Kong Special Administrative Region. The New Arrangement will, upon its effectiveness, supersede the Arrangement. Therefore, before the New Arrangement becomes effective it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in PRC if the parties in the dispute do not agree to enter into a choice of court agreement in writing. As a result, it may be difficult or impossible for investors to effect service of process against our assets or management in China in order to seek recognition and enforcement of foreign judgments in China.

Furthermore, China has not entered into treaties or arrangements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the U.S., the United Kingdom, or most other western countries, and Hong Kong has no arrangement for the reciprocal enforcement of judgments with the U.S. As a result, recognition and enforcement in PRC or Hong Kong of judgment of a court in the U.S. or any other jurisdictions mentioned above in relation to any matter that is not subject to a binding arbitration provision may be difficult or impossible.

### **RISKS RELATING TO THE [REDACTED]**

**No public market currently exists for our Shares; an active trading market for our Shares may not develop and the market price and trading volume of our Shares may decline or become volatile, which could lead to substantial losses to investors.**

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

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## RISK FACTORS

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In addition, the [REDACTED] and [REDACTED] of the Shares may be subject to significant volatility in responses to various factors, including:

- variations in our operating results;
- changes in financial estimates by securities analysts;
- announcements made by us or our competitors;
- regulatory developments in China affecting us, our customers or our competitors;
- investors’ perception of us and of the investment environment in Asia, including Hong Kong and China;
- developments in China’s healthcare market;
- changes in pricing made by us or our competitors;
- acquisitions by us or our competitors;
- the depth and liquidity of the market for our Shares;
- additions to or departures of, our executive officers and other members of our senior management;
- release or expiry of lock-up or other transfer restrictions on our Shares;
- sales or anticipated sales of additional Shares; and
- the general economy and other factors.

Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our Shares may be subject to changes in price not directly related to our performance.

**There will be a gap of several days between [REDACTED] and [REDACTED] of our Shares, and the price of our Shares when [REDACTED] begins could be lower than the [REDACTED].**

The [REDACTED] price to the [REDACTED] of our Shares sold in the [REDACTED] is expected to be determined on the [REDACTED]. However, the Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be five Business Days after the [REDACTED]. As a result, investors may not be able to sell or otherwise deal in the Shares during that period. Accordingly, holders of our Shares are subject

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## RISK FACTORS

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to the risk that the price of the Shares when [REDACTED] begins could be lower than the [REDACTED] as a result of adverse market conditions or other adverse developments that may occur between the time of sale and the time [REDACTED] begins.

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

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

**You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or other equity securities in the future.**

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in pro forma net tangible asset value. In order to expand our business, we may consider offering and issuing additional Shares in the future. Purchasers of the [REDACTED] may experience dilution in the net tangible asset value per share of their Shares if we issue additional Shares in the future at a price which is lower than the net tangible asset value per Share at that time. Furthermore, we may issue Shares pursuant to the Share Schemes, which would further dilute Shareholders' interests in our Company.

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

We currently intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the research and development, regulatory filings and commercialization of our drug candidates. As a result, we might not pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our Shares as a source for any future dividend income.

Our Board has complete discretion as to whether to distribute dividends. Even if our Board 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.

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## RISK FACTORS

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Accordingly, the return on your investment 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 after the [REDACTED] or even maintain the price at which you purchased the Shares. You may not realize a return on your investment in our Shares and you may even lose your entire investment in our Shares.

**We are a Cayman Islands company and the laws to protect the interests of minority shareholders may be different from those provided for in Hong Kong.**

Our Company is incorporated in the Cayman Islands and as such our corporate affairs are governed by our Memorandum and Articles of Association, the Cayman Companies Act and the common law of the Cayman Islands. The rights of Shareholders to take legal action against our Directors and us, actions by minority Shareholders and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority Shareholders differ in some respects from those established under statutes and judicial precedent in existence in Hong Kong or the jurisdictions where minority Shareholders may be located. Please refer to the section headed “Summary of the Constitution of the Company and Cayman Islands Company Law” in Appendix III to this document.

**Facts, forecasts and statistics obtained from official government sources in this document relating to the pharmaceutical industry may not be fully reliable.**

Facts, forecasts and statistics in this document relating to the pharmaceutical industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. However, neither we, the Joint Sponsors, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED] nor our or their respective affiliates or advisers have verified the information sourced from public official documents or statements. Accordingly, the information from public official sources contained in this document may not be accurate and should not be unduly relied upon. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from public official sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

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

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

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

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

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

**WAIVER IN RELATION TO MANAGEMENT PRESENCE IN HONG KONG**

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

Our management, business operations and assets are primarily located outside Hong Kong. The principal management headquarters of our Group are primarily based in China. Our Company considers that our Group’s management is best able to attend to its functions by being based in China. None of our executive Directors is or will be ordinarily resident in Hong Kong after the [REDACTED] of our Company. Our Directors consider that relocation of our executive Directors to Hong Kong will be burdensome and costly for our Company, and it may not be in the best interests of our Company and our Shareholders as a whole to appoint additional executive Directors who are ordinarily resident in Hong Kong. As such, we do not have, and for the foreseeable future will not have, sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 of the Listing Rules.

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

- (1) We have appointed two authorized representatives pursuant to Rule 3.05 of the Listing Rules, who will act as our principal channel of communication with the Stock Exchange. The two authorized representatives appointed are Dr. Gong and Ms. Li Ching Yi (李菁怡) (“**Ms. Li**”). Ms. Li is situated and based in Hong Kong. Each of our authorized representatives will be available to meet with the Stock Exchange in Hong Kong within a reasonable time frame upon the request of the Stock Exchange and will be readily contactable by telephone, facsimile and email;
- (2) As and when the Stock Exchange wishes to contact our Directors on any matters, each of our authorized representatives has the means to contact all of our Directors (including the independent non-executive Directors) promptly at all times;
- (3) Although our executive Directors are not ordinary residents in Hong Kong, each of our Directors possesses or can apply for valid travel documents to visit Hong Kong and is able to meet with the Stock Exchange within a reasonable period of time, when required;

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

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- (4) We have appointed China Securities (International) Corporate Finance Company Limited as our compliance adviser, pursuant to Rule 3A.19 of the Listing Rules, who will have access at all times to our authorized representatives, Directors and senior management, and will act as an additional channel of communication between the Stock Exchange and us; and
- (5) We have provided the Stock Exchange with the contact details of each Director (including their respective mobile phone number, office phone number and e-mail address).

Our Company will inform the Stock Exchange as soon as practicable in respect of any change in the authorized representatives, the Directors and/or the compliance adviser in accordance with the Listing Rules.

**WAIVER IN RESPECT OF JOINT COMPANY SECRETARIES**

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

Our Company had appointed Ms. Xia Fang (夏芳) (“**Ms. Xia**”) and Ms. Li as our joint company secretaries. Ms. Li is an associate member of The Chartered Governance Institute (formerly known as The Institute of Chartered Secretaries and Administrators) in the United Kingdom and The Hong Kong Institute of Chartered Secretaries, and therefore meets the qualification requirements under Note 1 to Rule 3.28 of the Listing Rules and is in compliance with Rule 8.17 of the Listing Rules.

Ms. Xia has been our board secretary since September 1, 2020. She has extensive experience in administrative management but presently does not possess any of the qualifications under Rules 3.28 and 8.17 of the Listing Rules. While Ms. Xia may not be able to solely fulfill the requirements of the Listing Rules, our Company believes that it would be in the best interests of our Company and the corporate governance of our Company to appoint Ms. Xia as our joint company secretary due to her thorough understanding of the internal administration and business operations of our Group.

Accordingly, while Ms. Xia does not possess the formal qualifications required of a company secretary under Rule 3.28 of the Listing Rules, we have applied to the Stock Exchange for, and the Stock Exchange has [granted], a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules such that Ms. Xia may be appointed as a joint company secretary of our Company. Pursuant to the Guidance Letter HKEX-GL108-20, the waiver will be for a fixed period of time (“**Waiver Period**”) and on the following conditions: (i) the proposed company secretary must be assisted by a person who

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

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possesses the qualifications or experience as required under Rule 3.28 (“**Qualified Person**”) and is appointed as a joint company secretary throughout the Waiver Period; and (ii) the waiver can be revoked if there are material breaches of the Listing Rules by the issuer. The waiver is valid for an initial period of three years from the [REDACTED], and is granted on the condition that Ms. Li, as a joint company secretary of our Company, will work closely with, and provide assistance to, Ms. Xia in the discharge of her duties as a joint company secretary and in gaining the relevant company secretary experience as required under Rule 3.28 of the Listing Rules and to become familiar with the requirements of the Listing Rules and other applicable Hong Kong laws and regulations. Given Ms. Li’s professional qualifications and experience, she will be able to explain to both Ms. Xia and our Company the relevant requirements under the Listing Rules. Ms. Li will also assist Ms. Xia in organizing Board meetings and Shareholders’ meetings of our Company as well as other matters of our Company which are incidental to the duties of a company secretary. She is expected to work closely with Ms. Xia, and will maintain regular contact with Ms. Xia, the Directors and the senior management of our Company. The waiver will be revoked immediately if Ms. Li ceases to provide assistance to Ms. Xia as a joint company secretary for the three-year period after the [REDACTED] or where there are material breaches of the Listing Rules by our Company. In addition, Ms. Xia will comply with the annual professional training requirement under Rule 3.29 of the Listing Rules and will enhance her knowledge of the Listing Rules during the three-year period from the [REDACTED].

In the course of preparation of the [REDACTED], Ms. Xia attended a training session on the respective obligations of the Directors and senior management and our Company under the relevant Hong Kong laws and the Listing Rules provided by our Company’s Hong Kong legal adviser, and has been provided with the relevant training materials. Our Company will further ensure that Ms. Xia has access to the relevant training and support that would enhance her understanding of the Listing Rules and the duties of a company secretary of an issuer listed on the Stock Exchange, and to receive updates on the latest changes to the applicable Hong Kong laws, regulations and the Listing Rules. Furthermore, both Ms. Xia and Ms. Li will seek and have access to advice from our Company’s Hong Kong legal and other professional advisers as and when required. Our Company has appointed China Securities (International) Corporate Finance Company Limited as the Compliance Adviser upon our [REDACTED] pursuant to Rule 3A.19 of the Listing Rules, which will act as our Company’s additional channel of communication with the Stock Exchange, and provide professional guidance and advice to our Company and its joint company secretaries as to compliance with the Listing Rules and all other applicable laws and regulations. Prior to the end of the three-year period, the qualifications and experience of Ms. Xia and the need for ongoing assistance of Ms. Li will be further evaluated by our Company. We will liaise with the Stock Exchange to enable it to assess whether Ms. Xia, having benefited from the assistance of Ms. Li for the preceding three years, will have acquired the skills necessary to carry out the duties of company secretary and the “relevant experience” within the meaning of Note 2 to Rule 3.28 of the Listing Rules so that a further waiver will not be necessary.



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

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Please refer to the section headed “Directors and Senior Management” in this document for further information regarding the qualifications of Ms. Xia and Ms. Li.

**WAIVER IN RELATION TO EXEMPTION FROM 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**

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

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

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

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

Our Company is a bio-pharmaceutical company with research and development capabilities. Our Company is a Biotech Company as defined under Chapter 18A of the Listing Rules and is seeking a [REDACTED] under Chapter 18A. Rule 18A.03(3) of the Listing Rules require that an eligible biotech company must have been in operation in its current line of business for at least two financial years prior to [REDACTED] under substantially the same management. Rule 18A.06 of the Listing Rules requires that an eligible biotech company must comply with Rule 4.04 of the Listing Rules modified so that references to “three financial

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

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

In compliance with the abovementioned requirements under the Listing Rules, the accountants’ report of our Company set out in Appendix I to this document is prepared to cover the two financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022.

As such, the Joint Sponsors have applied to the SFC for a certificate of exemption from strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance regarding the inclusion of the accountants’ report covering the full three financial years immediately preceding the issue of this document on the following grounds:

- (a) our Company is primarily engaged in the research and development, application and commercialization of biotech products, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules. Our Company will fulfil the additional conditions for [REDACTED] applicable to a Chapter 18A company;
- (b) the Accountants’ Report for each of the two financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022 has been prepared and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;
- (c) notwithstanding that the financial results set out in this document are only for the two financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022 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) given that our Company is only required to disclose its financial results for the two financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022 in accordance with Chapter 18A of the Listing Rules and preparation of the financial results and audited financial report for the year ended December 31, 2019 would require additional work to be performed by our Company and the Reporting Accountants, strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of

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

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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; and

- (e) the Accountants' Report covering the two financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, together with other disclosure in this document, has already provided the potential investors with adequate and reasonable up-to-date information in the circumstances to form a view on the track record of our Company, and that all information which is necessary for the investing public to make an informed assessment of the business, assets and liabilities, financial position, management and prospects has been included in this document. Therefore, the exemption would not prejudice the interest of the investing public.

The SFC has [granted] a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting our Company from strict compliance with section 342(1)(b) in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance on the condition that (i) particulars of the exemption are set out in this document; (ii) this document will be issued on or before [REDACTED].

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**INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]**

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[REDACTED]

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**INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]**

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[REDACTED]

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**INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]**

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[REDACTED]

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**INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]**

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[REDACTED]

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**DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]**

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**DIRECTORS**

<b>Name</b>	<b>Address</b>	<b>Nationality</b>
<i>Executive Director</i>		
Gong Zhaolong (龔兆龍)	Room 602, Building 7 Lane 112, Puxiao Road Minhang District, Shanghai PRC	American
<i>Non-executive Directors</i>		
Zhu Pai (朱湃)	C-805, Building 7, Xiangrui Garden Longzhu Avenue, Nanshan District Shenzhen, Guangdong PRC	Chinese
Zhou Feng (周峰)	Room 602, Building 11 Lane 358, Qingtong Road Pudong New Area Shanghai PRC	Chinese
Chen Yawen (陳雅雯)	Room 1001, No. 3, Xincheng Mansion Baoli Road, Jiading District, Shanghai PRC	Chinese



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**DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]**

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*Independent Non-executive Directors*

Li Jin	Room 701, Unit 7, Building 41 No. 2, Xierqi West Road Haidian District, Beijing PRC	American
Lin Tat Pang (連達鵬)	Flat 1705, Block 50 Heng Fa Chuen Chaiwan, Hong Kong, China	Chinese
Liu Xinguang (劉信光)	Room 402, Unit 3, Building 8 Qingxi Jiayuan, Dingxiu, Dongxiaokou Town Changping District, Beijing PRC	Chinese

For further information regarding our Directors, please see the section headed “Directors and Senior Management.”

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**DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]**

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**PARTIES INVOLVED IN THE [REDACTED]**

**Joint Sponsors**

**China International Capital Corporation**

**Hong Kong Securities Limited**

29/F, One International Finance Centre

1 Harbour View Street

Central

Hong Kong

**China Securities (International)**

**Corporate Finance Company Limited**

18/F, Two Exchange Square

8 Connaught Place

Central

Hong Kong

[REDACTED]

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**DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]**

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**Legal Advisers to the Company**

*As to Hong Kong and United States laws:*

**O'Melveny & Myers**

31/F, AIA Central  
1 Connaught Road Central  
Hong Kong

*As to PRC law:*

**Commerce & Finance Law Offices**

12-14th Floor, China World Office 2  
No.1 Jianguomenwai Avenue  
Beijing  
PRC

*As to Cayman Islands law:*

**Conyers Dill & Pearman**

29th Floor  
One Exchange Square  
8 Connaught Place  
Central  
Hong Kong

**Legal Advisers to the Joint Sponsors and  
the [REDACTED]**

*As to Hong Kong and United States laws:*

**Herbert Smith Freehills**

23/F, Gloucester Tower  
15 Queen's Road Central  
Hong Kong

*As to PRC law:*

**Zhong Lun Law Firm**

6/10/11/16/17F, Two IFC  
8 Century Avenue  
Pudong New Area  
Shanghai  
PRC

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**DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]**

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**Auditor and Reporting Accountants**

**Ernst & Young**

*Certified Public Accountants*

*Registered Public Interest Entity Auditor*

27/F One Taikoo Place

Taikoo Place

979 King’s Road

Quarry Bay

Hong Kong

**Industry Consultant**

**Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.**

1018, Tower B 500 Yunjin Road

Xuhui District, Shanghai

PRC

**Compliance Adviser**

**China Securities (International)**

**Corporate Finance Company Limited**

18/F, Two Exchange Square

8 Connaught Place

Central

Hong Kong

[REDACTED]

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## CORPORATE INFORMATION

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<b>Registered office</b>	Cricket Square Hutchins Drive P.O. Box 2681 Grand Cayman KY1-1111 Cayman Islands
<b>Corporate headquarters</b>	Building 11 118 Furong Hua Road Pudong New District Shanghai PRC
<b>Principal place of business in Hong Kong</b>	14/F, Golden Centre 188 Des Voeux Road Central Hong Kong
<b>Company's website</b>	<a href="https://www.3d-medicines.com/">https://www.3d-medicines.com/</a> (The contents on this website do not form part of this document)
<b>Joint Company Secretaries</b>	Ms. Xia Fang Building 6, Zone 3 Hongkun Park 7 Liangshuihe 1st Street BDA, Beijing 100176 PRC  Ms. Li Ching Yi (李菁怡) (ACIS, ACS) 14/F, Golden Centre 188 Des Voeux Road Central Hong Kong
<b>Authorized representatives</b>	Dr. Gong Zhaolong (龔兆龍) Building 11 118 Furong Hua Road Pudong New District Shanghai PRC  Ms. Li Ching Yi (李菁怡) (ACIS, ACS) 14/F, Golden Centre 188 Des Voeux Road Central Hong Kong

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## CORPORATE INFORMATION

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**Audit Committee**

Dr. Lin Tat Pang (*Chairman*)  
Mr. Zhu Pai  
Dr. Li Jin

**Remuneration Committee**

Mr. Liu Xinguang (*Chairman*)  
Dr. Gong Zhaolong  
Dr. Li Jin

**Nomination Committee**

Dr. Gong Zhaolong (*Chairman*)  
Dr. Li Jin  
Mr. Liu Xinguang

**Principal [REDACTED]**

[REDACTED]

**Hong Kong [REDACTED]**

[REDACTED]

**Principal bank**

**China CITIC Bank**  
**Shanghai Xujiahui Sub-branch**  
1F, Building A, CCIG Plaza  
331 North Caoxi Road  
Xuhui District  
Shanghai  
PRC

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## INDUSTRY OVERVIEW

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*The information and statistics set out in this section and other sections of this document have been extracted from various official government publications, available sources from public market research and other sources from independent suppliers, and from the independent report (the “**Frost & Sullivan Report**”) prepared by Frost & Sullivan. We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the [REDACTED]. The information from official government sources have not been independently verified by us, the Joint Sponsors, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], any of their respective directors, employees, agents or advisors, or any other person or party involved in the [REDACTED], and no representation is given as to its accuracy. Accordingly, the information from official government sources contained herein may not be accurate and should not be unduly relied upon. Unless otherwise noted, the amounts related to market size in China in this section used an exchange rate of US\$1 = RMB6.5.*

### ONCOLOGY DRUG MARKET

#### Cancer Incidence Globally and in China

Cancer incidence has been increasing both globally and in China. The global cancer incidence was 19.7 million in 2021 and is estimated to reach 24.0 million in 2030. In China, cancer is the second leading cause of death. The cancer incidence in China was 4.7 million in 2021 and is expected to reach 5.8 million in 2030.

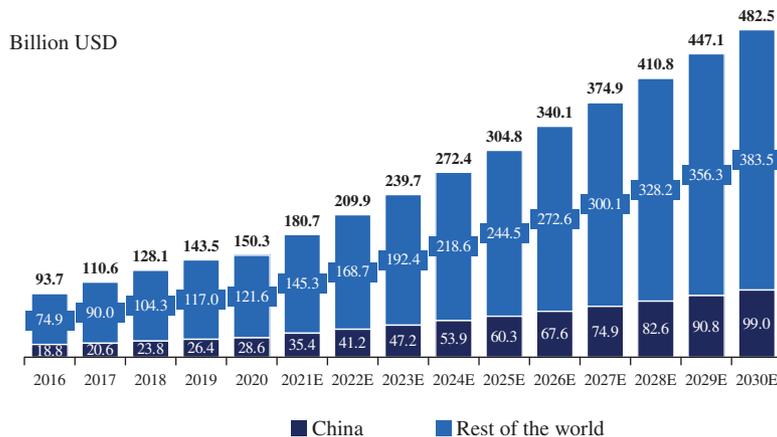
#### Oncology Drug Market Size Globally and in China

The global and China’s market size for oncology drugs is projected to continue its growth at a substantial rate. The global oncology drug market size is expected to grow from US\$150.3 billion in 2020 to US\$304.8 billion in 2025 and US\$482.5 billion in 2030, representing a CAGR of 15.2% from 2020 to 2025, and 9.6% from 2025 to 2030. China’s oncology drug market is expected to grow from US\$28.6 billion in 2020 to US\$60.3 billion in 2025 at a CAGR of 16.1%, and further to US\$99.0 billion in 2030 at a CAGR of 10.4%, outpacing the global growth rate.

## INDUSTRY OVERVIEW

### Global Oncology Drug Market Size, 2016-2030E

CAGR	China	Global
2016-2020	11.1%	12.5%
2020-2025E	16.1%	15.2%
2025E-2030E	10.4%	9.6%



Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, FDA, Frost & Sullivan Report

### Growth Drivers of Oncology Drug Market

- *Trend of Treating Cancer as a Chronic Disease.* Attributable to the availability of more innovative therapies and drugs, the survival time of cancer patients has become longer. With the trend of cancer becoming a chronic disease, the medication time of cancer patients increases with the prolonged survival period.
- *Demand for Effective Therapies Targeting Unmet Needs.* Driven by aging population, environmental pollution and unhealthy lifestyles such as smoking, lack of exercise and high-calorie diet, the number of global oncology patients will further increase. However, to date, there is no cure for many oncology diseases.
- *Growing Needs for Innovative Drugs.* China’s oncology drug market is currently dominated by chemotherapy drugs, but has undergone a transformation to more advanced and effective targeted and immuno-oncology therapies, and the unmet demand for innovative drugs is increasing.

### Future Trends of Oncology Drug Market

- *Managing Cancer as a Chronic Disease.* Cancer will be treated as a chronic disease, similar to diabetes and hypertension. Cancer requires not only in-hospital treatment, but also out-of-hospital follow-up rehabilitation, monitoring and maintenance, so there is an increasing demand for more convenient and effective treatment methods (such as subcutaneous injection which is easier to operate, takes less time and enables faster adoption by patients than other injection methods).

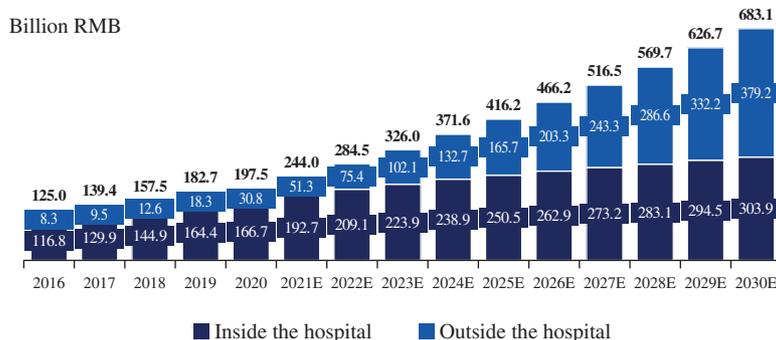


## INDUSTRY OVERVIEW

- Expanding Combination Therapies.* Combination therapy will become a development trend, as it will bring greater therapeutic effects, which points out the future direction for the development of cancer therapy globally and in China. Clinical studies have shown that the combination of PD-1/PD-L1 antibody and chemotherapy, targeted therapies including VEGF pathway inhibitors, or other types of immunotherapy can significantly improve the efficacy.
- Precision Treatment.* With the development of gene sequencing technology and the improvement of detection efficiency, as well as the identification of biomarkers which indicates a new room for the development of oncology treatment, it is possible to carry out precise immunotherapy based on a patient’s own tumor status. Biomarker based tissue agonistic indications become possible which results in improved response rates and potentially increased survival of cancer patients.
- Growing Market of Oncology Drugs Used Outside Hospital.* The market size of oncology drug outside the hospital is expanding. In 2016, the sales revenue of oncology drugs outside the hospital in China accounted for 6.6% of the total oncology drug market. This percentage increased to 15.6% in 2020, and is expected to further increase to 39.8% and 55.5% in 2025 and 2030, respectively.

### Breakdown of China Oncology Pharmaceutical Market by Inside the Hospital and Outside the Hospital, 2016-2030E

CAGR	Inside the Hospital	Outside the Hospital	Total
2016-2020	9.3%	39.0%	12.1%
2020-2025E	8.5%	40.0%	16.1%
2025E-2030E	3.9%	18.0%	10.4%



Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, Frost & Sullivan Report

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## INDUSTRY OVERVIEW

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- *Indication Expansion.* Due to its superior therapeutic efficacy in approved indications, the efficacy and potential of PD-1/PD-L1 antibodies in new indications is being continuously explored clinically. For example, Opdivo, the world’s first PD-1 inhibitor, was originally approved for melanoma and non-small-cell lung cancer (NSCLC). Then, due to its efficacy in the treatment of classical Hodgkin’s lymphoma, MSI-H/dMMR colorectal cancer, urothelial cancer and head and neck cancer, its indications were expanded. It is foreseeable that in the future, immunotherapy will be explored in more tumor treatment areas due to continuous clinical exploration, bringing new treatment options to more patients.
- *Emerging Innovative Therapies.* Today, emerging innovative therapies such as peptide vaccines have been recognized as potentially effective therapies for treating specific cancer subsets. The understanding of basic cancer biology has grown exponentially, and the increasingly complex techniques of genetic engineering and the use of synthetic biology to control cell therapies have driven the clinical progress.
- *Improving Affordability of High-value Innovative Drugs.* The average disposable income of the Chinese population is expected to continue to grow rapidly, and the patients’ willingness and ability to pay for high-value medicines will thus be improved. The increase of per capita disposable income will promote the acceptance of more expensive medical treatments and the accessibility of innovative drugs.

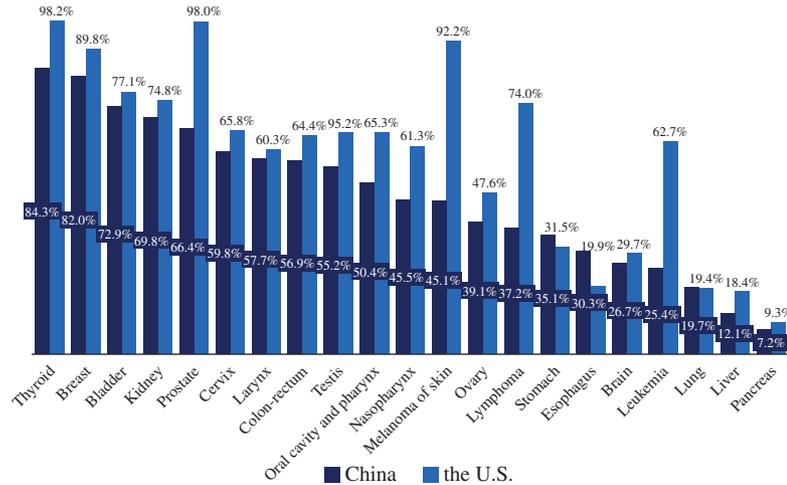
### *Managing Cancer as a Chronic Disease*

- *Rising Demands of Treating Cancer as a Chronic Disease.* With the launch of more oncology drugs and the understanding of health management, the overall 5-year survival rate of cancer patients has become higher, being 40.5% in China, making cancer a chronic disease. For example, the 5-year survival rate of CRC is 56.9%, and the 5-year survival rate of kidney cancer is 69.8%.

However, China’s 5-year survival rate lags far behind the U.S. in many types of cancers, according to the investigation in China (2012-2015) and the U.S. (2009-2015). Benefiting from the development of innovative therapies and drugs, such rate in China has increased significantly in recent years.

## INDUSTRY OVERVIEW

### 5-year Survival Rate of Cancers in China and the U.S.



Source: NIH, ACS, NCCR, Frost & Sullivan Report

- Advancing Injection Methods.** The diversification of injection methods provides the possibility of treating cancer as a chronic disease. Compared with intravenous injection, subcutaneous injection has obvious advantages, and leading multinational pharmaceutical companies such as Pfizer, Roche, Merck and Bristol-Myers Squibb are developing PD-1/PD-L1 inhibitors administered by way of subcutaneous injection.

The following table sets out a comparison of between intravenous injection and subcutaneous injection:

○ Low ● High	Intravenous Injection	Subcutaneous Injection
<b>Location</b>	Vein	Subcutaneous tissue
<b>Administration Angle</b>	25°	45° or 90°
<b>Capacity for Osmolarity</b>	1,000 mOsm /kg	600 mOsm /kg
<b>Injection Time</b>	●	○
<b>Absorption Speed</b>	●	○
<b>Aseptic Conditions &amp; Medical Staff Requirement</b>	●	○
<b>Suitable Scenarios</b>	<ul style="list-style-type: none"> <li>Emergency situations or situations that require immediate releases of drug effect</li> <li>High concentration and large amount administrations</li> <li>Continuous medication deliveries</li> </ul>	<ul style="list-style-type: none"> <li>Drug deliveries that need slow release and long work time</li> <li>Situations where patients need to periodically use a drug for a long term and the convenience of injection is important</li> </ul>

Source: Patient Prefer Adherence. 2015; 9: 923–942., The Patient, 8 (2). pp. 145-153., Frost & Sullivan analysis

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## INDUSTRY OVERVIEW

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- (i) *Preference.* According to the phase II PrefHER study of Roche's Herceptin Hylecta, Roche public presentation, once the subcutaneous injection method is available for patients, it will likely be widely accepted and adopted compared with intravenous injections. In Roche's PrefHer study, it is found that the majority (86%) of people preferred Herceptin Hylecta over intravenous Herceptin. Two years since Roche's Herceptin Hylecta entered the market in 2013, it replaced 35% of the intravenous Herceptin market share worldwide. This trend is similarly observed in the treatment of diabetes and other chronic diseases. For cancer patients who need to receive long-term treatments, the accumulated saved time using the subcutaneous route of injection makes it much more appealing than the intravenous injection method.
- (ii) *Convenience.* According to Br J Cancer. 2021 Apr 12; 124(8):1346–1352, subcutaneous injection is more convenient than intravenous injection. Derived costs for healthcare providers' time and consumables per intravenous treatment were £132.05 and £12.92, respectively, compared with £31.99 and £1.17 per subcutaneous treatment, respectively, resulting in a total difference of £111.81 between two formulations per treatment. According to a study comparing subcutaneous and intravenous formulation of trastuzumab in Eur J Obstet Gynecol Reprod Biol. 2018 Feb; 221: 46-51, the administration of trastuzumab subcutaneous was translated in a cost saving of C212.93 (\$231.73) per patient episode compared to trastuzumab IV, which could lead to a total potential saving of C3,832.74 (\$4,171.06) over a full course of treatment (18 cycles). According to the phase III HannaH study of Roche's Herceptin Hylecta, in general, subcutaneous administration only takes 2 to 5 minutes, while intravenous administration of conventional antibodies usually takes 30 to 90 minutes.
- (iii) *Cost-efficiency.* According to Breast. 2016 Oct; 29:140-6., British Journal of Cancer. 2021 Feb; 124(Suppl.2), the indirect cost of subcutaneous injection is lower than that of intravenous injection. In this regard, an oncology drug that can be administered through subcutaneous injection will be in a more advantageous position to expand its user base, and in turn to increase its sales revenue and market share. In addition, as subcutaneous injection can be carried out in lower-tier hospitals and clinics, patients can save accommodation and transportation expenses for traveling to big cities to visit higher-tier hospitals. Furthermore, a better use triage of medical resource can reduce the investment burden of the society and make a more efficient distribution of medical resources.
- (iv) *Safety.* According to Ann Emerg Med. 2005 Nov; 46(5): 456-61., J Clin Nurs. 2019 Jun; 28(11-12): 2206-2213, Ann Emerg Med. 2005 Nov; 46(5): 456-61., J Infus Nurs. May-Jun 2015; 38(3): 189-203, compared with intravenous injection, subcutaneous injection has better safety as there is less infusion-related reaction. Peripheral intravenous injection is associated with an overall failure rate of 35-50%. Besides, around 10% of cancer patients will develop intravenous intolerance and cannot receive intravenous administration, indicating the unmet medical needs of such cancer patients for an alternative way of drug administration.

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## INDUSTRY OVERVIEW

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- (v) *Efficacy*. Subcutaneous formulation generally produces at least similar efficacy versus intravenous administration. Take Herceptin as an example, compared with intravenous Herceptin, the subcutaneous administration of Herceptin Hylecta has a relatively higher therapeutic advantage. According to Roche public announcement, the pathological complete response rate of Herceptin Hylecta is 45.4%, which is higher than that of intravenous Herceptin which is 40.7%.
- *Increasing Indirect Costs of Cancer Treatment*. Indirect costs include costs related to cancer treatment, including transportation costs, accommodation costs and additional nutrition supply costs. The indirect costs of cancer treatment in 2020 were more than twice the direct costs of cancer treatment. Although patients tend to seek treatment in Class III hospitals in the early stage of cancer treatment (generally the first six months), they usually turn to primary and secondary hospitals, or even medical centers in their communities during the maintenance period after the early stage treatment that usually lasts for several years, which is expected to improve the market of more convenient treatment methods such as easily and widely performed subcutaneous injection.
  - *Healthcare System Reform*. Under the graded diagnosis and treatment system, higher-level hospitals are encouraged to focus on the issuance of diagnosis and treatment plans. A system for the management of the whole process of cancer treatment from diagnosis, treatment to rehabilitation, and from hospitals to community medical institutions, and for the realization of separate treatment of acute and chronic diseases will be gradually established. In addition, DTP pharmacies, the “dual-channel” qualification, as well as dynamic adjustment to the NRDL will promote the overall efficiency and affordability of innovative therapies for cancer treatment.

## GLOBAL AND CHINA’S BIOLOGICS MARKET

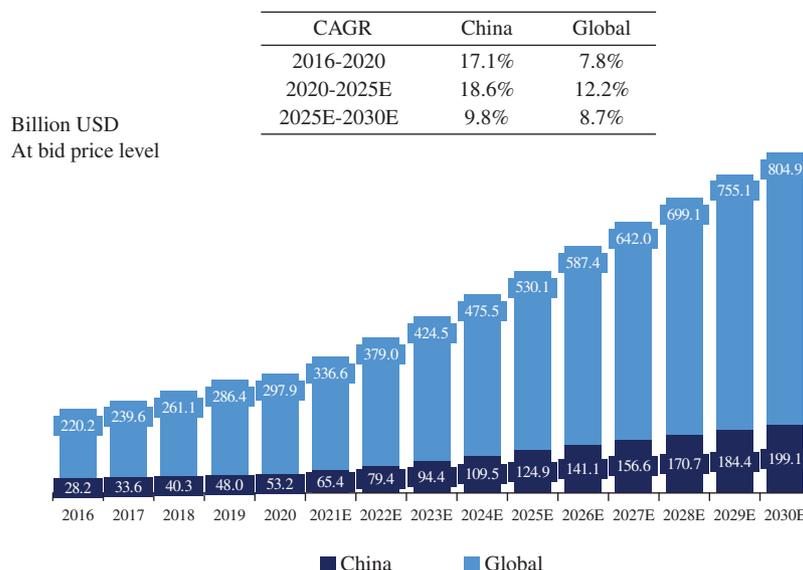
Biologics are pharmaceutical products manufactured using biological methods and sources, and are designed to regulate the activity of natural substances, such as enzymes, antibodies or hormones. The major types of biologics include antibody, peptide vaccines, gene therapies, cell therapies and others. Among the various types of biologics, antibody and peptide vaccines stand at the frontier of the research and development of biologics, especially in the oncology therapeutic area. Representing the cutting-edge of the research and development of innovative drugs, biologics may offer the most effective means to treat a variety of medical conditions and illnesses that are currently underserved, and thus promise a tremendous clinical and market potential as a novel drug modality.

The global biologics market increased from US\$220.2 billion in 2016 to US\$297.9 billion in 2020 at a CAGR of 7.8%, and is expected to further reach US\$530.1 billion in 2025 at a CAGR of 12.2% from 2020 to 2025, and US\$804.9 billion in 2030 at a CAGR of 8.7% from 2025 to 2030. Comparing to the global biologics market, China’s market size has witnessed a faster growth, increasing from US\$28.2 billion in 2016 to US\$53.2 billion in 2020 at a CAGR of 17.1%, and is expected to further reach US\$124.9 billion in 2025 at a CAGR of 18.6% from 2020 to 2025, and US\$199.1 billion in 2030 at a CAGR of 9.8% from 2025 to 2030.

## INDUSTRY OVERVIEW

The penetration rate of biologics in the China market was 13.8% in 2016. In 2019, while seven out of the top ten best-selling drugs sold globally were biologics, only three of the top ten drugs sold in China were biologics. However, the penetration rate of biologics in China is growing fast, reaching 23.9% in 2020, and is expected to further reach 43.3% in 2030, indicating a huge potential for biologics market growth in China.

### Global Biologics Market Size, 2016-2030E



Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, FDA, Frost & Sullivan Report

## HEALTHCARE SERVICE SYSTEM IN CHINA

China’s medical resources are not abundant and the geographical distribution of existing medical resources is uneven. The most developed cities such as Beijing and Shanghai have the largest number of Class III hospitals per million population, while in relatively underdeveloped areas such number is less than one per million population. The unbalanced distribution of medical institutions in China requires a more intensive participation of medical institutions of lower tiers in the provision of medical services.

Graded diagnosis and treatment system was introduced by the Chinese government in September 2015. It refers to the treatment of different diseases by medical institutions of different levels and with different service capabilities according to the priority of the disease and the degree of difficulty of treatment, thus to improve the overall efficiency of medical resources utilization. For example, after one month implementation of the graded diagnosis and treatment system, the number of outpatient and emergency patients in Beijing’s Class III hospitals decreased by 15.1%, which has shown a preliminary effect.

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## INDUSTRY OVERVIEW

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Medical treatments that are comparatively more convenient, time-saving and easier to operate are more accessible to patients in lower-tier cities and rural areas where primary health institutions are more widely spread. Particularly, intravenous injection of oncology drugs is usually performed in the oncology departments in higher-tier hospitals. If subcutaneous administration of oncology drugs becomes available, it can be expected to be more widely carried out in county-level hospitals, community health centers and clinics.

### **Favorable Policies for Biologics Development in China**

- *Streamlined Drug Review and Approval System.* Issued in October 2017, the *Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices* (the “*Reform Opinions*”) adopted a fast track and priority review channel for drugs addressing unmet medical needs, such as cancer, and an oncology therapy may receive a conditional approval to enter the market. Nowadays, the clinical trial application approval process is shortened from a previous cycle of 12 to 18 months to 60 days, and clinical trial data generated outside China may be accepted in the review process if certain requirements are met.
- *Shortened Oncology Drug Development Period.* Before 2010, it took an average of 2,794 days for oncology drugs to reach NDA approval after IND approval. However, after 2010, such time was shortened to 1,494 days. The overall approval period is expected to be further shortened, thus saving substantial time for new oncology drugs to enter the market.
- *Promotion of Biologics by NRDL.* As of December 31, 2020, a total of 119 innovative patented drugs had been included in the List B catalogue of the National Reimbursement Drug List (NRDL), including 37 new drugs in the category of “anti-tumor drugs and immune-modulators,” with an inclusion of all four domestic PD-1 drugs. Since the NRDL strictly limits the drug prices by introducing competition among different drugs for the same indication, the prices of drugs included in the NRDL decreased sharply, allowing an increasing affordability and a greater sales volume of biologics. The NRDL’s dynamic adjustment also presented a trend of shortened period of innovative oncology drugs entering into the NRDL.
- *Increasing Affordability of Innovative Drugs.* Chengdu mode was implemented in 2016. It is a reform to the Chinese government’s existing medicine expense reimburse system, under which certain innovative drugs, typically oncology drugs and orphan drugs reimbursable by the governmental health insurance plan, enjoy the same reimburse rate in out-of-hospital pharmacies and in-hospital pharmacies. In addition, DTP (direct-to-patient) pharmacies that have obtained the “dual-channel” qualification are designated as additional drug suppliers covered by governmental health insurance. The successful implementation of Chengdu mode and “dual-channel” payment contributes to the increasing affordability and accessibility of innovative drugs.

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## INDUSTRY OVERVIEW

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- *Favorable Policies for Oncology Drugs and Orphan Drugs.* According to the *Announcement on the Release of the Second Batch on Anticancer Drugs and Orphan Drugs Applicable to the VAT Policy* (the “VAT Announcement”) issued in September 2020, manufacturers, distributors and retailers of oncology drugs containing six active pharmaceutical ingredients and 14 orphan drugs as listed in the VAT Announcement are qualified to enjoy a reduced 3% VAT, effective from October 1, 2020. In addition, the *Reform Opinions* stipulate that orphan drugs and medical devices for the treatment of rare diseases that have been approved for marketing in foreign jurisdictions may be conditionally approved for marketing in China. Moreover, applicants of registration for rare disease treatment drugs and medical devices can apply for exemption of clinical trials if certain requirements are met.

### MAJOR CANCER TYPES AND INDICATIONS

#### Overview of Major Cancer Types

The world’s top ten cancers account for more than 60% of all cancer incidences. The global incidence of lung cancer, colorectal cancer and prostate cancer has a higher CAGR than that of other cancers. In China, among all types of cancers, lung cancer, gastric cancer and colorectal cancer rank top three by incidence, and the proportion of new patients suffering from these cancers exceeds 40.6% in 2021.

#### PD-1/PD-L1 Monoclonal Antibodies

PD-1/PD-L1 is a clinically-validated immune checkpoint for immuno-oncology therapies. The introduction of immune checkpoint inhibitors offers breakthrough treatment for certain cancer indications that previously lacked effective therapies. To date, all of the immune checkpoint inhibitors on the market are antibodies administered by intravenous infusion.

In recent years, the clinical development strategy of PD-1/PD-L1 monoclonal antibodies has gradually shifted from monotherapy to combination therapy. According to an article published by Nature in November, 2018, 76.3% of the global clinical trials combined PD-1/PD-L1 monoclonal antibodies with other therapies, including immunotherapy, targeted therapy, chemotherapy or radiation therapy. At the same time, many experimental results showed that combination therapy can significantly improve the efficacy of monotherapy.

#### *Market Size of PD-1/PD-L1 Inhibitors Globally and in China*

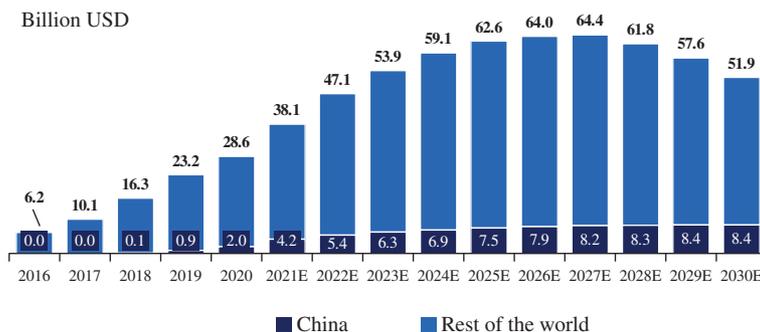
The global PD-1/PD-L1 monoclonal antibody market size was US\$28.6 billion in 2020, and is expected to reach US\$62.6 billion in 2025, representing a CAGR of 17.0%. Such market in China was US\$2.0 billion in 2020, and is expected to reach US\$7.5 billion in 2025, representing a CAGR of 30.5% from 2020 to 2025, significantly outpacing the growth rate of the global market for the same period.



## INDUSTRY OVERVIEW

### Global PD-1/PD-L1 mAbs Market Size, 2016-2030E

CAGR	China	Global
2016-2020		46.3%
2020-2025E	30.5%	17.0%
2025E-2030E	2.3%	-3.7%



Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, FDA, Frost & Sullivan Report

### Major Indications for PD-1/PD-L1 Inhibitors

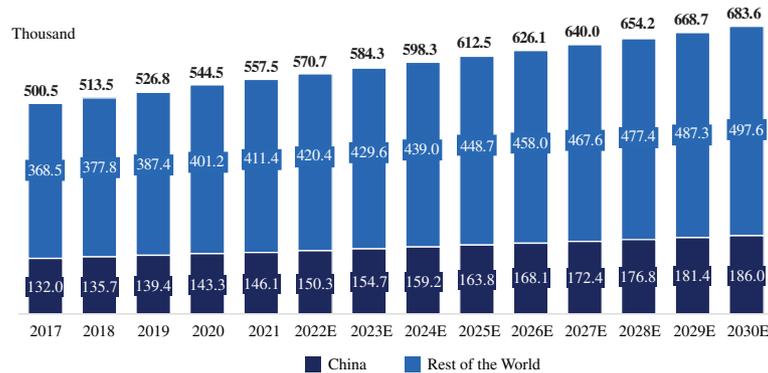
#### MSI-H/dMMR

MSI-H is short for microsatellite instability-high, and dMMR stands for DNA mismatch repair-deficient. MSI-H/dMMR can occur when a cell is unable to repair mistakes happened during its division process. The normal tissue DNA repair system is called mismatch repair (MMR), which can correct DNA replication errors. However, due to the lack of DNA mismatch repair in tumor cells or defects in the replication repair process, the possibility of gene mutations increases. MSI-H has a high prevalence in many cancer types, such as endometrial carcinoma (25%), lynch syndrome (16.3%), colorectal cancer (12%) and gastric cancer (9%).

The global incidence of MSI-H/dMMR solid tumor reached approximately 557,500 in 2021, and is expected to reach approximately 683,600 in 2030. China’s incidence of MSI-H/dMMR solid tumor reached approximately 146,100 in 2021, and is expected to reach approximately 186,000 in 2030.

## INDUSTRY OVERVIEW

### Global Incidence of MSI-H/dMMR Solid Tumor, 2017-2030E



Source: International Agency for Research on Cancer (“IARC”), GBD study, Global Cancer Observatory, NCCR, Frost & Sullivan Report

#### Unmet Clinical Needs for Treating MSI-H/dMMR Tumors

- Limited Drug Options.** On May 23, 2017, the FDA approved Keytruda (pembrolizumab) for the treatment of previously treated metastatic MSI-H/dMMR solid tumors and metastatic MSI-H/dMMR colorectal cancer. The FDA has also approved Opdivo (nivolumab) monotherapy or combined with low-dose Yervoy (ipilimumab) for the treatment of previously treated metastatic MSI-H/dMMR colorectal cancer as well as JEMPERLI (dostarlimab) for the treatment of previously treated advanced dMMR solid tumors. However, only three PD-1/L1 drugs had been approved for previously treated MSI-H/dMMR solid tumors in China as of the Latest Practicable Date.
- Limited Application to First-line Treatment.** Due to the lack of clinical data related to MSI-H/dMMR solid tumors, only a few cancers have been approved for the first-line treatment. For example, pembrolizumab mAbs has only been approved as a first-line treatment for MSI-H/dMMR colorectal cancer, and was used as a second-line or later treatment of MSI-H/dMMR gastric cancer, small intestine cancer or endometrial cancer.
- Underdevelopment of Precision Treatment.** At present, the precise treatment of MSI-H/dMMR is still in the development stage. In the future, through the detection of biomarkers, personalized and precisely targeted therapy and immunotherapy will become the main direction of cancer treatment.

#### MSI-H/dMMR Drug Market Size Globally and in China

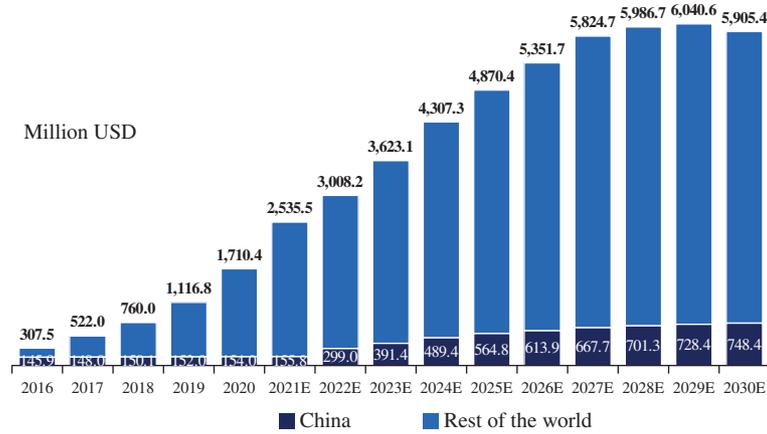
The global MSI-H/dMMR drug market size was US\$1,710.4 million in 2020, and is expected to reach US\$4,870.4 million in 2025 at a CAGR of 23.3% from 2020 to 2025, and to further reach US\$5,905.4 million in 2030. China’s MSI-H/dMMR drug market size was

## INDUSTRY OVERVIEW

US\$154.0 million in 2020, and is expected to reach US\$564.8 million in 2025 at a CAGR of 29.7% from 2020 to 2025, and to further reach US\$748.4 million in 2030. Pan-cancer nature will boost the growth of MSI-H/dMMR drug market globally and in China.

### Global MSI-H/dMMR Solid Tumor Drug Market Size, 2016-2030E

CAGR	China	Global
2016-2020	1.4%	53.6%
2020-2025E	29.7%	23.3%
2025E-2030E	5.8%	3.9%



*Notes:*

- (1) MSI-H / dMMR solid tumor drug market includes the treatment market of all target positive patients. The market includes chemotherapy drugs and immunotherapy with approved indications, excluding off label drugs.
- (2) At present, we only consider the price reduction of medical insurance and the normal annual price drop for cancer drugs, and do not consider the impact of volume-based procurement of chemotherapy drugs.

*Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, FDA, Frost & Sullivan Report*

## INDUSTRY OVERVIEW

### FDA Approved PD-1 mAbs for MSI-H/dMMR

As of the Latest Practicable Date, the FDA had approved three PD-1 mAbs for the treatment of MSI-H/dMMR solid tumor.

Product	Drugs	Company	Immune Checkpoint	2021 Revenue (million)	Price (USD)	2020 Annual Cost (thousand)	Patent Expiration Date	FDA Approved Indications	Injection Methods	Date of Approval
Keytruda	Pembrolizumab	MSD	PD-1	\$17,186	25mg/ml 4ml:5,264.7 8ml:10,519.8	\$168.3	2037-07-18	MSI-H/dMMR solid tumors	Intravenous	May 2017
								First-line MSI-H/dMMR CRC		June 2020
Opdivo	Nivolumab	Bristol Myers Squibb	PD-1	\$7,523	10mg/ml 4ml:1,171.7 10ml:2,914.9 24ml:6,982.5	\$181.5	2037-06-01	MSI-H/dMMR CRC	Intravenous	August 2017
Jemperli	Dostarlimab-gxly	Glaxo SmithKline	PD-1	\$7	500mg/10ml: 10,835.1	\$184.2	2036-02-03	dMMR endometrial cancer	Intravenous	April 2021
								dMMR recurrent or advanced solid tumor		August 2021

Note: 2021 Revenue indicates sales revenue for all indications

Source: FDA, Annual Reports of Listed Pharmaceutical Companies, Company Official Websites, NRDL, Frost & Sullivan

### NMPA Approved and Clinical Stage PD-1/L1 mAbs for MSI/dMMR in China

As of the Latest Practicable Date, the NMPA had approved four PD-1/PD-L1 mAbs for the treatment of MSI-H/dMMR, among which three are for MSI-H/dMMR solid tumors and one is for only MSI-H/dMMR colorectal cancer. The following tables set out the lists of approved and clinical-stage PD-1/PD-L1 mAbs indicated for the treatment of MSI-H/dMMR in China.

Competitive Landscape for Approved PD-1/PD-L1 mAbs Indicated for the Treatment of MSI-H/dMMR in China

Drugs	Drug Type	Company	Indications	Injection Method	Marketed/First Posted Date	NRDL	Price (RMB)	Dosage	Annual Cost (Thousand RMB)
Envafohimab/ KN035	PD-L1 mAb	3DMed/ Alphamab	Unresectable or metastatic MSI-H/dMMR solid tumors	Subcutaneous	2021-11-24	-	200mg/ml 1ml: 5,980.0	150mg/ week	311.0 <sup>(1)</sup>
Pembrolizumab	PD-1 mAb	MSD	Unresectable or metastatic MSI-H/dMMR colorectal cancer	Intravenous	2021-06-15	-	100mg/4ml 4ml: 17,918.0	200mg/ 3 weeks	621.2
Tislelizumab/ BGB-A317	PD-1 mAb	Beigene	Unresectable or metastatic MSI-H/dMMR solid tumors	Intravenous	2022-03-11	2022 NRDL: Class B	100mg/10ml 10ml: 1,450	200mg/ 3 weeks	50.3
Serplulimab/ HLX-10	PD-1 mAb	Shanghai Henlius Biotech	Unresectable or metastatic MSI-H/dMMR solid tumors	Intravenous	2022-03-22	-	100mg/10ml 10ml: 5,588	3mg/kg/ 2 weeks	283.3

Notes: As of the Latest Practicable Date

The annual cost is calculated based on the assumptions that each patient weighs 65kg and the annual medication time is 52 weeks.

- (1) Assuming that each patient use one 1-ml sized KN035 per week.

Source: NMPA, Annual Reports of Listed Pharmaceutical Companies, Company Official Websites, NRDL, Frost & Sullivan

## INDUSTRY OVERVIEW

Competitive Landscape for Clinical-Stage PD-1/PD-L1 mAbs Indicated for the Treatment of MSI-H/dMMR in China

Drugs	Drug Type	Company	Indications	Injection Method	Clinical Stage	Location	First Posted Date
HX008/ Pucotenlimab	PD-1 mAb	Akeso Biopharma, HanX Bio, Lepu Biopharma	Locally advanced or metastatic gastric adenocarcinoma; MSI-H/dMMR solid tumor	Intravenous	NDA	China	2021-10-26
Nivolumab	PD-1 mAb	BMS	Unresectable or metastatic dMMR/MSI-H CRC	Intravenous	Phase III	MRCT	2020-06-23
					Phase II	China	2019-12-18
Pembrolizumab	PD-1 mAb	MSD	MSI-H/dMMR solid tumors	Intravenous	Phase III	China	2022-02-11
AK-104/ Cadonilimab	PD-1 bi- specific Ab	Akeso, Inc	Locally advanced unresectable or metastatic MSI-H/dMMR	Intravenous	Phase II	China	2020-02-25
QL1604	PD-1 mAb	Qilu Pharmaceutical	Advanced dMMR/MSI-H solid tumor	Intravenous	Phase II	China	2020-05-22
RB-0004	PD-1 mAb	Reyoung (Suzhou) Biopharmaceuticals	MSI-H/dMMR solid tumors; TMB-H solid tumors; lymphomas	Intravenous	Phase I	China	2020-12-18

Note: As of the Latest Practicable Date.

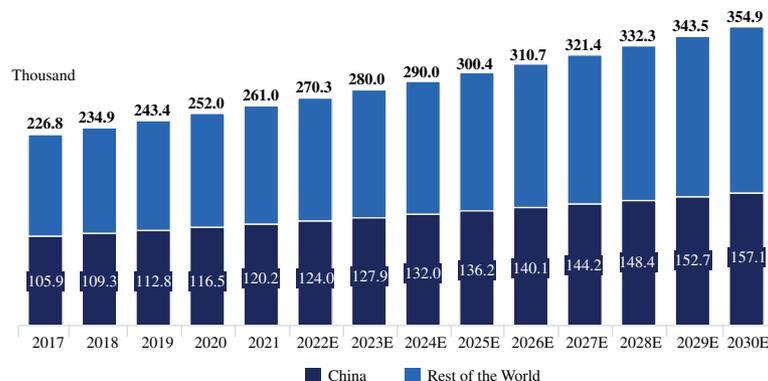
Source: CDE, Annual Reports of Listed Pharmaceutical Companies, Company Official Websites, NRDL, Frost & Sullivan

### Biliary Tract Carcinoma

Biliary tract carcinoma (BTC or cholangiocarcinoma) is a rare and highly fatal malignant tumor. It can be formed anywhere in the bile duct.

The global BTC incidence reached approximately 261,000 in 2021, and is expected to reach approximately 354,900 in 2030. The incidence of BTC in China reached approximately 120,200 in 2021 and is expected to reach approximately 157,100 in 2030, accounting for 44.4% of the global incidence.

### Global Incidence of Biliary Tract Carcinoma, 2017-2030E



Source: IARC, GBD study, Global Cancer Observatory, NCCR, Frost & Sullivan Report

## INDUSTRY OVERVIEW

### Unmet Needs for BTC Treatment

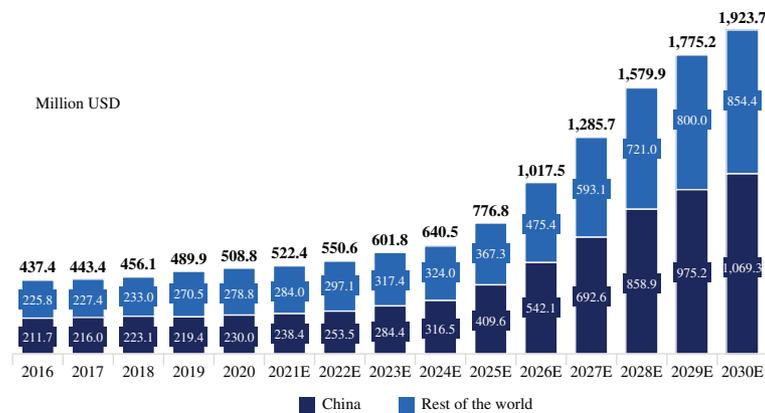
Although the incidence rate of BTC is not high, once it develops, only 30% of the BTC patients are eligible to receive surgery, which is a radical cure for BTC currently available. Even if a surgery is possible, surgical treatment also has certain limitations and the prognosis is very poor. The 5-year survival rate can hardly exceed 40% due to the scarcity of effective treatment.

Currently there are limited treatment options for BTC patients. A majority of the patients will present with locally advanced or metastatic disease. While chemotherapy is the mainstream in the market, it has limited benefits but many side effects. It is found that monoclonal antibodies and some multi-target drugs may bring some improvements in overall response rate (ORR) and progression-free survival (PFS).

### BTC Drug Market Size Globally and in China

The market for global BTC drug market was US\$508.8 million in 2020, and is expected to reach US\$776.8 million in 2025 and US\$1,923.7 million in 2030. China’s BTC drug market reached US\$230.0 million in 2020 and is expected to reach US\$409.6 million in 2025 and US\$1,069.3 million in 2030. The scarcity of effective treatment and approved drug implies a huge market potential of BTC drug globally and in China.

**Global BTC Market, 2016-2030E**



Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, FDA, Frost & Sullivan Report

## INDUSTRY OVERVIEW

Competitive Landscape for PD-1/L1 mAbs Indicated for BTC in China (as of the Latest Practicable Date)

Drugs	Drug Target	Company	Clinical Stage for the Indication	Location	Marketed/First Posted Date
Envaloflimab	PD-L1	3DMed/Alphamab	Phase III	China	2018/4/9
Pembrolizumab	PD-1	MSD	Phase III	China	2020/5/20
TQB2450	PD-L1	Akeso, Inc.	Phase III	China	2019/2/18
Durvalumab	PD-L1	AZ	Phase III	China	2020/8/10
Toripalimab	PD-1	Junshi	Phase II	China	2019/3/8
Atezolizumab	PD-L1	Roche	Phase II	China	2020/2/11
Dewallumab	PD-L1	Lee’s Pharmaceutical	Phase I	China	2021/10/27

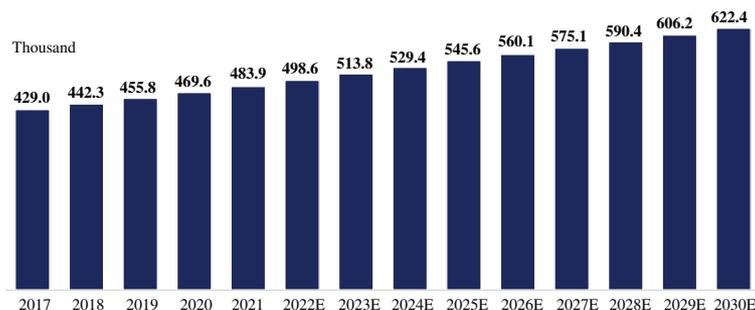
Source: CDE, Annual Reports of Listed Companies, ClinicalTrials.gov

### Gastric Cancer

Gastric cancer is a disease in which the cells forming the inner lining of the stomach become abnormal and start to divide uncontrollably, forming a cancerous tumor mass. Cancer may spread from the stomach to other parts of the body, especially the liver, lungs, bones, lining of the abdomen and lymph nodes. In most cases, gastric cancer will develop over several years.

The incidence of gastric cancer in China reached approximately 483,900 and is expected to reach approximately 622,400 in 2030, accounting for 43.4% of the global incidence in 2030.

### Incidence of Gastric Cancer in China, 2017-2030E



Source: NCCR, Frost & Sullivan Report

## INDUSTRY OVERVIEW

### Unmet Needs for Gastric Cancer Treatment

The current treatments for advanced gastric cancer have huge limitations, because targeted treatment options are very limited, and the treatment paradigm is mainly dominated by chemotherapy, which has a low benefit but a high risk.

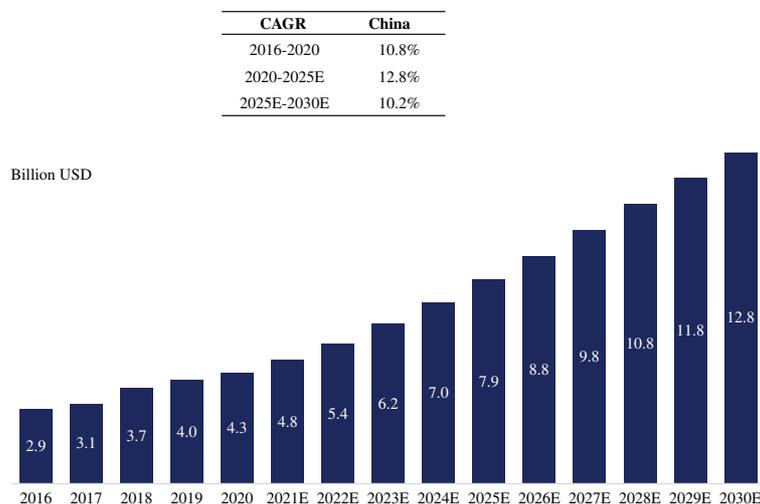
Unmet medical needs for treatment of gastric cancer are identified due to a couple of reasons, one of which is due to chemotherapy as the main first-line treatment for HER2-negative patients. HER2-negative gastric cancer patients account for 80% to 88% of all gastric cancer patients, and the current main first-line treatment is chemotherapy, the side effects of which include nausea, vomiting, diarrhea, hair loss, among others. Currently, there is no targeted drug that can be used as first-line therapy to treat HER2-negative gastric cancer.

Currently, there are only three targeted drug, apatinib, trastuzumab and disitamab vedotin, and one immunotherapy, nivolumab, treating advanced gastric cancer in the market in China. The *2018 Clinical Guidelines for the Diagnosis and Treatment of Gastric Cancer* published by the Chinese Society of Clinical Oncology (CSCO) recommend apatinib and nivolumab in the third-line therapy. There are two HER2-targeted immunotherapies, trastuzumab and disitamab vedotin in the market treating HER2-positive advanced gastric cancer in China.

### Gastric Cancer Drug Market Size in China

China’s gastric cancer drug market reached US\$4.3 billion in 2020 and is expected to reach US\$7.9 billion in 2025 at a CAGR of 12.8% from 2020 to 2025, and to further reach US\$12.8 billion in 2030 at a CAGR of 10.2% from 2025 to 2030.

#### China Gastric Cancer Market Size, 2016-2030E



Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, Frost & Sullivan Report



## INDUSTRY OVERVIEW

Competitive Landscape for PD-1/L1 mAbs Indicated for Gastric Cancer in China (as of the Latest Practicable Date)

Drugs	Drug Target	Company	Clinical Stage for the Indication	Location	Marketed/First Posted Date
Nivolumab	PD-1	BMS	Approved	China	2018/6/15
Sintilimab	PD-1	Innovent	Approved	China	2022/6/24
Tislelizumab	PD-1	Beigene	NDA	China	2022/6/22
Pembrolizumab	PD-1	MSD	Phase III	China	2017/1/23
Sugemalimab	PD-L1	Cstone Pharmaceuticals	Phase III	China	2019/1/17
Camrelizumab	PD-1	Henrui	Phase III	China	2019/1/24
Serplulimab	PD-1	Shanghai Henlius Biotech	Phase III	China	2019/9/16
Pucotenlimab	PD-1	Lepu Biopharm	Phase III	China	2020/6/15
Retifanlimab	PD-1	Zai Lab	Phase III	China	2020/9/27
Toripalimab	PD-1	Junshi	Phase III	China	2021/11/30
BAT1306	PD-1	Bio-Thera Solutions	Phase II	China	2019/1/8
Atezolizumab	PD-L1	Roche	Phase II	China	2020/10/23
<b>Envafohimab</b>	<b>PD-L1</b>	<b>3DMed/Suzhou Alphamab</b>	<b>Phase II</b>	<b>China</b>	<b>2018/7/24</b>

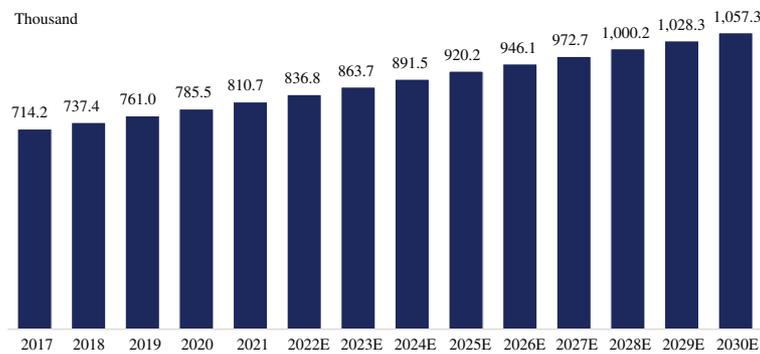
Source: CDE, NMPA, Annual Reports of Listed Companies, ClinicalTrials.gov

### Non-small-cell Lung Cancer

NSCLC is any type of epithelial lung cancer other than small cell lung cancer (SCLC). All types can occur in unusual histological variations and develop into mixed cell type combinations. Approximately 85% of lung cancer is NSCLC, and 15% is SCLC.

In China, the number of patients with NSCLC is sizable, and reached approximately 810,700 in 2021, and is expected to reach approximately 1,057,300 in 2030.

### Incidence of NSCLC in China, 2017-2030E



Source: NCCR, Frost & Sullivan Report

## INDUSTRY OVERVIEW

### Unmet Needs for NSCLC Treatment

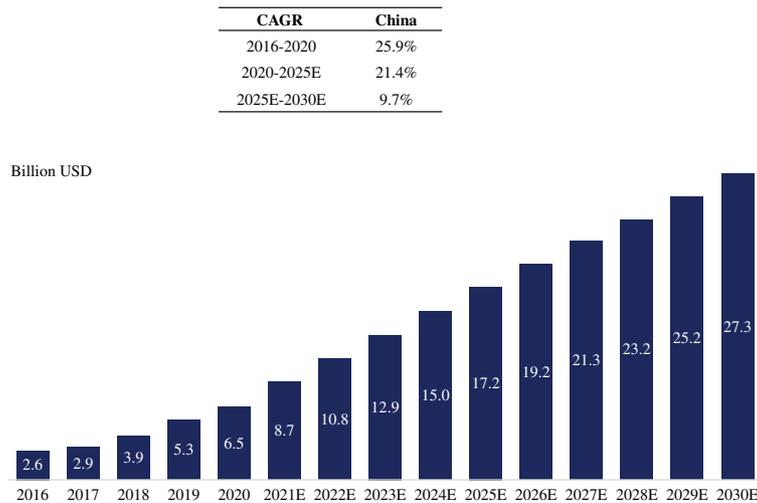
In 2021, the number of lung cancer deaths in China accounted for 42.1% of all lung cancer deaths globally. Most patients with NSCLC are diagnosed when their disease is at an advanced stage, of which about 17.0% are in stage III and 50.0% are in stage IV, resulting in poor survival and high mortality.

Drug resistance is the main reason that causes the failure of NSCLC treatment and leads to tumor recurrence and disease progression. The combination of PD-1 antibody with chemotherapy in first-line treatment of NSCLC does not need PD-L1 expression. In contrast, when PD-1 mAbs is used as monotherapy, PD-L1 expression is required. Around 60% of patients would develop drug resistance after treatment of seven months to two years.

### NSCLC Drug Market Size in China

China’s NSCLC drug market reached US\$6.5 billion in 2020 and is expected to reach US\$17.2 billion in 2025 at a CAGR of 21.4% from 2020 to 2025, and to further reach US\$27.3 billion in 2030 at a CAGR of 9.7% from 2025 to 2030.

#### China NSCLC Market Size, 2016-2030E



Source: NCCR, Frost & Sullivan Report

## INDUSTRY OVERVIEW

Competitive Landscape for PD-1/L1 mAbs Indicated for NSCLC in China (Stage II and above) (as of the Latest Practicable Date)

Drugs	Drug Target	Company	Clinical Stage	Location	Marketed/First Posted Date
Nivolumab	PD-1	BMS	Approved	China	2018/6/15
Durvalumab	PD-L1	AZ	Approved	China	2019/12/6
Pembrolizumab	PD-1	MSD	Approved	China	2019/10/24
Camrelizumab	PD-1	Henrui	Approved	China	2020/6/17
Tislelizumab	PD-1	Beigene	Approved	China	2021/1/12
Sintilimab	PD-1	Innovent	Approved	China	2021/2/2
Atezolizumab	PD-L1	Roche	Approved	China	2021/4/27
Sugemalimab	PD-L1	Cstone Pharmaceuticals	Approved	China	2021/12/22
Penpulimab	PD-1	Chia Tai Tianqing & Akesobio	NDA	China	2021/7/13
Serplulimab	PD-1	Shanghai Henlius Biotech	NDA	China	2021/9/16
Toripalimab	PD-1	Junshi	NDA	China	2021/12/14
Avelumab	PD-L1	Merck	Phase III	China	2017/11/27
Cemiplimab	PD-1	Sanofi	Phase III	China	2019/7/24
SCT I10A	PD-1	Sinocelltech-Group	Phase III	China	2020/1/23
TQB2450	PD-L1	Tai-Tianqing	Phase III	China	2020/3/17
Adebrelimab	PD-L1	Henrui	Phase III	China	2020/4/10
Retifanlimab	PD-1	Zai Lab	Phase III	China	2020/6/23
Prolgolimab	PD-1	Shang Yao Bo Kang	Phase III	China	2021/4/8
Pucotenlimab	PD-1	Lepu-Biopharm	Phase III	China	2021/7/5
Envafolimab	PD-L1	3DMed/Alphamab	Phase II	China	2021/8/18

Source: CDE, NMPA, Annual Reports of Listed Companies, ClinicalTrials.gov

### *Urothelial Carcinoma*

Urothelial carcinoma (UC), also called transitional cell carcinoma, is a type of cancer that typically occurs in the urinary system. UC is the most common form of Bladder cancer. It accounts for 95% of UC cases. The incidence of UC in China reached approximately 79,700 in 2021 and is expected to reach approximately 105,900 in 2030.

Currently, the standard first-line treatment for advanced UC is platinum-based chemotherapy. For patients who are not eligible for platinum based chemotherapy, single agent PD-1/PD-L1 antibody is an alternative. Avelumab is a standard care in the U.S. and Europe in patients who have not progressed after completing the first-line chemotherapy. However, avelumab has not been approved in China. For the second-line treatment, monotherapy with PD-1/PD-L1 antibody or chemotherapy are treatment options. In China, only two PD-1 antibodies have been conditionally approved for second-line treatment.

## INDUSTRY OVERVIEW

Competitive Landscape for PD-1/L1 mAbs Indicated for Urothelial Carcinoma in China (as of the Latest Practicable Date)

Drugs	Drug Target	Company	Clinical Stage	Location	Marketed/First Posted Date
Tislelizumab	PD-1	Beigene	Approved	China	2020/4/10
Toripalimab	PD-1	Junshi	Approved	China	2021/4/7
Atezolizumab	PD-L1	Roche	Phase III	China	2016/9/22
Nivolumab	PD-1	BMS	Phase III	China	2017/8/28
Pembrolizumab	PD-1	MSD	Phase III	China	2020/5/25
Dewallumab	PD-L1	Lee's Pharmaceutical	Phase I	China	2018/6/11

Source: CDE, NMPA, Annual Reports of Listed Companies, ClinicalTrials.gov

### Tumor Mutational Burden

Tumor mutational burden (TMB) refers to the number of somatic gene mutations present in a tumor. It is a predictive biomarker being studied to evaluate its association with response to Immuno-Oncology (I-O) therapy. Measured in mutations per megabase (mb), the level of TMB is considered high (TMB-H) if it reaches 20 mutations per mb. TMB-H proportion varies across different cancer types, from mesothelioma (1.2%) to SCLC (40%). The incidence of TMB-H solid tumor in China reached 175.1 thousand in 2021 and it is expected to reach 220.8 thousand in 2030.

Tumors with high mutation rates may respond well to checkpoint inhibitors (CPI); thus, using CPI to treat MSI-H patients with TMB can be considered.

Competitive Landscape for PD-1/L1 mAbs Indicated for TMB-H Advanced Cancer in China (as of the Latest Practicable Date)

Drugs	Drug Target	Company	Clinical Stage for the Indication	Location	Marketed/First Posted Date
Envafolimab	PD-L1	Alphamab/3DMed	Phase II	China	2021/5/18
MSB2311	PD-L1	Transcenta	Phase I	China	2019/7/8

Source: CDE, ClinicalTrials.gov

### Endometrial Cancer

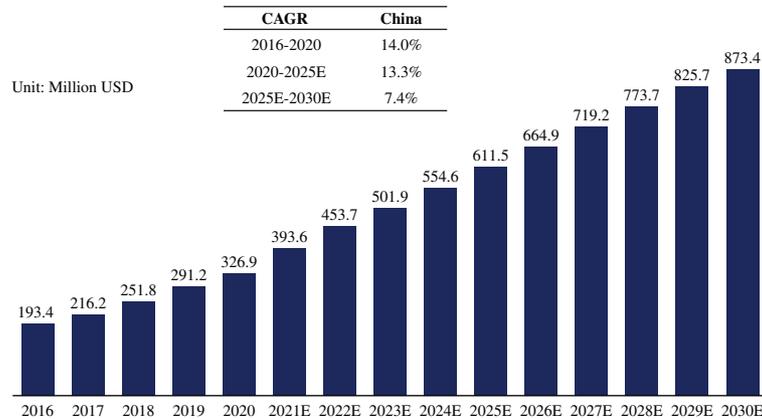
Endometrial cancer, also known as uterine body cancer, is a group of epithelial malignant tumors in endometrium. Mostly occurring in perimenopausal and postmenopausal women, it is one of the three most common malignant tumors in female genital tract and accounts for about 20%-30% of gynecological malignant tumors in China. The incidence of endometrial cancer in China reached 83.1 thousand in 2021 and it is expected to reach 93.0 thousand in 2030.

## INDUSTRY OVERVIEW

### Endometrial Cancer Drug Market Size in China

The market for endometrial cancer drug in China reached US\$326.9 million in 2020 and is expected to reach US\$611.5 million in 2025 and US\$873.4 million in 2030.

#### China Endometrial Cancer Market Size, 2016-2030E



Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, Frost & Sullivan Analysis

Competitive Landscape for PD-1/L1 mAbs Indicated for Endometrial Cancer in China (as of the Latest Practicable Date)

Drugs	Drug Target	Company	Clinical Stage for the Indication	Location	Marketed/First Posted Date
Pembrolizumab	PD-1	MSD	Phase III	China	2019/9/25
Durvalumab	PD-L1	AZ	Phase III	China	2021/3/18
Envalolimab	PD-L1	3DMed/ Suzhou Alphamab	Phase II	China	2021/11/1

Source: CDE, Annual Reports of Listed Companies, ClinicalTrials.gov

### Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) is the most common type of liver cancer, accounting for 85%-90% of all patients with liver cancer. 80%-90% people who get it also have an ongoing (or “chronic”) liver disease, such as cir/r hosis.

## INDUSTRY OVERVIEW

Competitive Landscape for PD-1/L1 mAbs Indicated for HCC in China (Stage II and above) (as of the Latest Practicable Date)

Drugs	Drug Target	Company	Clinical Stage for the Indication	Location	Marketed/First Posted Date
Camrelizumab	PD-1	Henrui	Approved	China	2020/3/4
Atezolizumab	PD-L1	Roche	Approved	China	2020/9/29
Tislelizumab	PD-1	Beigene	Approved	China	2021/6/22
Sintilimab	PD-1	Innovent	Approved	China	2021/6/25
Pembrolizumab	PD-1	MSD	Phase III	China	2017/3/10
Durvalumab	PD-L1	AZ	Phase III	China	2018/6/20
Toripalimab	PD-1	Junshi	Phase III	China	2018/12/6
CS1003	PD-1	Cstone Pharmaceuticals	Phase III	China	2019/12/18
QL1604	PD-1	Qilu	Phase III	China	2020/5/27
Nivolumab	PD-1	BMS	Phase III	China	2020/1/16
SCT H10A	PD-1	Sinocelltech Group	Phase III	China	2020/10/19
Serplulimab	PD-1	Shanghai Henlius Biotech	Phase III	China	2021/6/24
Rulonilimab	PD-1	Shandong Xinshidai	Phase III	China	2022/7/8
<b>Envafohimab</b>	<b>PD-L1</b>	<b>3DMed/ Suzhou Alphamab</b>	<b>Phase II</b>	<b>China</b>	<b>2021/8/18</b>
Spartalizumab	PD-1	Novartis AG	Phase II	China	2018/3/20
BAT1306	PD-1	Bio-Thera Solutions	Phase II	China	2018/12/25
Pucotenlimab	PD-1	Lepu Biopharm	Phase II	China	2020/11/3
Penpulimab	PD-1	Chia Tai Tianqing & Akesobio	Phase II	China	2018/11/19

Source: CDE, NMPA, Annual Reports of Listed Companies, ClinicalTrials.gov

### Renal Cell Carcinoma

Renal cell carcinoma (RCC) is a kidney cancer that originates in the lining of the proximal convoluted tubule, a part of the very small tubes in the kidney that transport primary urine. It is the most common type of kidney cancer in adults, responsible for approximately 90%–95% of cases. The incidence of kidney cancer in China reached 75,400 in 2021 and it is expected to reach 92,200 in 2030.

### Unmet Needs for RCC Treatment

- Limited Treatment Options for Advanced RCC.* Although the 5-year survival rate of early stage RCC after operation can reach 92%, such rate of advanced RCC is as low as around 20%. Currently, palliative surgery is a treatment option for advanced RCC, which involves removal of the primary tumor followed by targeted therapy. If

## INDUSTRY OVERVIEW

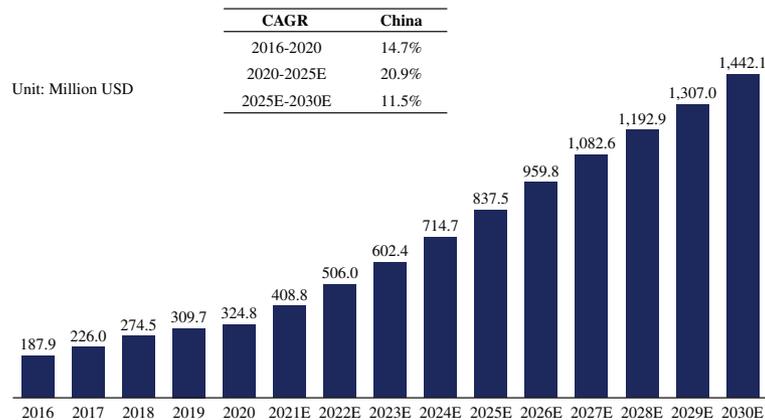
a patient is not eligible for surgery, then targeted therapy should be administered. The treatment trend for advanced RCC has also turned to targeted therapy combined with immunotherapy, but there still lacks indications for immunotherapy in China.

- *Limited Drug Options.* Currently in China, the number of targeted drugs, such as sunitinib and sorafenib, is far less than that in the United States, which leaves doctors with limited drug options. Everolimus is the only approved kidney cancer mTOR inhibitor.

### *Kidney Cancer Drug Market Size in China*

The market for kidney cancer drug in China reached US\$324.8 million in 2020 and is expected to reach US\$837.5 million in 2025 and US\$1,442.1 million in 2030.

### China Kidney Cancer Market Size, 2016-2030E



Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, Frost & Sullivan Analysis

Competitive Landscape for PD-1/L1 mAbs Indicated for Renal Cell Carcinoma in China (as of the Latest Practicable Date)

Drugs	Drug Target	Company	Clinical Stage for the Indication	Location	Marketed/First Posted Date
Nivolumab	PD-1	BMS	Phase III	China	2018/3/20
Toripalimab	PD-1	Junshi	Phase III	China	2020/6/24
Atezolizumab	PD-L1	Roche	Phase III	China	2018/5/11
Pembrolizumab	PD-L1	MSD	Phase III	China	2022/03/14
Envafolimab	PD-L1	3DMed/Suzhou Alphamab	Phase II	China	2021/8/18

Source: CDE, Annual Reports of Listed Companies, ClinicalTrials.gov

## INDUSTRY OVERVIEW

### *Competitive Landscape of PD-1/PD-L1 Inhibitors Globally and in China*

As of the Latest Practicable Date, China had approved eight PD-1 monoclonal antibodies, six of which are domestic products, and four PD-L1 monoclonal antibodies, two of which are imported products. As of the Latest Practicable Date, China had registered 692 clinical trials for PD-1/PD-L1, of which 606 trials were ongoing. The following tables illustrate the competitive landscape of PD-1 and PD-L1 in clinical stage III or later stages as of the Latest Practicable Date in China.

### **China Competitive Landscape of PD-L1 Inhibitors (Phase III/NDA)**

Drugs	Company	Indications in Phase III Clinic Trial	Injection Methods	Dosage	Development Phase
ZKAB001/ Dewallumab	Lee's Pharmaceutical	Osteosarcoma, ES-SCLC	Intravenous	5mg/kg, every 3 weeks	Submit listing application in Oct. 2021. The indication is recurrent and metastatic cervical cancer
KL-A167	Kelun-biotech	NA	Intravenous	900mg, every 2 weeks	Submit listing application in Nov. 2021. The indication is recurrent and metastatic nasopharyngeal cancer
SHR-1316/ Adebrelimab	Hengrui	NSCLC	Intravenous	12ml: 0.6g, every 3 weeks	Submit listing application in Nov. 2021. The indication is SCLC.
Avelumab	Merck/Pfizer	NSCLC, head and neck squamous cell carcinoma	Intravenous	10 mg/kg, every 1-2 weeks	Clinical phase III starts in Nov. 2017
TQB2450	Chia Tai Tianqing Pharmaceutical	Triple negative breast cancer, biliary system adenocarcinoma, non-small cell lung cancer, head and neck squamous cell carcinoma, renal cell carcinomas, ES-SCLC	Intravenous	1200mg, every 3 weeks	Clinical phase III starts in Feb. 2019
GR1405	Genrix Bio	NPC	Intravenous	10mg/kg, every 3 weeks	Clinical phase III starts in May 2021

*Abbreviations:* NSCLC: Non small-cell lung cancer, SCLC: Small-cell lung cancer, TNBC: Triple-negative breast cancer, G/GEJ carcinoma: Gastric adenocarcinoma or gastroesophageal junction adenocarcinoma; HCC: hepatocellular carcinoma; CRC: Colorectal cancer

*Note:* only PD-1 mAbs in clinical stage III or later stages before March 14, 2022 are included, no bispecific antibodies or ADC.

*Source:* CDE, Frost & Sullivan Report



## INDUSTRY OVERVIEW

### China Competitive Landscape of PD-1 Inhibitors (Phase III/NDA)

Drugs	Company	Indications in Phase III Clinic Trial	Injection Methods	Dosage	Development Phase	Details in Indications
<b>GB226/</b> <b>Geptanolimab</b>	Genor Biopharma	NA	Intravenous	3mg/kg, every 2 weeks	Submit listing application in Jul. 2020	Indications of listing application: peripheral T-cell lymphoma
<b>HLX 10/</b> <b>serplulimab</b>	Shanghai Henlius Biotech	NSCLC, esophageal squamous cell carcinoma, CRC, cervical cancer, gastric cancer, SCLC, liver cancer	Intravenous	4.5mg/kg, every 3 weeks	Submit listing application in Apr. 2021	Indications of listing application: dMMR/MSIH solid tumor and squamous NSCLC
<b>HX008/</b> <b>Pucotenlimab</b>	Lepu Bio	G/GEJ carcinoma	Intravenous	200mg, every 3 weeks	Submit listing application in June 2021	Indications of listing application: melanoma, the pre-NDA meeting application is MSIH/dMMR solid tumors in July 2021
<b>Cemiplimab</b>	Sanofi	NSCLC	Intravenous	350mg, every 3 weeks	Clinical phase III starts in Nov. 2019	Indications of phase III clinical trial: NSCLC
<b>SCT-110A</b>	Sinocelltech	HNSCC, NSCLC, HCC	Intravenous	15mg/kg, every 3 weeks	Clinical phase III starts in Sep. 2019	Indications of phase III clinical trial: Head and neck squamous cell carcinoma, NSCLC, HCC
<b>CS1003</b>	Cstone Pharmaceuticals	HCC	Intravenous	200mg, every 3 weeks	Clinical phase III starts in Dec. 2019	Indications of phase III clinical trial: HCC
<b>Sasanlimab</b>	Pfizer	Non-muscular invasive bladder carcinoma	Subcutaneous	2ml, every week	Clinical phase III starts in Oct. 2020	Indications of phase III clinical trial: Non-muscular invasive bladder carcinoma
<b>Retifanlimab/</b> <b>INCMGA00012</b>	Incyte, ZAI Laboratory	NSCLC	Intravenous	375mg, every 3 weeks	Clinical phase III starts in June 2020	Indications of phase III clinical trial: NSCLC
<b>QL1604</b>	Qilu Pharmaceutical	HCC	Intravenous	3mg/kg, every 3 weeks	Clinical phase II/III starts in May 2020	Indications of phase II/III clinical trial: HCC
<b>Progolimab</b>	SPH-BIOCAD	NSCLC; Progressive recurrent or metastatic cervical cancer	Intravenous	3mg/kg, every 3 weeks	Clinical phase III starts in Apr. 2021	Indications of phase II/III clinical trial: NSCLC, cervical cancer

Note: no bispecific antibodies or ADC is included.

Source: CDE, Frost & Sullivan

### NRDL Plan Further Increases PD-1/PD-L1 Inhibitors Market Size in China

As of the Latest Practicable Date, 13 PD-1/PD-L1 monoclonal antibodies have been approved for marketing in China since June 2018. With the approvals of new drugs and new indications, as well as the increased accessibility to the NRDL plan, China’s PD-1/PD-L1 monoclonal antibody market is expected to grow rapidly, reaching US\$7.5 billion in 2025, at a CAGR of 30.5% from 2020 to 2025.

As of the Latest Practicable Date, four PD-1 mAbs are included in the NRDL plan. After being included in the NRDL plan, the price of PD-1 mAb has been reduced by approximately 60.0% to 80.0%. As it is expected that PD-L1 inhibitors will also be included under a separate catalogue in the NRDL in the future, patients’ access to anti-PD-1/PD-L1 mAbs will continue to increase, leading to a continued growth in the market size of PD-1/PD-L1 inhibitors.

## INDUSTRY OVERVIEW

### China Approved PD-1 Inhibitors

INN	Trade Name	Company	Approval Date	Indications	Price (RMB)	Dosage	Injection Methods	2021 Revenue (\$ million)	NRDL Status	Annual Cost (Thousand RMB)	Half-life Period	Patent Expiration Date
Nivolumab	Opdivo	BMS	Jun-2018	NSCLC, squamous cell carcinoma of the head and neck, adenocarcinoma of the stomach or gastroesophageal junction, MPM	100mg: 9,250RMB; 40mg: 4,587RMB	3mg/kg every 2 weeks	Intravenous	17,186 (Global)	-	479.0 <sup>1</sup>	26.7 days	2037-04-10
Pembrolizumab	Keytruda	MSD	Jul-2018	Melanoma, NSCLC, esophageal squamous cell carcinoma, head and neck squamous cell carcinoma, CRC, esophageal cancer, MSI-H/dMMRCRC	100mg: 17,918RMB	200mg every 3 weeks	Intravenous	7,523 (Global)	-	621.2	25 days	2036-02-22
Toripalimab	Tuoyi 拓益	Junshi (君實生物)	Dec-2018	Melanoma, nasopharyngeal carcinoma, urothelial carcinoma	80mg: 825RMB	3mg/kg every 2 weeks	Intravenous	\$63.9	Class B	52.3	12.6 days	2033-06-26
Sintilimab	TYVYT 達伯舒	Innovent (信達生物)	Dec-2018	classical Hodgkin lymphoma, NSCLC, HCC	100mg: 1,080RMB	200mg every 2 weeks	Intravenous	N/A	Class B	37.4	19.6 days	2036-08-09
Camrelizumab	Aimika 艾瑞卡	Hengrui (江蘇恒瑞)	May-2019	classical Hodgkin lymphoma, HCC, NSCLC, Esophageal squamous cell carcinoma, NPC	200mg: 2,928RMB	200mg every 2 weeks	Intravenous	N/A	Class B	76.1	5.5 days	2034-11-14
Tislelizumab	Baizhen 百澤安	Beigene (百濟神州)	Dec-2019	classical Hodgkin lymphoma, urothelial carcinoma, NSCLC, HCC	100mg: 1,450RMB	200mg every 3 weeks	Intravenous	255.1	Class B	50.3	26 days	2033-09-13
Penpulimab	Anniko 安尼可	Chia Tai Tianqing (正大天晴)/ Akeso Biopharma (康方生物)	Aug-2021	Recurrent or refractory classical Hodgkin's lymphoma	100mg: 4,875RMB	200mg every 2 weeks	Intravenous	32.8	-	253.5	-	-
Zimberelimab	Yutao 譽妥	WuXi Biologics (藥明生物)/ GloriaBio (醫衛生物)	Aug-2021	Recurrent or refractory classical Hodgkin's lymphoma	120mg: 3,300RMB	240mg every 2 weeks	Intravenous	N/A	-	171.6	-	-
Serplulimab	Hansizhuang 漢斯狀	Henlius Biotech (復宏漢霖)	Mar-2022	MSI-H/dMMR solid tumors	100mg: 5,588RMB	3mg/kg every 2 weeks	Intravenous	N/A	-	283.3	-	-

Notes: the annual cost is calculated based on the assumptions that each patient weighs 65kg and the annual medication time is 52 weeks unless specified otherwise.

(1) Assuming that each patient uses 1 large-size and 2 small-size Opdivo every two weeks.

Source: Annual Reports of Listed Pharmaceutical Companies, CDE, NRDL, Frost & Sullivan Report

### China Approved PD-L1 Inhibitors

INN	Trade Name	Company	Approval Date	Indications	Price (RMB)	Dosage	Injection Methods	2020 Revenue (\$ million)	NRDL Status	Annual Cost (Thousand RMB)	Half-life Period	Patent Expiration Date
Atezolizumab	Tecentriq	Roche	Feb-2020	SCLC, HCC	1,200mg: 32,800RMB	1,200mg every 3 weeks	Intravenous	2,965.0 (Global)	-	568.5	27 days	2035-11-10
Durvalumab	Imfinzi	AZ	Dec-2019	NSCLC	120mg: 6,066RMB; 500mg: 18,088RMB	10mg/kg, every 2 weeks	Intravenous	2,042.0 (Global)	-	628.0 <sup>(1)</sup>	17 days	2037-04-24
Envafohimab	恩維達	3D Medicines/ Alphamab oncology/ Simcere	Nov-2021	MSI-H/dMMR advanced solid tumor	200mg: 5,980RMB	150mg every week	Subcutaneous	-	-	311.0 <sup>(2)</sup>	23 days	-
Sugemalimab	擇捷美	Cstone Pharma	Dec-2021	NSCLC	600mg: 12,375RMB	1,200mg every 3 weeks	Intravenous	-	-	429.0	12 days	-

Notes: The annual cost is calculated based on the assumptions that each patient weighs 65kg and the annual medication time is 52 weeks unless specified otherwise.

(1) Assuming that each patient uses 1 large-size and 1 small-size Imfinzi every two weeks.

(2) Assuming that each patient use one 1-ml sized KN035 per week.

Source: Annual Reports of Listed Pharmaceutical Companies, CDE, Frost & Sullivan

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## INDUSTRY OVERVIEW

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### **WT1 Cancer Vaccine**

The Wilms Tumor 1 (WT1) gene plays an important role in cell proliferation, differentiation, apoptosis, organ development and maintenance of tissue cells. The WT1 antigen is one of the most widely expressed cancer antigens in multiple malignancies. WT1 immunotherapy has the potential to target various cancers that over-express WT1, creating a large potential market with a wide coverage of patients. The potential number of patients to be achieved is estimated to be 924,600 in China in 2030.

Galinpepimut-S (GPS), as a therapeutic cancer vaccine, is a peptide vaccine consisting of four peptide chains and targeting the WT1 protein which is present and over-expressed in an array of hematological malignancies and solid tumors. GPS potentially targets the indications of acute myeloid leukemia, colorectal cancer, malignant pleural mesothelioma, multiple myeloma, and ovarian cancer.

### ***Acute Myeloid Leukemia***

Acute myeloid leukemia (AML) is a cancer of the myeloid line of blood cells, characterized by the rapid growth of abnormal cells that build up in the bone marrow and blood and interfere with normal blood cell production. As an acute leukemia, AML progresses rapidly and is typically fatal within weeks or months if untreated.

The incidence of AML in China reached approximately 20,600 in 2021 and is expected to reach approximately 23,600 in 2030, with a substantial portion of AML patients being young and middle-aged people.

### ***Unmet Needs for AML Treatment***

- *Easy Development of AML From MDS.* Myelodysplastic syndrome (MDS) is a clonal disease of hematopoietic stem cells. According to statistics, approximately 30% to 40% of MDS patients will eventually develop AML, which is generally difficult to cure and the prognosis is very poor.
- *Limited Treatment Options.* Combination chemotherapy with multiple cytotoxic drugs is a common method for the treatment of MDS and MDS/AML, but its remission rate is low. The only possible cure is allogeneic hematopoietic stem cell transplantation (allo-HSCT). However, due to the shortage of donor sources, high cost and transplant complications, the clinical application of allo-HSCT is limited.

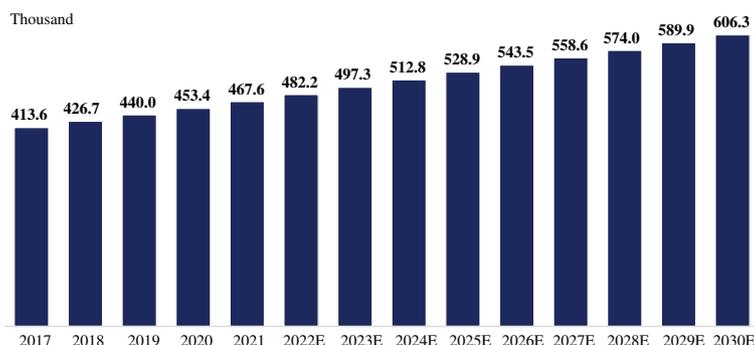
### ***Colorectal Cancer***

Colorectal cancer (CRC) is the development of colon or rectal cancer. Colon cancer is cancer of the large intestine (colon, the last part of the digestive tract). Most cases of colon cancer start in small, benign masses called adenomatous polyps. Over time, some of these polyps will become colon cancer.

## INDUSTRY OVERVIEW

China has the highest CRC incidence rate in the world, ranking the third by incidence among all cancers in China in 2021. The CRC incidence in China reached approximately 467,600 in 2021, and is expected to reach approximately 606,300 in 2030.

### Colorectal Cancer Incidence in China, 2017-2030E



Source: NCCR, Frost & Sullivan Report

### Unmet Needs for CRC Treatment in China

CRC is the 4th leading cause of death among all cancers in China. The mortality-to-incidence ratio (MIR), a population-based indicator of survival of the disease, of CRC in China was 0.48, as compared to 0.37 in the U.S. in 2019. Approximately 35% of CRC patients present with stage IV metastatic disease at the time of initial diagnosis. Currently, there is limited choice of effective therapy or drug to cure CRC, with the potential exception of patients with MSI-H/dMMR CRC which can be effectively treated with PD1/PD-L1 antibodies.

### Global Competitive Landscape of WT1 Cancer Vaccine

As of the Latest Practicable Date, there were four WT1 cancer vaccines undergoing clinical trials globally, three of which were in phase III, one was in phase I/II. The following table illustrates the global competitive landscape of WT1 cancer vaccines as of the Latest Practicable Date.

Drug Name	Phase	Company	Active Indications	Drug Type	Therapeutic strategy	Location	First Posted Date
Galinpepimut-S/3D189	III	3DMed/Sellas Life Sciences Group	Acute myeloid leukemia; Multiple myeloma; Mesothelioma; CRC; Ovarian cancer; TNBC; SCLC	Therapeutic Vaccine	Monotherapy/Combination therapy	US	3-Dec-18
TLP0-001	III	Tella; Wakayama Medical University	Pancreatic cancer	Dendritic cell vaccine	Combination therapy	Japan	1-May-17
DSP-7888	III	Sumitomo Dainippon Pharma Oncology Inc	Glioblastoma; advanced solid tumor	Therapeutic Vaccine	Combination therapy	MRCT	11-May-17
INO-5401	I/II	Inovio Pharmaceuticals	Glioblastoma; Urothelial Carcinoma	DNA Vaccine; Therapeutic Vaccine	Combination therapy	Spain; US	9-Apr-18

Note: PHASE indicates the highest clinical phase among active indications.

Source: Annual Reports of Listed Pharmaceutical Companies, FDA, PMDA, Frost & Sullivan Report

## INDUSTRY OVERVIEW

In view of the existence of multiple vaccine platforms, the use of combined cancer vaccine therapy is more feasible and attractive. Several combinations including vaccines plus cytokines, checkpoint inhibitors, small molecule inhibitors, radiation therapy and chemotherapy have been tested. The combination of therapeutic vaccines and immune checkpoint inhibitors appears to have the greatest potential to improve clinical outcomes.

### GAS6-AXL Pathway Drugs

The GAS6-AXL signaling pathway has been involved in promoting tumor cell proliferation, survival, migration, invasion, angiogenesis and immune evasion. GAS6-AXL inhibition has shown activity both as a single agent and in combination with other oncology therapies including radiation therapy, immuno-oncology agents, and drugs that affect DNA replication and repair in preclinical studies.

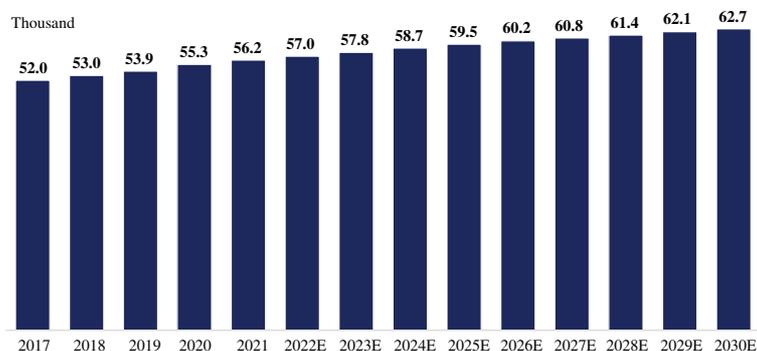
GAS6-AXL pathway drugs have the potential to impair multiple stages of tumor progression, thus creating a large potential market with a wide coverage of cancer indications.

### Ovarian Cancer

Ovarian cancer (OC) is a cancer that forms in or on an ovary. It results in abnormal cells that have the ability to invade or spread to other parts of the body. Common areas to which the cancer may spread include the lining of the abdomen, lymph nodes, lungs and liver.

The incidence of OC in China reached approximately 56,200 in 2021 and is expected to reach approximately 62,700 in 2030.

**Incidence of Ovarian Cancer in China, 2017-2030E**



Source: NCCR, Frost & Sullivan Report

## INDUSTRY OVERVIEW

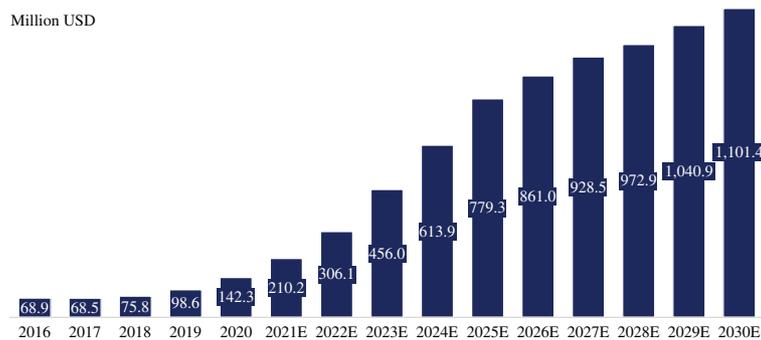
### *Unmet Needs for OC Treatment*

- *Limited Clinical Efficacy of First-line Maintenance Treatment with Chemotherapy +/- Bevacizumab.* Although OC is relatively sensitive to first-line chemotherapy, more than 50% of patients still develop resistance and relapse after initial treatment. Maintenance therapy is essential to control disease progression, however the clinical efficacy of chemotherapy as a maintenance treatment is difficult to determine, and the PFS of patients treated with chemotherapy and bevacizumab is not ideal.
- *Limited Treatment Options after Recurrence.* It is common that OC patients have multiple recurrences, and the time interval of recurrences becomes shorter after each relapse. With the progress of disease and corresponding treatment lines, drug resistance gradually occurs. However, effective drugs for subsequent lines of treatments are limited.

### *OC Drug Market Size in China*

China’s OC drug market reached US\$142.3 million in 2020 and is expected to reach US\$779.3 million in 2025 and US\$1,101.4 million in 2030.

#### **China Ovarian Cancer Market Size, 2016-2030E**



Source: NCCR, Frost & Sullivan Report

## INDUSTRY OVERVIEW

### Global Competitive Landscape of GAS6-AXL Pathway Drugs

As of the Latest Practicable Date, there were eleven GAS6-AXL pathway drugs undergoing clinical trials globally, one of which was in phase III, five were in phase II, one was in phase I/II, and four were in phase I. The following table illustrates the global competitive landscape of GAS6-AXL pathway drugs as of the Latest Practicable Date:

Drug Name	Company	Clinical Phase	Active Indications	Targets	Drug type	Therapeutic strategy	Location	First Posted Date
AVB-S6-500/3D229	Aravive Biologics; Aravive Inc; 3DMed	Phase III	Fallopian tube cancer; Transitional cell carcinoma; Renal cell carcinoma; Ovarian cancer; Peritoneal carcinoma; Ovary epithelial carcinoma; Urothelial Carcinoma; Pancreatic Neoplasms	GAS6/AXL	Biologics (Fusion protein)	Monotherapy/combination therapy	US; China; Europe	21-Aug-18
BA-3011	Bioatla Inc; AstraZeneca PLC	Phase II	NSCLC; Osteosarcoma; Melanoma; Synovial sarcoma; Leiomyosarcoma; Sarcoma; Pancreatic cancer; Ewing's sarcoma; Liposarcoma; Solid Tumor; Ovarian Neoplasms	AXL	Biologics (ADC)	Monotherapy	US	7-Feb-18
HK-001/Butylidenephthalide	Everfront Biotech Co Ltd	Phase II	Glioma; Amyotrophic lateral sclerosis	AXL	Chemical drugs (natural extracts)	Monotherapy	China Taiwan region	31-Jul-17
ONO-7475	Ono Pharmaceutical	Phase II	Leukemia; Myelodysplastic syndrome; Acute myeloid leukemia; Solid tumors	AXL	Chemical drugs (organic heterocyclic drugs)	Monotherapy/combination therapy	US	5-Jun-17
Duberminib/TP-0903	Sumitomo Dainippon Pharma Oncology Inc	Phase II	Chronic lymphocytic leukemia; NSCLC; Melanoma; CRC; Ovarian cancer, AML, Solid Tumor	AXL	Chemical drugs (organic heterocyclic drugs)	Monotherapy/combination therapy	US	6-Apr-16
Bemcentinib/BGB324	Bergensbio; Bergensbio Asa; MSD; Rigel Pharmaceuticals Inc	Phase II	Myelodysplastic syndrome; Melanoma; Breast cancer; NSCLC; Lung adenocarcinoma. Acute myeloid leukemia; Non-alcoholic fatty liver disease; Idiopathic pulmonary fibrosis; COVID-19; Pancreatic Neoplasms; Brain and Central Nervous System Tumors	AXL	Biologics (ADC)	Monotherapy	US; France; Germany; Netherlands; Italy; Norway	2-Jul-15
Enapotamab vedotin	Genmab	Phase I/II	Ovarian Cancer; Cervical Cancer; Endometrial Cancer; Non Small Cell Lung Cancer; Thyroid Cancer; Melanoma; Sarcoma;	AXL	Biologics (ADC)	Monotherapy	Belgium; Denmark; Netherlands; Spain; UK; US	9-Dec-16
BGB-149	Bergensbio	Phase I	Ovarian Neoplasms	AXL	Biologics (Human monoclonal antibody)	Monotherapy	South Korea; UK; Norway; Singapore	19-May-21
PF-07265807	Pfizer Inc	Phase I	Neoplasm Metastasis	AXL	Chemical drugs (organic heterocyclic drugs)	Monotherapy	US	7-Jul-20
SLC-391 XZB-004	Signalchem Lifesciences Co Xuanzhu Biotechnology	Phase I	Solid Tumor	AXL	Chemical drugs (organic heterocyclic drugs)	Monotherapy	Canada	19-Jun-19
CCT301-38	Shanghai PerHum Therapeutics Co., Ltd.	Phase I	Relapsed or Refractory AXL Positive Sarcomas	AXL	CAR-T	Monotherapy	Canada	22-Nov-21

Note: PHASE indicates the highest clinical phase among active indications, as of the Latest Practicable Date.

Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, FDA, ClinicalTrials.gov, Frost & Sullivan Report

## INDUSTRY OVERVIEW

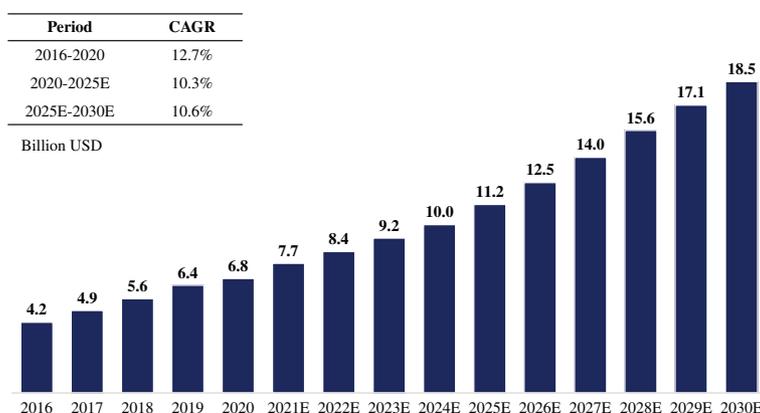
### COX-2 Inhibitor

Cyclooxygenase-2 (COX-2) is an enzyme responsible for the production of prostaglandins, which contribute to inflammation. COX-2 is constitutively expressed in several tissues and organs such as brain, kidneys and reproductive tract. COX-2 inhibitors are a type of nonsteroidal anti-inflammatory drug (NSAID) that directly targets COX-2, which is responsible for inflammation and pain, as validated by the clinical effectiveness of selective COX-2 inhibitors.

In 2017, the incidence of treated cancer pain patients in China was approximately 2.0 million, and reached approximately 2.3 million in 2021. It is expected that such number will continue to grow and reach approximately 2.9 million in 2030.

The cancer pain drug market in China reached US\$6.8 billion in 2020 and is expected to grow to US\$11.2 billion in 2025, representing a CAGR of 10.3%. This market is expected to further increase at a CAGR of 10.6% from 2025 to 2030, reaching US\$18.5 billion in 2030.

#### China Cancer Pain Drug Market Size, 2016-2030E



Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, NRDL, Frost & Sullivan Report

#### Unmet Needs for Cancer Pain Treatment

- **Opioid Intolerance.** Due to differences in drug reactions, some patients are not able to achieve an effective balance between pain relief and minimal adverse reactions. For example, 10% to 30% of patients are “morphine intolerant patients” who often do not respond well to oral morphine or cannot tolerate the side effects of morphine.
- **Limited Choice of Cancer Pain Drugs.** At present, NSAIDs and opioids are the only drugs that can treat cancer pain. NSAIDs can treat mild cancer pain, and opioids can treat moderate and severe cancer pain. However, long-term use of opioids can cause physical and mental dependence and severe side effects.



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### Global Competitive Landscape of COX-2 Inhibitor

The following table illustrates the global competitive landscape of Monotherapy COX-2 inhibitors as of the Latest Practicable Date:

Drug Name	Clinical Phase	Company	Active Indications	Target	Drug type	Therapeutic strategy	Location	First Posted Date		
RMX1001/3D1001*	Phase I	AskAt/3DMed	Acute pain; Chronic pain				China	23-August-19		
MK-966	Phase III	Tremeau Pharmaceuticals Inc	Arthritis				MRCT	24-Dec-2020		
HR18042	Phase II	Jiangsu HengRui Medicine	Pain; Moderate to Severe Acute Pain	COX-2	Chemical drugs	Monotherapy		25-Nov-20		
HR021618			Pain After Abdominal Surgery; Postsurgical Pain Management				China	22-May-20		
HTX-034	Phase II	Heron Therapeutics	Bunions						US	21-May-20
ATB-346	Phase II	Antibe Therapeutics	Osteoarthritis						Canada	7-Jun-19
ECP-1014	Phase I	Euclises Pharmaceuticals	Solid Tumor						China	18-Jun-21

\* Note: RMX1001/3D1001 has completed phase II clinical trial in the U.S. in March 28, 2006 for postoperative dental pain.

Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, Frost & Sullivan Report

### EP4 Receptor Antagonists

EP4 is known to be involved in the regulation of various processes in the body, including platelet aggregation, vasodilation, arterial closure, endothelial barrier, angiogenesis, inflammation, sepsis, kidney disease, bone pores and tumor growth. EP4 inhibitors can change the microenvironment by acting on the EP4 receptor, thereby promoting the body’s immune function, and have been proved to have strong anti-cancer activity and immune benefits in preclinical in vitro and in vivo experiments.

EP4 receptor antagonist has demonstrated analgesic effect against various pain conditions including osteoarthritis, indicating a potential for cancer pain treatment in the future.

## INDUSTRY OVERVIEW

### *Global Competitive Landscape of EP4 Receptor Antagonists*

As of the Latest Practicable Date, there were six EP4 receptor antagonists undergoing clinical trials globally, two of which were in phase II and four were in phase I. The following table illustrates the global competitive landscape of EP4 receptor antagonists as of the Latest Practicable Date:

Drug Name	Clinical Phase	Company	Active Indications	Targets	Drug type	Therapeutic Strategy	Location	First Posted Date
3D1002/RMX1002/Grapiprant	Phase II	3DMed	Solid Tumor, Osteoarthritis; Pain	PTGER4	Chemical drugs	Combination therapy	China	22-Dec-21
CR-6086	Phase II	Rottapharm	Rheumatoid Arthritis, DMARD-naive and Early Disease Patients	PTGER4	Chemical drugs	Combination therapy	Czechia	23-May-17
YY001	Phase I	Yuyao Biotech; MingMedBiotech	Solid Tumor	PTGER4	Chemical drugs	Monotherapy	China	27-Jun-22
INV-1120	Phase I	Ionova	Solid Tumor	PTGER4	Chemical drugs	Monotherapy/ Combination therapy	China	30-Jul-21
KF-0210	Phase I	Keythera pharm	Advanced CRC, NSCLC, Esophageal squamous cell carcinoma, gastric cancer, bladder cancer, etc.	PTGER4	Chemical drugs	Monotherapy	China	25-Jun-21
AN0025	Phase I	Adlai Nortye	Esophageal cancer	PTGER4	Chemical drugs	Combination therapy	China	25-Jun-21
TPST-1495	Phase I	Tempest Therapeutics	Solid Tumor; Colorectal Cancer; Non Small Cell Lung Cancer; Squamous Cell Carcinoma of Head and Neck; Urothelial Carcinoma; Endometrial Cancer; Gastroesophageal Junction Adenocarcinoma; Gastric Adenocarcinoma	PTGER4; PTGER2	Chemical drugs	Combination therapy	US	14-Apr-20
ONO-4578/ BMS-986310	Phase I	BMS; Ono Pharmaceutical	Tumor; Solid tumor	PTGER4	Chemical drugs	Combination therapy	Japan	16-May-17
E-7046/ AN0025	Phase I	Adlai Nortye Biopharma Co Ltd; Eisai Co Ltd;	Triple-negative Breast Cancer; NSCLC, Squamous or Non-Squamous; Urothelial Carcinoma of the Bladder; Microsatellite Stable (MSS) Colorectal Cancer (CRC);Cervical Cancer	PTGER4	Chemical drugs	Combination therapy	US; United Kingdom; Poland	15-May-17

*Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, FDA, ClinicalTrials.gov, Frost & Sullivan Report*

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### REPORT COMMISSIONED BY FROST & SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report on the therapeutic biologics market globally and in China. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking and strategic and market planning for a variety of industries. The contract sum to Frost & Sullivan is RMB1,230,000 for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [REDACTED] or on the results of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [REDACTED]. We have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of the biologics market for potential investors. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing the Frost & Sullivan Report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

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## REGULATORY OVERVIEW

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### OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

This section summarizes the principal laws and regulations in the PRC that are relevant to our business.

### DRUG REGULATORY REGIME

#### Major Regulatory Authorities

The drug industry in the PRC is mainly administered by three governmental agencies: the National Medical Product Administration (國家藥品監督管理局) (the “**NMPA**”), a department under the State Administration for Market Regulation (國家市場監督管理總局), the National Health Commission (國家衛生健康委員會) (the “**NHC**”) and the National Healthcare Security Administration (國家醫療保障局) (the “**NHSA**”).

The NMPA, which inherits the drug supervision function from its predecessor the China Food and Drug Administration, or the CFDA (before March 2018), is the primary drug regulator responsible for almost all of the key stages of the life-cycle of pharmaceutical products, including non-clinical researches, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution and pharmacovigilance.

The NHC, formerly known as the National Health and Family Planning Commission, is China’s chief healthcare regulator. It is primarily responsible for drafting national healthcare policy and regulating public health, medical services, and health contingency system, coordinating the healthcare reform, and overseeing the operation of medical institutions and practicing of medical personnel.

The NHSA, a new authority established in May 2018, is responsible for drafting and implementing policies, plans and standards on medical insurance, maternity insurance and medical assistance; administering healthcare fund; formulating a uniform medical insurance catalogue and payment standards on drugs, medical disposables and healthcare services; formulating and administering the bidding and tendering policies for drugs and medical disposables.

#### Reform of the Drug Approval System

On August 9, 2015, the State Council promulgated 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》) (the “**Reform Opinions**”), which established a framework for reforming the evaluation and approval system for drugs and medical devices. The Reform Opinions indicated enhancing the standard of approval for drug registration and accelerating the evaluation and approval process for innovative drugs.

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On March 4, 2016, the General Office of the State Council promulgated the Guiding Opinions on Promoting the Sound Development of the Medical Industry (《關於促進醫藥產業健康發展的指導意見》), which aims to accelerate the development of innovative drugs and biological products with major clinical needs, to speed up the promotion of green and intelligent pharmaceutical production technologies, to strengthen scientific and efficient supervision, and to promote the development of industrial internationalization.

On October 8, 2017, the General Office of Chinese Communist Party’s Central Committee and the General Office of the State Council jointly issued the Opinion on Strengthening the Reform of the Drug and Medical Device Review and Approval Process to Encourage Drug and Medical Device Innovation (《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 Opinion**”), which seek to streamline the clinical trial process and shorten the timeline. The Innovation Opinion provided special fast-track approval for new drugs and medical devices in urgent clinical need, and drugs and medical devices for rare diseases.

On December 21, 2017, the CFDA promulgated the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》), which further clarified that a fast-track clinical trial approval or drug registration pathway will be available to innovative drugs. The aforementioned opinion was repealed by the Announcement of NMPA on Issuing Three Documents including Working Procedures for Review of Breakthrough Therapeutics (Trial) (issued and took effect on July 7, 2020) (《國家藥監局關於發佈〈突破性治療藥物審評工作程序(試行)〉等三個文件的公告》).

On May 17, 2018, the NMPA and NHC jointly promulgated the Circular on Issues Concerning Optimizing Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》), which further simplified and accelerated the clinical trial approval process.

### **Regulations in relation to the Registration of New Drugs**

#### ***Non-Clinical Research and Animal Testing***

The non-clinical safety evaluation study for drugs for the purpose of applying for marketing approval shall be conducted in accordance with the Good Laboratory Practice for Non-clinical Drug Research (《藥物非臨床研究質量管理規範》), which was promulgated on August 6, 2003 and revised on July 27, 2017 by the CFDA. On April 16, 2007, the CFDA issued the Administrative Measures for the Certification of Good Laboratory Practices for Non-Clinical Drug Research (《藥物非臨床研究質量管理規範認證管理辦法》), which sets forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake drug non-clinical research.

The State Science and Technology Commission, now known as the Ministry of Science and Technology, promulgated the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) on November 14, 1988, which were most recently amended by the State Council on March 1, 2017. The State Science and Technology

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Commission and the State Bureau of Quality and Technical Supervision (now merged into the State Administration for Market Regulation) jointly promulgated the Administration Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) on December 11, 1997. The Ministry of Science and Technology and other regulatory authorities promulgated the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) on December 5, 2001. All of these laws and regulations require a Certificate for Use of Laboratory Animals for performing experimentation on animals.

### *Clinical Trial Application*

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, the Center for Drug Evaluation under the NMPA (the “**CDE**”) is responsible for the application of conducting new drug clinical trials. According to Registration Measures, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. In accordance with the Circular 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 on July 24, 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 business days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

After obtaining the clinical trial authorization from the NMPA, the applicant must register the clinical trial at the Drug Clinical Trial Information Platform for public disclosure in accordance with the Announcement 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 on September 6, 2013. The applicant shall complete the initial registration within one month after obtaining the clinical trial authorization and complete follow-up registrations before the first subject’s enrollment in the trial.

### *Conduction of Clinical Trial and the Communication with CDE*

Clinical trials must be conducted in accordance with the Announcement on Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》), which was promulgated by the NMPA and NHC on April 23, 2020 and took effect on July 1, 2020, which also sets forth the requirements for conducting the clinical trial, including preparation of clinical trials, clinical trial protocol, duties of the sponsor and investigators and protection of the trial subjects.

The drug clinical trial institution refers to institutions that have the conditions to conduct clinical trials in accordance with the requirements of the Good Clinical Practice for Drug Trials (the “**GCP**”) and relevant technical guidelines for clinical trials according to the Regulations for the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which was promulgated by the NMPA and NHC on November 29, 2019 and came into effect on December 1, 2019.

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On September 1, 2003, the Good Practice for Clinical Trial of Drugs (藥物臨床試驗質量管理規範) promulgated by the CFDA came into effect, and was later repealed by Good Practice for Clinical Trial of Drugs (Revised in 2020) (藥物臨床試驗質量管理規範(2020修訂), together the “GCP”) on July 1, 2020. According to the GCP, the drug clinical trials shall be commenced after the approval of the Ethics Committee.

On November 11, 2015, CFDA published the Circular Concerning Several Policies on Drug Registration, Review and Approval (CFDA Announcement No. 230 of 2015) (《關於藥品註冊審評審批若干政策的公告》(國家食品藥品監督管理總局2015年第230號公告)), according to which, clinical trial applications for new drugs shall be approved on a one-off basis, and will no longer be filed in stages and reviewed and approved in stages. According to such announcement, the state changed the original drug clinical trial approval issued separately for each phase of the drug clinical trial to one approval that can cover Phase I to Phase III clinical trials.

On June 2, 2016, CFDA published the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (Trial) (《藥物研發與技術審評溝通交流管理辦法(試行)》) (the “**Communication Measures (Trial)**”). On September 30, 2018, the Communication Measures (Trail) was repealed by 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》), the “**Communication Measures 2018**”) published by NMPA, which added several scenarios where communication with CDE is possible (but not mandatory), such as adding clinical trial applications for new indications.

On July 1, 2020, the Registration Measures promulgated by the State Administration for Market Regulation came into effective, according to which, clinical trials shall be reviewed and approved by the Ethics Committee. The applicant shall develop a clinical trial protocol prior to the commencement of subsequent phases of clinical trials, which shall be reviewed and approved by the ethics committee, and the applicant shall submit the corresponding clinical trial protocol and supportive information on the designated website of CDE prior to the commencement of the clinical trial. Meanwhile, Registration Measures also incorporates the communication system into the fundamental system for drug registration management, and proposes that the applicant may communicate with CDE and other professional and technical institutions on major issues prior to the clinical trial application, during the course of the clinical trial, prior to the marketing approval application and other key stages, and shall consult with CDE under special circumstances.

On December 10, 2020, NMPA published 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》) (the “**Communication Measures (2020)**”) to repeal the Communication Measures 2018. To better reflect the service nature of communication and on the basis of ensuring the safety of the subjects of the clinical trials, the Communication Measures (2020) classifies the meetings to be held in the key stages of drug research and development into three scenarios, namely (i) where communication shall be carried out in accordance with the law; (ii) where communication shall be carried out in principle; and (iii)

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where communication can be carried out. Specifically, (i) as to the application for conditional approval and/or the application of priority review, the applicant shall consult and confirm with CDE in accordance with the law prior to submitting applications for marketing approval to NMPA; (ii) prior to the application of the first new drug clinical trials, and the application for marketing approval of biological products for prevention and therapeutic use, the applicant shall in principle consult CDE, but if the applicant believes that there is no need to consult, it can explain the reason for which in application materials; (iii) as to all other scenarios, the applicant can consult CDE but are not specifically required to.

To implement the research and development concept driven by clinical value and centered on the need of patients, and to promote the scientific and orderly development of anti-tumor drugs, 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(徵求意見稿)》) was issued by the CDE on July 2, 2021, and later on November 15, 2021, upon NMPA’s review and approval, 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》) (No. 46[2021], the “**Guiding Principles**”) was officially released and implemented by CDE. According to the Registration Measures, persons engaging in drug development and drug registration activities shall comply with the relevant laws, regulations, rules, standards and norms; with reference to the relevant technical guidelines formulated and published by the CDE and other specialized technical agencies, therefore, the Guiding Principle is a one of the various technical guidelines issued by CDE for the reference of the applicant in the process of drug development. The Guiding Principles aim to put forward suggestions on the clinical research and development of anti-tumor drugs from the perspective of patients’ needs, with a view to guiding applicants of anti-tumor drug clinical trials to implement the research and development concept driven by clinical value and centered on the need of patients during its research and development activities, and providing references for promoting the scientific and orderly development of anti-tumor drugs. The Guiding Principles do not discuss any specific methodologies.

As of the Latest Practicable Date, we had obtained the New Drug Certificate for our Core Product and put it on the market for sale, and we had obtained required clinical trial approvals for the candidate drugs at the clinical stage. Besides, we will design the clinical trial protocols according to the Guiding Principles and obtain the clinical trial approvals before conducting new clinical trials. Given our strong R&D team and extensive experience in the field of anti-tumor drugs, we believe that we will continue to adhere to the principles proposed in the Guiding Principles, and our Directors confirm that the Guiding Principles will not have any material adverse impact on our business and operations.

### *Regulations relating to International Multi-Center Clinical Trials and Acceptance of Overseas Clinical Trial Data*

On January 30, 2015, the CFDA promulgated the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) (《關於發佈國際多中心藥物臨床試驗指南(試行的通告)》) (the “**IMCT Guidelines**”), which took effect on March 1, 2015, to provide



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guidance for the regulation of application, implementation and administration of international multi-center clinical trials in China. Pursuant to the IMCT Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicant plans to make use of the data derived from the international multi-center clinical trials for application to the CFDA for approval of New Drug Application (the “NDA”), such international multi-center clinical trials shall satisfy the requirements set forth in the PRC Drug Administration Law (《中華人民共和國藥品管理法》) and its implementation regulations and relevant laws and regulations.

On July 6, 2018, the NMPA issued the Technical Guiding Principles for the Acceptance of the Overseas Clinical Trial Data of Drugs (《接受藥品境外臨床試驗數據的技術指導原則》) (the “**Guiding Principles**”), which provides that overseas clinical data can be submitted for all kinds of registration applications in China, including the clinical trial authorization and NDA. The Guiding Principles clearly list the basic principles and requirements on the acceptance of overseas clinical trial data, and distinguish different levels of acceptance based on the quality of the data itself and different circumstances. The Guiding Principles require that the applicant shall ensure that the overseas clinical trial data are truthful, complete, accurate and traceable, and the generating process of the overseas clinical trial data shall comply with the relevant requirements of the Good Clinical Practice of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

### *New Drug Application*

Pursuant to the Registration Measures, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes, and preparation for acceptance of verification and inspection for drug registration, the applicant may apply to the NMPA for approval of NDA. The NMPA then determines whether to approve the application according to applicable laws and regulations. The applicant must obtain approval of NDA before the drugs can be manufactured and sold in the China market. According to the Registration Measures, for (1) drugs which are used for the treatment of severe life-threatening diseases currently lacking effective treatment and the data of clinical trials can confirm the efficacy and forecast the clinical value of the drugs; (2) drugs which are urgently needed for public health and data of clinical trials can reveal the efficacy and forecast the clinical value of the drugs; (3) vaccines which are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, and the benefit is assessed outweigh the risk, such drugs can apply for conditional approval.

### *Reclassification of Drugs*

On March 4, 2016, the CFDA issued the Reform Plan for Registration Category of Chemical Drugs (《化學藥品註冊分類改革工作方案》) (the “**Drug Reclassification Plan**”), which outlined the reclassifications of drug applications. Under the Drug Reclassification Plan, Category 1 refers to new drugs that have not been marketed anywhere in the world. Improved new drugs that are not marketed anywhere in the world fall into Category 2. Generic drugs, that have equivalent quality and efficacy to the originator’s drugs have been marketed abroad but

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not yet in China, fall into Category 3. Generic drugs, that have equivalent quality and efficacy to the originator's drugs and have been marketed in China, fall into Category 4. Category 5 drugs are drugs which have already been marketed abroad but are not yet approved in China. The Chemical Drug Registration Classification and Application Data Requirements (《化學藥品註冊分類及申報資料要求》) which was promulgated by NMPA on June 29, 2020, and took effect on July 1, 2020 (for the chemical drug registration classification part) and October 1, 2020 (for the chemical drug registration application data requirements part), reaffirmed the principles of the classification of chemical drugs set forth by the Reform Plan for Registration Category of Chemical Medicine, and made minor adjustments to the subclassifications of Category 5. According to such rule, Category 5.1 are innovative chemical drugs and improved new chemical drugs while Category 5.2 are generic chemical drugs, all of which shall have been already marketed abroad but not yet approved in China.

On June 29, 2020, the NMPA issued the Registration Category of Biological Products and the Data Requirements for Declaration (《生物製品註冊分類及申報資料要求》), which took effect on July 1, 2020 stipulated that the therapeutic biological products should be classified into 3 categories, in which Category 1 refers to therapeutic biological products that have not been marketed anywhere in the world; Category 2 refers to improved new therapeutic biological products; and, Category 3 refers to therapeutic biological products that have been marketed in China or abroad.

### *Prioritized Examination and Approval for Registration of Certain Drugs*

On November 11, 2015, the CFDA promulgated 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》), which provides that a fast-track clinical trial approval or drug registration pathway can be available for the applications for certain drugs, including the registration of innovative new drugs treating HIV, cancer, serious infectious diseases and orphan diseases, and registration of pediatric drugs, etc.

On July 7, 2020, the NMPA promulgated the Announcement on Promulgating Three Documents Including the Working Procedures for the Evaluation of Breakthrough Therapy Designation Drugs (for Trial Implementation) (《國家藥監局關於發佈<突破性治療藥物審評工作程序(試行)>等三個文件的公告》), which stipulates that during the clinical trial period, innovative drugs or modified new drugs that are used to prevent and treat the disease that is serious life-threatening or severely affecting the quality of life and there is no effective prevention and treatment method, or compared with existing treatment methods that have sufficient evidence to show that they have obvious clinical advantages, then any applicant can apply for breakthrough therapeutic drug programs during Phase I and II clinical trials, but usually no later than the commencement of Phase III clinical trials.

In addition, on May 17, 2018, the NMPA and NHC jointly promulgated the Circular on Issues Concerning Optimizing Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》), which further simplified and accelerated the drug approval process.

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### *Special Examination and Approval Procedures*

On November 18, 2005, the CFDA promulgated the Procedures of the CFDA for the Special Examination and Approval of Drugs (《國家食品藥品監督管理局藥品特別審批程序》), which stipulates that in the case of any threatening or actual public health emergency, the CFDA shall take a series of measures to facilitate the approval procedures so that the drugs needed in responding to the public health emergency can be approved as soon as possible.

### *Marketing Authorization Holder System*

Under the authorization of the Standing Committee of the National People's Congress, the General Office of the State Council issued the Pilot Plan for the Drug Marketing Authorization Holder System (《藥品上市許可持有人制度試點方案》) on May 26, 2016, which provides a detailed pilot plan for the marketing authorization holder system, or MAH System, for drugs in 10 provinces (cities) in China and the plan ended on November 4, 2018. The pilot period was later extended to November 4, 2019 by the SCNPC.

Pursuant to the PRC Drug Administration Law (《中華人民共和國藥品管理法》), which was promulgated on September 20, 1984 by the Standing Committee of the National People's Congress and recently revised on August 26, 2019 and took effect on December 1, 2019, the MAH system will be applicable throughout the country. Under the MAH System, domestic drug research and development institutions and enterprises are eligible to be holders of drug registrations. The legal representative and the key person-in-charge of a drug marketing authorization holder shall be fully responsible for the quality of drugs. And holders of drug registrations shall establish a pharmaceutical quality assurance system, equipped with specialized staff solely responsible for the quality of medicines management.

### *Sampling and Collecting Human Genetic Resources Filing*

On June 10, 1998, the Ministry of Science and Technology and the Ministry of Health promulgated the Interim Administrative Measures on Human Genetic Resources (《人類遺傳資源管理暫行辦法》), which established the rules for protecting and utilizing human genetic resources in the PRC. According to 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》) issued by the Ministry of Science and Technology on July 2, 2015 and the Circular on Implementing the Administrative Licensing for the Sampling, Collection, Trading, Exporting of Human Genetic Resources, or Taking Such Resources out of PRC (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) issued by the Ministry of Science and Technology on August 24, 2015, the sampling and collection of human genetic resources through clinical trials by a foreign-invested sponsor shall be required to be filed with the China Human Genetic Resources Management Office through the online system. On October 26, 2017, the Ministry of Science and Technology

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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》) simplifying the approval of sampling and collecting human genetic resources for the purpose of marketing a drug in the PRC.

The Regulations of the PRC on the Administration of Human Genetic Resources promulgated by the State Council on May 28, 2019 (《中華人民共和國人類遺傳資源管理條例》) and came into effect on July 1, 2019 repealed the Interim Administrative Measures on Human Genetic Resources, and 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 exporting of human genetic resource materials. However, the two parties shall file the type, quantity and usage of the human genetic resource to be used with the administrative department of science and technology under the State Council before clinical trials.

On October 17, 2020, the *PRC Biosecurity Law* (《中華人民共和國生物安全法》) (the “**Biosecurity Law**”) was promulgated by Standing Committee of the National People’s Congress, taking effect from April 15, 2021. The Biosecurity Law establishes a comprehensive legislative framework for the pre-existing regulations in such areas as epidemic control of infectious diseases for humans, animals and plants; research, development, and application of biology technology; biosecurity management of pathogenic microbials laboratories; security management of human genetic resources and biological resources; countermeasures for microbial resistance; and prevention of bioterrorism and defending threats of biological weapons. According to the Biosecurity Law, the research and development activities of high-risk and medium-risk biotechnology shall be carried out by a legal person organization established within the territory of the PRC, upon obtaining the approval or record-filing; the establishment of a pathogenic microorganism laboratory shall be subject to approval or record-filing requirements in accordance with the law; (i) collecting human genetic resources of important genetic families or specific areas in the PRC, or collecting human genetic resources of which the types and quantities are subject to provisions of the competent department of science and technology under the State Council, (ii) preserving the PRC’s human genetic resources, (iii) using the PRC’s human genetic resources to carry out international scientific research cooperation, or (iv) transporting, mailing, and carrying the PRC’s human genetic resource materials out of the country shall subject to approval of the competent department of science and technology.

### ***Administrative Protection and Monitoring Periods for New Drugs***

The PRC Drug Administration Law is the framework law regulating pharmaceutical products and the industry. According to the Implementing Rules for PRC Drug Administration Law (《中華人民共和國藥品管理法實施條例》) issued on March 2, 2019 and the Drug Reclassification Plan, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of five years for new Category 1 drugs approved to be

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manufactured, commencing from the date of approval, to continually monitor the safety of those new drugs. During the monitoring period of a new drug, the NMPA will not accept other applications for new drugs containing the same active ingredient.

### **Regulations in relation to the Manufacturing of Drugs**

#### *Drug Manufacturing Permit*

Pursuant to the PRC Drug Administration Law, a drug manufacturer must obtain a Drug Manufacturing Permit from the NMPA before it starts to manufacture drug products. Prior to granting such permit, the relevant government authority will inspect the applicant’s production facilities, and decide whether the sanitary conditions, quality assurance system, management structure and equipment within the facilities have met the required standards. Each Drug Manufacturing Permit is valid for a period of five years and the manufacturer is required to apply for renewal of the permit within six months prior to its expiration date and will be subject to reassessment by the authority in accordance with then-prevailing legal and regulatory requirements for the purposes of such renewal.

#### *Good Manufacturing Practice*

Pursuant to the Certification Measures for Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》) issued by the CFDA on August 2, 2011, when establishing a pharmaceutical manufacturer or a new factory or expanding the production scope, the drug manufacturer must apply for Good Manufacturing Practice certification (the “**GMP certification**”). The drug manufacturer that has obtained the GMP certificate should reapply for the GMP certificate 6 months prior to its expiration date. Pursuant to the PRC Drug Administration Law, since December 1, 2019, the GMP certification has been canceled, applications for GMP certification are no longer accepted, and GMP certificate is no longer issued, but drug manufacturers are still required to comply with the GMP rules. According to the Administrative Measures for the Inspection of Pharmaceuticals (Trial)(《藥品檢查管理辦法(試行)》) which was promulgated and effective on May 24, 2021 by the NMPA, and simultaneously repealed the Certification Measures for Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》), if a drug manufacturing enterprise applies for a Drug Manufacturing Permit for the first time, it will be subject to on-site inspection under relevant contents of the GMP. If a drug manufacturing enterprise applies for re-issuance of Drug Manufacturing Permit, drug regulatory departments or drug inspection institutions shall conduct examination pursuant to risk management principle, taking into account the enterprise’s compliance with pharmaceutical administration laws and regulations, operation status of GMP and quality system, and may conduct GMP compliance inspection where necessary.

The drug manufacturer must conduct the manufacturing process according to the Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) (2010 version) issued by the Ministry of Health on January 17, 2011, which sets forth the requirements on the

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manufacturer’s organization and staff qualifications, manufacture premises and facilities, equipment, hygiene conditions, manufacture management, product management, maintenance of sales records and the procedure of handling customer complaints and adverse reaction reports.

### *Contract Manufacturing of Drugs*

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委託生產監督管理規定》) issued by the CFDA on August 14, 2014 (the “**Contract Manufacturing Regulations**”), in the event a drug manufacturer in China that has obtained a drug marketing authorization temporarily lacks manufacturing conditions as a result of technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities, it can entrust the manufacturing of that drug to another domestic drug manufacturer. Such contract manufacturing arrangements need to be approved by the provincial branch of the CFDA. The Contract Manufacturing Regulations prohibit the contract manufacturing arrangement of certain special drugs, including narcotic drugs, psychoactive drugs, biochemical drugs and active pharmaceutical ingredients.

According to the PRC Drug Administration Law, a drug manufacturer can entrust the manufacturing of its drug to another qualified drug manufacturer. Entrusted manufacturing of blood products, narcotic drugs, psychotropic drugs, medical toxic drugs, and pharmaceutical precursor chemicals is prohibited, unless otherwise stipulated by the drug administrative department of the State Council.

The PRC Drug Administration Law specifies that drug marketing authorization holders may produce drugs by themselves or entrust drug manufacturers with the production of such drugs. A drug marketing authorization holder that intends to manufacture drugs on its own shall obtain a drug manufacturing permit; if it intends to manufacture drugs on a commissioned basis, it shall entrust a qualified drug manufacturer. Drug marketing authorization holders and the commissioned manufacturers shall enter into an entrustment agreement and a quality agreement, and strictly perform the obligations under such agreements. Blood products, anesthetics, psychotropic pharmaceuticals, toxic pharmaceuticals for medical treatment, and pharmaceutical precursor chemicals may not be produced through entrustment, except as otherwise prescribed by the department of drug supervision and administration of the State Council.

### **Regulations in relation to Drug Distribution and Advertising**

#### *Drug Distribution*

According to the PRC Drug Administration Law and the Measures for the Supervision and Administration of Drug Distribution (《藥品流通監督管理辦法》) issued by the CFDA on January 31, 2007 and came into effect on May 1, 2007, drug enterprises shall be responsible for the quality of drugs they manufacture, distribute or use, purchase, sell, transport or store, and drug distributors must obtain the Drug Operation Permit.

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According to the Measures on the Administration of Drug Operation Permit (《藥品經營許可證管理辦法》) promulgated on February 4, 2004 and amended on November 17, 2017 by the CFDA, a Drug Operation Permit is valid for five years. Each holder of the Drug Operation Permit must apply for an extension of its permit six months prior to expiration, and extensions are granted only after a reexamination of the permit holder by the authority which issued the permit.

### *Good Supply Practices*

According to the Good Supply Practice for Drugs (《藥品經營質量管理規範》) (the “**Good Supply Practice**”) promulgated by NMPA on April 30, 2000 and last amended on July 13, 2016, drug distributors shall strictly implement the Good Supply Practice. Enterprises shall take effective measures for quality control at such stages as procurement, storage, sales and transportation of drugs to ensure the quality of drugs and shall develop a drug traceability system as per relevant requirements of the state to realize the traceability of drugs. In addition, the CFDA revised the Guidelines for On-site Inspection of Drug Operation and Quality Management Specifications (《藥品經營質量管理規範現場檢查指導原則》) in 2016, in order to further regulate the organization of the supervision and inspection of drug distributors.

### *Advertising of Drugs*

According to the Advertising Law of the PRC (《中華人民共和國廣告法》), which was promulgated by the Standing Committee of the National People’s Congress on October 27, 1994 and last amended on April 29, 2021, certain contents such as statement on cure rate or efficiency shall not be included in the advertisement of drugs.

According to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food, and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) issued by the State Administration for Market Regulation on December 24, 2019 and came into effect on March 1, 2020, the advertisements for drugs shall not be released without being reviewed and the contents of a drug advertisement shall be based on the drug instructions approved by the drug administration departments.

### **Price Controls and Two-invoice System**

Instead of direct price controls which were historically used in China, the government regulates prices mainly by establishing a consolidated procurement mechanism, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices.

According to the Certain Regulations on the Trial Implementation of Centralised Tender Procurement of Drugs by Medical Institutions (《醫療機構藥品集中招標採購試點工作若干規定》) promulgated on July 7, 2000 and the Notice of NMPA on Further Improvement on the Implementation of Centralised Tender Procurement of Drugs by Medical Institutions (《國家

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藥品監督管理局關於進一步做好醫療機構藥品集中招標採購工作的通知》) promulgated on July 23, 2001, not-for-profit medical institutions established by county or higher level government are required to implement centralised tender procurement of drugs.

The Ministry of Health promulgated the Working Regulations of Medical Institutions for Procurement of Drugs by Centralised Tender and Price Negotiations (for Trial Implementation) (《醫療機構藥品集中招標採購和集中議價採購工作規範(試行)》) on March 13, 2002, which provides rules for the tender process and negotiations of the prices of drugs, operational procedures, a code of conduct and standards or measures of evaluating bids and negotiating prices. According to the Notice of the Financial Planning Department of Ministry of Health on Issue of Opinions on Further Regulating Centralised Procurement of Drugs by Medical Institutions (《衛生部財務規劃司關於印發<進一步規範醫療機構藥品集中採購工作的意見>的通知》) promulgated on January 17, 2009, not-for-profit medical institutions owned by the government at the county level or higher or owned by state-owned enterprises (including state-controlled enterprises) shall purchase pharmaceutical products by online centralized procurement. Each provincial government shall formulate its catalogue of drugs subject to centralised procurement. Except for drugs in the National List of Essential Drugs (the procurement of which shall comply with the relevant rules on National List of Essential Drugs), certain pharmaceutical products which are under the national government's special control, such as toxic, radioactive and narcotic drugs and traditional Chinese medicines, in principle, all drugs used by not-for-profit medical institutions shall be covered by the catalogue of drugs subject to centralised procurement. The Opinions of the General Office of the State Council on Improvement of the Policy of Production, Circulation and Use of Drugs (《國務院辦公廳關於進一步改革完善藥品生產流通使用政策的若干意見》) promulgated on January 24, 2017 by the General Office of the State Council aims to deepen the reform of medicine health system, improve the quality of the drug and regulate the distribution and use of the drug. The Notice of the General Office of the State Council on Issuing Pilot Plan of Centralised Procurement and Use of the Drug Organised by the State (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》) promulgated on January 1, 2019 aims to improve the pricing mechanism of the drug, which also further regulates the scope and mode of centralized procurement.

The centralized tender process takes the form of public tender operated and organized by provincial or municipal government agencies. The centralised tender process is in principle conducted once every year in the relevant province or city in China. The bids are assessed by a committee composed of pharmaceutical and medical experts who will be randomly selected from a database of experts approved by the relevant government authorities. The committee members assess the bids based on a number of factors, including but not limited to, bid price, product quality, clinical effectiveness, product safety, qualifications and reputation of the manufacturer, after-sale services and innovation. Only pharmaceuticals that have won in the centralised tender process may be purchased by public medical institutions funded by the governmental or state-owned enterprise (including state-controlled enterprises) in the relevant region.



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In order to further optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms (《深化醫藥衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, the “two-invoice System” (兩票制) will be fully implemented in the PRC. According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (for Trial Implementation) (《印發關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)的通知》), which came into effect on December 26, 2016, the two-invoice system means one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the medical institution, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the medical institution.

### Regulations in relation to Intellectual Properties

#### *Patent*

Patents in the PRC are mainly protected under the Patent Law of the PRC (《中華人民共和國專利法》), which was promulgated by the Standing Committee of the National People’s Congress on March 12, 1984 and amended on September 4, 1992, August 25, 2000, December 27, 2008 and October 17, 2020, and its Implementation Rules (《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 most recently amended on January 9, 2010. The Patent Law and its Implementation Rules provide for three types of patents, “invention,” “utility model” and “design.” “Invention” refers to any new technical solution relating to a product, a process or improvement thereof; “utility model” refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and “design” refers to any new design of the whole or part of the shape, pattern, their combination, or the combination of color and shape or pattern, of a product, which creates an aesthetic feeling and is suitable for industrial application. The duration of a patent right for “invention” is 20 years, the duration of a patent right for “design” is 15 years and the duration of a patent right for “utility model” is 10 years, from the date of application. The new Patent Law of the PRC provides a patent term extension for new drugs, according to which, new drugs may enjoy a compensation for the duration of patent rights which is up to 5 years, and the total patent term after the extension may not exceed more than 14 years from the date of marketing approval of the new drugs.

#### *Trademark*

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) (the “**Trademark Law**”), promulgated by the Standing Committee of the National People’s Congress on August 23, 1982 and most recently amended on April 23, 2019 and took effect on November 1, 2019, the period of validity for a registered trademark is 10 years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within twelve months prior to the date of expiry as required if the registrant needs to continue to use the trademark. Where the registrant fails to do so, a

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grace period of six months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be cancelled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offence, the case shall be timely referred to a judicial authority and decided according to law.

### *Trade Secrets*

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

### *Domain Names*

Domain names are protected under the Administrative Measures on the Internet Domain Names (《互聯網域名管理辦法》) issued by the Ministry of Industry and Information Technology (the “MIIT”) on August 24, 2017 and took effect on November 1, 2017, and the *Implementing Rules of China ccTLD Registration* (《國家頂級域名註冊實施細則》) issued by the China Internet Network Information Center on June 18, 2019. MIIT is the main regulatory authority responsible for the administration of PRC internet domain names. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

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### Regulations in relation to Product Liability and Tort

According to the General Principles of the Civil Law of the PRC (《中華人民共和國民法通則》) promulgated on April 12, 1986 and amended on August 27, 2009 and the General Rules of the Civil Law of the PRC (《中華人民共和國民法總則》) promulgated on March 15, 2017 and took effect on October 1, 2017, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury.

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) promulgated by the Standing Committee of the National People's Congress on February 22, 1993 and most recently amended on December 29, 2018, is the principal governing law relating to the supervision and administration of product quality, which clarified liabilities of the manufactures and sellers. Manufactures shall not be liable when they are able to prove that: (1) the product has never been circulated; (2) the defects causing injuries or damage did not exist at the time when the product was circulated; or (3) the science and technology at the time when the product was circulated were at a level incapable of detecting the defects. A seller shall pay compensation if it fails to indicate neither the manufacturer nor the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

According to the Tort Liability Law of the PRC (《中華人民共和國侵權責任法》), promulgated by the Standing Committee of the National People's Congress on December 26, 2009 and took effect on July 1, 2010, manufacturers shall assume tort liability where the defects in relevant products cause damage to others. Sellers shall assume tort liability where the defects in relevant products causing damage to others are attributable to the sellers. The aggrieved party may claim for compensation from the manufacturer or the seller of the relevant product in which the defects have caused damage. The producers or the sellers shall be liable under tort if they fail to take remedial measures in a timely manner or have not made efforts to take remedial measures, thus causing damages. If the products are produced or sold with known defects, causing deaths or severe adverse health issues, the infringed party has the right to claim punitive damages in addition to compensatory damages.

On May 28, 2020, the National People's Congress promulgated the Civil Code of the PRC (《中華人民共和國民法典》) which became effective on January 1, 2021 and simultaneously repealed the General Principles of the Civil Law of the PRC, the General Rules of the Civil Law of the PRC and the Tort Law of the PRC, according to which, a patient may make a claim against the drug marketing authorization holder, a medical institution or producer for any damage arising from defects of drugs.

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### Regulations in relation to Company Establishment and Foreign Investment

#### *Company Establishment*

The establishment, operation and management of corporate entities in China are governed by the Company Law of the PRC (《中華人民共和國公司法》) (the “**Company Law**”), which was promulgated by the Standing Committee of the National People’s Congress on December 29, 1993 and came into effect on July 1, 1994. It was subsequently amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018. Pursuant to the Company Law, companies are classified into categories, namely limited liability companies and limited companies by shares. The Company Law shall also apply to foreign-invested limited liability companies and companies limited by shares. According to the Company Law, the provisions otherwise prescribed by the laws on foreign investment shall prevail.

The Company Law is the principal law governing dividend distributions of PRC companies. PRC companies may pay dividends only out of their accumulated profits, if any, determined in accordance with PRC accounting principles. In addition, PRC companies are required to set aside each year at least 10% of their after-tax profit based on PRC accounting principles to their statutory general reserves funds until the cumulative amount of such reserve fund reaches 50% of their registered capital. These reserves or funds are not distributable as dividends. 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. Upon approval of the competent governmental authorities, foreign investors may utilize RMB dividends to invest or re-invest in enterprises established in China.

#### *Foreign Direct Investment*

According to the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “**FIL**”), which was promulgated by the National People’s Congress on March 15, 2019 and came into effect on January 1, 2020, and the Regulations for Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》), which was promulgated by the State Council on December 26, 2019 and came into effect on January 1, 2020, the foreign investment refers to the investment activities in China carried out directly or indirectly by foreign natural persons, enterprises or other organizations, including the following: (1) Foreign Investors establishing foreign-invested enterprises in China alone or collectively with other investors; (2) Foreign Investors acquiring shares, equities, properties or other similar rights of Chinese domestic enterprises; (3) Foreign Investors investing in new projects in China alone or collectively with other investors; and (4) Foreign Investors investing through other ways prescribed by laws and regulations of the State Council. The State adopts the management system of pre-establishment national treatment and negative list for foreign investment. The pre-establishment national treatment refers to granting to Foreign Investors and their investments, in the stage of investment access, the treatment no less favorable than that granted to domestic investors and their investments; the negative list refers to special

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administrative measures for access of foreign investment in specific fields as stipulated by the State. The State will grant national treatment to foreign investments outside the negative list. The negative list will be released by or upon approval of the State Council.

Foreign investment in China is subject to the Catalogue for the Encouraged Investment Industries (2020 Edition) (《鼓勵外商投資產業目錄(2020年版)》) issued on December 27, 2020 and took effect on January 27, 2021, and the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2021 Edition) (《外商投資准入特別管理措施(負面清單)》) (2021年版) issued on December 27, 2021 and took effect on January 1, 2022, which together comprise the encouraged foreign-invested industries catalogue and the special administrative measures for the access of foreign investments to the restricted or the prohibited foreign-invested industries. The latter sets out restrictions such as percentage of shareholding and qualifications of senior management. According to the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》) which took effect on January 1, 2020, foreign investments that are not subject to special access administrative measures are only required to complete an online filing to the commerce departments.

### *Regulations on Data Security*

The Cyberspace Administration of China (“CAC”), jointly with the other 12 governmental authorities, promulgated the Cybersecurity Review Measures (《網絡安全審查辦法》) on December 28, 2021, which became effective on February 15, 2022. Pursuant to Article 2 of the Cybersecurity Review Measures, to ensure the security of the supply chain of critical information infrastructure, security of network and data and safeguard national security, a cybersecurity review is required when national security has been or may be affected where critical information infrastructure operators (關鍵信息基礎設施運營者) purchase network product or service and network platform operators (網絡平台運營者) conduct data process activities. In addition, Article 7 of the Cybersecurity Review Measures stipulates that when a network platform operator in possession of personal information of over one million users intends to “list abroad” (國外), it must apply to CAC for a cybersecurity review. Our Directors believe that, as of the Latest Practicable Date, (i) the Company has not been determined or identified as a critical information infrastructure operator by any governmental authorities; (ii) the Company has not engaged in any data processing activities that affect or may affect national security; and (iii) the Company has not been involved in any investigations on cybersecurity review initiated by CAC, and has not received any inquiry, notice, warning or sanctions in this regard.

Based on the above, our PRC Legal Advisers are of the view that (1) it is unlikely that the Company would be determined or identified as a critical information infrastructure operator as long as there is no material change to the Group’s current business; and (2) given the expression used in the Cybersecurity Review Measures is to “list abroad” and the fact that Hong Kong is not a country or region outside the PRC, as long as there is no specific official guidance or implementation rules to include Hong Kong in the scope of “abroad” in the future,

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the Company’s proposed [REDACTED] in Hong Kong is unlikely to be considered as to “list abroad”. Therefore, the Company has no obligation to proactively apply for cybersecurity review under the Cybersecurity Review Measures for its application of the proposed [REDACTED] in Hong Kong.

On November 14, 2021, the CAC released the Regulations on the Administration of Cyber Data Security (Draft for Comments) (《網絡數據安全管理條例(徵求意見稿)》) (the “**Draft Regulations**”). The Draft Regulations applies to data processing activities by utilizing internet as well as cyber data security supervision and management activities within the PRC. Under the Draft Regulations, “Cyber data” refers to any information that is electronically recorded, whereas “data processing activities” refers to activities such as data collection, storage, usage, processing, transmission, provision, disclosure and deletion. In general, any company which is engaged in data processing activities through internet within the PRC will be subject to the Draft Regulations. As advised by our PRC Legal Advisers, by collecting, storing and otherwise processing certain information via internet in connection with its business operations, the Group could be subject to relevant requirements under the Draft Regulations in terms of personal data protection, cyber security management, assessment and report and other applicable aspects, assuming such regulation is implemented in the current form.

Article 13 of the Draft Regulations stipulates that data processors shall apply for cybersecurity review when carrying out activities including (i) seeking to be listed in Hong Kong that affect or may affect national security; and (ii) other data processing activities that affect or may affect national security. Our Directors believe that the Group has not engaged in any data processing activities that affect or may affect national security and thus the Company is unlikely to be deemed as a data processor that affect or may affect national security. Given that the Draft Regulations is still in the draft form for comments and has not come into force as of the Latest Practicable Date, the applicability of various requirements under the Draft Regulations is still subject to further official guidance and applicable implementation rules.

According to the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》), the “**Security Assessment Measures**”), which was promulgated by the CAC on July 7, 2022 and will take effect on September 1, 2022, data processors shall apply for cross-border security assessment with the CAC through the local provincial-level cyberspace administration department under any of the following circumstances: (i) cross-border transfer of important data by data processors; (ii) cross-border transfer of personal information by critical information infrastructure operators and data processors that process more than 1 million personal information; (iii) cross-border transfer of personal information by data processors that have made cross-border transfer of personal information of 100,000 people or sensitive personal information of 10,000 people cumulatively since January 1 of the previous year; and (iv) other circumstances where an application for security assessment of cross-border data transfer is required as prescribed by the CAC.

Our Group is able to comply with the Cybersecurity Review Measures and the Draft Regulations assuming they are implemented in their current form, in all material aspects on the basis that (i) we have implemented comprehensive cyber security and data protection policies,

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procedures, and measures to ensure secured storage and transmission of data and prevent unauthorized access to or use of data, and our Directors are of the view that our Group’s current internal policies are in line with such requirements specified in the Cybersecurity Review Measures and the Draft Regulations as currently stipulated; (ii) as confirmed by our Internal Control Consultant, our Group has set up internal control policies in terms of personal information and data protection and cybersecurity in accordance with currently applicable laws and regulations; and (iii) as confirmed by our Directors, we will continuously pay close attention to the legislative and regulatory development in cybersecurity and data protection, maintain ongoing communication with relevant governmental authorities and implement all necessary measures in a timely manner to ensure continuous compliance with relevant laws and regulations. Based on the above, our PRC Legal Advisers are of the view that the Cybersecurity Review Measures and the Draft Regulations would have no material adverse impact on our Group’s business operations or our proposed [REDACTED] in Hong Kong, assuming the Cybersecurity Review Measures and the Draft Regulations are implemented in their current form.

### *Foreign Exchange Administration*

The principal law governing foreign currency exchange in the PRC is the PRC Administrative Regulations on Foreign Exchange (《中華人民共和國外匯管理條例》) (the “**Foreign Exchange Regulations**”), which was promulgated by the State Council on January 29, 1996 and most recently revised on August 5, 2008. According to the Foreign Exchange Regulations, international payments in foreign currencies and transfer of foreign currencies under current items shall not be restricted. Foreign currency transactions under the capital account are still subject to limitations and require approvals from, or registration with, the State Administration of Foreign Exchange of the PRC (外匯管理局) (the “SAFE”) or its local counterpart and other relevant PRC governmental authorities.

According to the Circular on Reforming the Management Approach regarding the Settlement of Foreign Exchange 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 “**Circular 19**”), which was promulgated by the SAFE on March 30, 2015, came into effect on June 1, 2015 and revised on December 30, 2019, a foreign-invested enterprise may, according to its actual business needs, settle with a bank the portion of the foreign exchange capital in its capital account, i.e., a bank account opened by a foreign-invested enterprise where the foreign shareholder(s) are required to remit and deposit the amount of respective capital contributions, for which the relevant foreign exchange bureau has confirmed monetary contribution rights and interests (or for which the bank has registered the account-crediting of monetary contribution). Meanwhile, the use of such RMB should still comply with the restrictions set in the Circular 19 that it cannot be directly or indirectly used for making payments beyond the business scope of the enterprise or payments prohibited by national laws and regulations, investing in securities unless otherwise provided by laws and regulations, granting the entrust loans in RMB (unless permitted by the scope of business), repaying the inter-enterprise borrowings (including

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advances by the third party) repaying the bank loans in RMB that have been lent to a third party, and paying the expenses related to the purchase of real estate not for self-use, except for the foreign-invested real estate enterprises.

The Provisions on the Administration of Foreign Exchange in Foreign Direct Investments by Foreign Investors (《外國投資者境內直接投資外匯管理規定》) (the “**FDI Provisions**”), which were promulgated by the SAFE on May 10, 2013 and amended on October 10, 2018, regulate and clarify the administration over foreign exchange administration in foreign direct investments. On December 30, 2019, the SAFE repealed the provision about annual inspection for foreign-invested enterprises in appendix 1 and all provisions in appendix 3 of the FDI Provisions by issuing Notice of the SAFE on Repealing and Invalidating 5 Regulatory Documents on Foreign Exchange Administration and the Clauses of 7 Regulatory Documents on Foreign Exchange Administration (《國家外匯管理局關於廢止和失效5件外匯管理規範性文件及7件外匯管理規範性文件條款的通知》).

On June 9, 2016, the SAFE promulgated the Notice on Reforming and Standardizing the Administrative Provisions on Capital Account Foreign Exchange Settlement (《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 “**Circular 16**”). According to the Circular 16, enterprises registered in China could settle the external debts in foreign currencies to RMB at their own discretion. The SAFE Circular 16 sets a uniform standard for discretionary settlement of foreign currencies under capital accounts (including but not limited to foreign currency capital and external debts), which is applicable to all enterprises registered in China. It reiterated that the RMB funds obtained from the settlement of foreign currencies shall not be used directly or indirectly for purposes beyond the company’s scope of business, and shall not be used for domestic securities investment or investments and wealth management products other than principal-protected products issued by banks, unless otherwise expressly prescribed. Furthermore, such RMB funds shall not be used for disbursing loans to non-affiliated enterprises, unless the scope of business expressly provides so; and shall not be used to construct or purchase real estate not for self-use (except for real estate enterprises).

### *Circular 37*

The Circular on Related Issues concerning Foreign Exchange Administration for Domestic Residents to Engage in Overseas Investment and Financing and in Round-trip Investment via Special Purpose Companies (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the “**Circular 37**”) was promulgated by the SAFE on July 4, 2014. Under Circular 37, PRC residents, individuals or institutions are required to register with the bureau of foreign exchange administration before they invest in a special purpose vehicle (the “**SPV**”) with legitimate assets or equity interests inside and outside the PRC. In addition, any PRC resident that is a shareholder of an offshore SPV is required to amend its SAFE registration in a timely manner after any major changes of the offshore SPV being made, such as any increase or decrease of capital, stock right assignment or exchange, or merger or division, or any alteration in the basic information, such as name and operating duration of the individual domestic resident shareholder. Failure to comply with the



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registration procedures set forth in the Circular 37 may result in restrictions being imposed on the subsequent foreign exchange activities of the relevant PRC residents, including the remitting back of dividends and profits. PRC residents who invest in an SPV with legitimate assets or equity interests inside and outside the PRC prior to the implementation of the Circular 37, but fail to conduct the foreign exchange registration of overseas investments, must submit an explanatory statement and state the reasons for doing so to the SAFE. The SAFE may allow complementary registration under the principles of legality and legitimacy. In the event of any violation of foreign exchange regulations by the PRC resident that applies for complementary registration, administrative penalties could be imposed in accordance with relevant laws.

According to the Circular on Further Simplifying and Improving the Direct Investment-related Foreign Exchange Administration Policies (《關於進一步簡化和改進直接投資外匯管理政策的通知》), which was promulgated by the SAFE on February 13, 2015, came into effect on June 1, 2015, and revised on December 30, 2019, registrations under Circular 37 will be handled directly by the bank that has obtained the financial institution identification codes issued by the foreign exchange regulatory authorities and that has opened the capital account information system at the local foreign exchange regulatory authority. Foreign exchange regulatory authorities will perform indirect regulation over the direct investment-related foreign exchange registration via the banks.

### *Dividend Distribution*

On January 26, 2017, the SAFE promulgated the Notice on Improving the Verification of Authenticity and Compliance to Further Promote Foreign Exchange Control (《關於進一步推進外匯管理改革完善真實合規性審核的通知》), which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (i) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall make detailed explanations of sources of capital and utilization arrangements, and provide board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

### **Other Regulations in relation to Our Business**

#### *Enterprise Income Tax*

According to the PRC Enterprise Income Tax Law (《中華人民共和國企業所得稅法》) (the “**EIT Law**”), which was promulgated by the Standing Committee of the National People's Congress on March 16, 2007 and most recently amended on December 29, 2018, the income tax for both domestic and foreign-invested enterprises is at a uniform rate of 25% and the income tax for non-resident enterprise is at the rate of 20%. The Regulation on the Implementation of Enterprise Income Tax Law (《中華人民共和國企業所得稅法實施條例》) (the “**EIT Rules**”) was promulgated by the State Council on December 6, 2007 and amended

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on April 23, 2019. Pursuant to the EIT Law and the EIT Rules, a PRC resident enterprise is subject to enterprise income tax for the income derived from both inside and outside the PRC. A non-resident enterprise having offices or establishments inside the PRC is subject to enterprise income tax for the income derived in the PRC and the income derived from outside the PRC but with actual connection with such offices or establishments in the PRC. A non-resident enterprise without offices or establishments in the PRC or a non-resident enterprise whose earning income is not connected with its offices or establishments in the PRC will only be subject to tax on its PRC-sourced income. The income for such enterprise will be taxed at the reduced rate of 10%.

Pursuant to the EIT Law and the EIT Rules, income from equity investment between qualified resident enterprises such as dividends and bonuses, which refers to investment income derived by a resident enterprise from direct investment in another resident enterprise, is tax-exempt income. Moreover, the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Incomes (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) was promulgated by the State Taxation Administration (the “SAT”) on August 21, 2006 and was most recently amended by the Fifth Protocol ratified by the SAT on July 19, 2019 and came into effect on December 6, 2019. The Arrangement stipulates that a PRC resident enterprise which distributes dividends to its Hong Kong shareholders should pay income tax according to PRC law; however, if the beneficiary of the dividends is a Hong Kong resident enterprise, which directly holds no less than 25% equity interests of the aforementioned enterprise (i.e. the dividend distributor), the tax levied shall be 5% of the distributed dividends. If the beneficiary is a Hong Kong resident enterprise, which directly holds less than 25% equity interests of the aforementioned enterprise, the tax levied shall be 10% of the distributed dividends. Meanwhile, the Announcement of the State Administration of Taxation on Certain Issues Concerning the “Beneficial Owners” in the Tax Treaties (《國家稅務總局關於稅收協定中“受益所有人”有關問題的公告》), promulgated by the SAT on February 3, 2018 and came into effect on April 1, 2018, has stipulated some factors that are unfavorable to the determination of “beneficial owner.”

In addition, under the Circular of the SAT on Relevant Issues Concerning the Implementation of Dividend Clauses in Tax Treaties (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》), which was promulgated by the SAT and came into effect on February 20, 2009, all of the following requirements should be satisfied where a tax resident of the counterparty to the tax treaty needs to be entitled to such tax treatment specified in the tax treaty for the dividends paid to it by a PRC resident enterprise: (i) such tax resident who obtains dividends should be a company as provided in the tax treaty; (ii) the equity interests and voting shares of the PRC resident enterprise directly owned by such a tax resident reach a specified percentage; and (iii) the capital ratio of the PRC resident enterprise directly owned by such a tax resident reaches the percentage specified in the tax treaty at any time within 12 consecutive months prior to acquiring the dividends.

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### *Regulations on PRC enterprise income tax on indirect transfer of non-resident enterprises*

On February 3, 2015, the SAT issued the Announcement of the State Administration of Taxation on Certain Issues Concerning the Enterprise Income Tax on the Indirect Transfer of Properties by Non-resident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》) (the “**Circular 7**”), which was last amended on December 29, 2017. Circular 7 stipulates that when a non-resident enterprise transfers the assets (including equity interests) in an overseas holding company which directly or indirectly owns PRC taxable properties, including shares in a PRC company (or PRC Taxable Assets), for the purposes of avoiding PRC enterprise income taxes through an arrangement without reasonable commercial purpose, such indirect transfer should be reclassified and recognized to be a direct transfer of the assets (including equity interests) of a PRC resident enterprise in accordance with the Enterprise Income Tax Law, unless the overall arrangements relating to an indirect transfer of PRC Taxable Assets fulfil one of the conditions as stipulated under the Circular 7.

Further, according to the Announcement on Issues Relating to Withholding at Source of Income Tax of Non-resident Enterprises (《關於非居民企業所得稅源泉扣繳有關問題的公告》) issued by the SAT on October 17, 2017 and revised on June 15, 2018, the “income from property transfer” shall include the income from the transfer of equity interests and equity investment assets (hereinafter referred to as “equities”). The balance after deducting the net value of equities from the income from equity transfer is the taxable income from equity transfer. When calculating the income from equity transfer, an enterprise shall not deduct the amount that may be distributed from the shareholders’ retained proceeds that are attributable to such equities, such as the undistributed profits of the invested enterprise.

### *Environmental Protection*

The PRC Environmental Protection Law (《中華人民共和國環境保護法》) (the “**Environmental Protection Law**”), which was promulgated by the Standing Committee of the National People’s Congress on December 26, 1989, amended on April 24, 2014 and came into effect on January 1, 2015, provides a regulatory framework to protect and develop the environment, prevent and reduce pollution and other public hazards, and safeguard human health. The environmental protection department of the State Council is in charge of promulgating national standards for environmental protection. The Environmental Protection Law requires any facility that produces pollutants or other hazards to adopt environmental protection measures in its operations and establish an environmental protection responsibility system. Enterprises that are in violation of the Environmental Protection Law may be subject to a warning, payment of damages, imposition of a fine, or limitation or suspension of production depending on the seriousness of the case. If a criminal offense is committed, the offender may be subject to criminal penalties.

According to the PRC Law on Environment Impact Assessment (《中華人民共和國環境影響評價法》) promulgated by the Standing Committee of the National People’s Congress on October 28, 2002 and most recently amended on December 29, 2018, the Administrative Regulations on the Environmental Protection of Construction Projects (《建設項目環境保護管

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理條例》) promulgated by the State Council on November 29, 1998 and amended on July 16, 2017, the Interim Measures for the Environmental Protection Acceptance upon the Completion of Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) promulgated on November 20, 2017 and other relevant environmental laws and regulations, enterprises which plan to construct projects shall engage qualified professionals to provide the assessment reports, assessment form, or registration form on the environmental impact of such projects. The assessment reports, assessment form, or registration form shall be filed with or approved by the relevant environmental protection bureau prior to the commencement of any construction work. Upon completion of a construction project, the construction unit shall prepare an acceptance check report and make it available to the public. The principal part of a construction project may be put into production or use only after the affiliated environmental protection facilities have passed the acceptance check.

According to the Regulations on Urban Drainage and Sewage Disposal (《城鎮排水與污水處理條例》), which was promulgated on October 2, 2013 and came into effect on January 1, 2014, and the Measures for the Administration of Permits for the Discharge of Urban Sewage into the Drainage Network (《城鎮污水排入排水管網許可管理辦法》), which was promulgated on January 22, 2015 and came into effect on March 1, 2015, enterprises that engage in the activities of industry, construction, catering, and medical treatment, etc. that discharges sewage into urban drainage facilities shall apply to the relevant competent urban drainage department for collecting the permit for discharging sewage into drainage pipelines. Drainage entities covered by urban drainage facilities shall discharge sewage into urban drainage facilities in accordance with the relevant provisions of the state. Where a drainage entity needs to discharge sewage into urban drainage facilities, it shall apply for a drainage license in accordance with the provisions of these Measures. The drainage entity that has not obtained the drainage license shall not discharge sewage into urban drainage facilities.

### *Regulations on Fire Protection*

The Fire Prevention Law of the PRC (《中華人民共和國消防法》) (the “**Fire Prevention Law**”), which was promulgated on April 29, 1998 and most recently amended on April 29, 2021, provides that fire control design and construction of a construction project shall comply with the State’s fire control technical standards for construction projects. Developers, designers, builders, project supervisors, etc. shall be responsible for the quality of the fire control design and construction of the construction project pursuant to the law. The development project fire safety design examination and acceptance system shall be implemented for development projects which are required to have fire safety design in accordance with the national fire protection technical standards for project construction.

According to the Eight Measures for the Public Security and Firefighting Departments to Deepen Reform and Serve Economic and Social Development promulgated by the Ministry of Public Security of the PRC (《公安消防部門深化改革服務經濟社會發展八項措施》) on August 12, 2015, the fire protection design and completion acceptance fire protection record

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of construction projects with an investment of less than RMB300,000 or a building area of less than 300 square meters (or below the limit determined by the housing and urban construction department of the provincial people’s government) was cancelled.

### *Employee Stock Option Plans*

On February 15, 2012, the SAFE issued the Circular on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly Listed Companies (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) (the “**Share Option Rules**”). Under the Share Option Rules, the PRC citizens or residents habitually residing in the PRC continuously for over one year, with a few exceptions, and who have been granted, restricted shares or share options by an overseas listed company according to its employee share option or share incentive plan, are required to appoint a qualified PRC agent, register with the SAFE or its local counterparts and complete certain other procedures related to the shareholding plan, share option plan or other similar share incentive plans. Concurrent with registration with the SAFE or its local counterparts, the qualified PRC agent is required to obtain an approval from the SAFE for an annual allowance for the foreign exchanges in connection with shareholding or the exercise of a share option, and an approval for opening a special foreign exchange account at a PRC domestic bank to hold the funds required in connection with share purchases or share option exercises, returned principals or profits upon sale of shares, dividends issued on the stock and any other income or expenditures approved by the SAFE. Currently, foreign exchange income of the participating PRC residents received from the sale of share and dividends distributed by the overseas listed company are required to be fully remitted into such special domestic foreign currency account before distribution to such participants. In addition, the PRC agents are required to amend or deregister the registrations with the SAFE or its local counterparts in case of any material change in, or termination of, the share incentive plans within the time periods provided by the Share Option Rules.

### *Labor and Social Insurance*

The PRC Labor Law (《中華人民共和國勞動法》) which was promulgated by the Standing Committee of the National People’s Congress on July 5, 1994 and most recently amended and took effect on December 29, 2018, and the PRC Labor Contract Law (《中華人民共和國勞動合同法》) which was promulgated by the Standing Committee of the National People’s Congress on June 29, 2007 and amended on December 28, 2012 and took effect on July 1, 2013, govern the relationship between employers and employees and provides for specific provisions in relation to the terms and conditions of an employment contract. The PRC Labor Contract Law stipulates that employment contracts must be in writing and signed. It imposes more stringent requirements on employers in relation to entering into fixed-term employment contracts, hiring of temporary employees and dismissal of employees.

Under applicable PRC laws and regulations, including the PRC Social Insurance Law (《中華人民共和國社會保險法》), which was promulgated by the Standing Committee of the National People’s Congress on October 28, 2010 and amended on December 29, 2018, the

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Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》) promulgated by the State Council on January 22, 1999 and latest amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》), which was promulgated by the State Council on April 3, 1999, and most recently amended on March 24, 2019, employers and/or employees (as the case may be) are required to contribute to a number of social security funds, including funds for basic pension insurance, employment insurance, basic medical insurance, occupational injury insurance, maternity insurance, and housing provident funds. These payments are made to local administrative authorities and employers who fail to contribute may be fined and ordered to rectify within a stipulated time limit.

### Regulations in Relation to Overseas Listing

#### *Regulatory Development on Overseas Listing*

On December 24, 2021, the CSRC released the Administrative Provisions of the State Council on the Overseas Securities Offering and Listing by Domestic Companies (Draft for Comments) (《國務院關於境內企業境外發行證券和上市的管理規定(草案徵求意見稿)》) and the Administrative Measures for the Filing of Overseas Securities Offering and Listing by Domestic Companies (Draft for comments) (《境內企業境外發行證券和上市備案管理辦法(徵求意見稿)》) (collectively the “**Draft Regulations on Overseas Listing**”) for public comments until January 23, 2022.

The Draft Regulations on Overseas Listing, if adopted in their current form, will regulate both direct and indirect overseas offering and listing of PRC domestic companies by adopting a filing-based regulatory regime. Pursuant to the Draft Regulations on Overseas Listing, the issuers who meet the following criteria seeking to offer their securities or list overseas will be deemed as indirect overseas offering by PRC domestic companies: (a) whose PRC domestic operating entity generated more than 50% of the total assets, net assets, revenues or profits as shown in the issuer’s audited consolidated financial statements in the most recent accounting year, and (b) whose senior management in charge of business operation and management are mostly Chinese citizens or have domicile in China, and whose main places of business are located in China or main business activities are conducted in China. PRC domestic companies that directly or indirectly seek to offer or list their securities overseas are required to file with the CSRC within 3 working days after submitting their application documents to the regulator in the place of intended listing or offering. In addition, according to the Draft Regulations on Overseas Listing, overseas offerings and listings (i) that are prohibited by specific laws and regulations, (ii) that constitute threat to or endanger national security as reviewed and determined by competent authorities, (iii) that involve material ownership disputes, (iv) where the PRC domestic companies, their controlling shareholder or actual controller are convicted of or investigated for certain criminal offences, or directors, supervisors and senior management of the issuer involved in certain criminal offences or severe administrative penalties (together the “**Forbidden Circumstances**”), among other circumstances, are explicitly forbidden.

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As of the Latest Practicable Date, the Draft Regulations on Overseas Listing were released for public comments only and the final version and effective date of such regulations are subject to substantial uncertainties. Therefore, the [REDACTED] is currently not subject to any filing procedures with, or approval from, the CSRC. As of the Latest Practicable Date, we had not received any inquiries, notices, warnings, or sanctions regarding the [REDACTED] from the CSRC or any other PRC government authorities in terms of compliance with the proposed filing requirement under the new regulatory regime, if enacted. To our Directors’ best knowledge, we are not aware of the existence of any circumstances that would prohibit us from conducting overseas offering and listings under the Draft Regulations on Overseas Listing. Therefore, if the Draft Regulations on Overseas Listing become effective in their current form before the [REDACTED] is completed, other than the uncertainties of the filing procedures which may be further clarified in the final version of the Draft Regulations on Overseas Listing and/or their implementation rules, we do not foresee any impediment for us to comply with the Draft Regulations on Overseas Listing in any material respects.

### 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 (the “PHSA”) 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 pre-clinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Pre-clinical testing is conducted in accordance with FDA’s Good Laboratory Practice regulations. A sponsor of an IND must submit the results of the pre-clinical

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## REGULATORY OVERVIEW

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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 I, Phase II and Phase III, and may overlap.

- Phase I 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 II 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 III 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.

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



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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](http://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 require 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, pre-clinical 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 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 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 complete response 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.

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## REGULATORY OVERVIEW

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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 IV 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**

#### ***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. 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.

#### ***Breakthrough 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

## REGULATORY OVERVIEW

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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 pre-clinical and clinical data is as efficient as practicable.

### *Orphan Drugs*

Under the Orphan Drug Act, 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. 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 circumstance.

### *Post-Marketing Requirements*

Following 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 pre-clinical 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

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## REGULATORY OVERVIEW

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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. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products 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.

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## REGULATORY OVERVIEW

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### **Patient Protection and Affordable Health Care Act**

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively the “ACA”) became law in the United States March 2010, and have driven healthcare reform in the United States by extending health insurance coverage and substantially changing the way healthcare financed by both governmental and private insurers in the United States. With regard to pharmaceutical products specifically, the ACA, among other things, expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Among other things, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies’ share of sales to federal health care programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and there may be additional challenges and amendments to the ACA in the future. Since January 2017, President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed, for example, the Tax Act enacted by the Congress in 2017 which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated “Cadillac” tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurance tax. There may be other efforts to challenge, repeal or replace the ACA. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

### **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

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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.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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### OVERVIEW

Founded in 2014, we are a bio-pharmaceutical company with research and development capabilities. We are committed to the development and commercialization of oncology therapies with differentiated clinical profile in response to the trend of treating cancer as a chronic disease.

The history of our Group traces back to 2014 when Dr. Gong and other shareholders began to engage in the drug discovery and development business (the “**Biotechnology Business**”) through their then investment holding entity Etis Biotechnology (Shanghai) Co., Ltd. (埃提斯生物技术(上海)有限公司) (the “**Predecessor Holdco**”). Under the strong leadership of Dr. Gong, we have developed our Biotechnology Business to a major market player in developing oncology therapies. Dr. Gong is regarded as the Key Founder of our Biotechnology Business and is the single largest Shareholder of our Company. For further details of Dr. Gong’s background and experience, please refer to the section headed “Directors and Senior Management” in this document.

In early 2018, in order to seek separate financing and [REDACTED] of our Biotechnology Business and streamline corporate structure, the then existing shareholders of the Predecessor Holdco established our Company as holding company of the Biotechnology Business and commenced a series of business and corporate restructuring (the “**Business Restructuring**”). For further details, please refer to the paragraph headed “– Corporate Development” in this section. We carry out our operations mainly through our principal operating subsidiaries, 3DMed Beijing and 3D Medicines.

Since establishment of our Company, we have attracted various pre-[REDACTED] Investors including sophisticated healthcare and biotech funds. For details of our historical financing, please refer to the paragraphs headed “– Pre-[REDACTED] Investments” in this section.

### KEY MILESTONES

The following table sets forth certain key development milestones of our Group:

<b>Time</b>	<b>Milestone</b>
December 2014	We began engaged in drug discovery and development business through 3DMed Beijing, one of our principal operating subsidiaries.
February 2016	We entered into an agreement with the Alphasab Group in relation to, among others, co-development and exclusive commercialization rights of envafolimab (KN035) in oncological indications.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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<b>Time</b>	<b>Milestone</b>
December 2016	We received the IND approval from NMPA for envafolimab.
February 2017	We launched the first-in-human Phase I trial of envafolimab in the U.S.
March 2017	We launched Phase I trial of envafolimab in China.
October 2017	We launched Phase I trial of envafolimab in Japan.
November 2017	We made a global PCT patent application for 3D011.
April 2018	We launched a randomized Phase III trial in advanced biliary tract cancer (BTC) in the PRC for envafolimab.
August 2018	We launched a pivotal Phase II trial of envafolimab in previously treated advanced MSI-H/dMMR cancers.
September 2018	We obtained global rights to develop, manufacture, import, use, register, commercialize, and grant sub-license for our development of 3D185 from the Haihe Biopharma Group for treatment of tumor and pulmonary fibrosis globally.
December 2018	We launched the first-in-human Phase I trial of 3D185.
September 2019	We received the IND approval from FDA for 3D185.
October 2019	3DMed Beijing received the High-tech Enterprise Certificate (高新技術企業證書).
December 2019	We entered into a collaboration and clinical trial agreement with the Alphamab Group and TRACON for clinical development and commercialization of envafolimab for the treatment of sarcoma in the U.S., Canada, Mexico and each of their dependent territories.
January 2020	We received orphan drug designation from FDA for envafolimab for the treatment of advanced BTC.



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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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<u>Time</u>	<u>Milestone</u>
March 2020	We entered into a tripartite collaboration agreement with the Alphamab Group and the Simcere Group for the manufacturing, promotion and distribution of envafolimab in the PRC.
October 2020	We licensed-in the development, manufacturing and commercialization rights of 3D1001 and 3D1002 in the PRC from the Haihe Biopharma Group.
November 2020	We entered into a collaboration and license agreement with Aravive Inc. for an exclusive sub-license to develop and commercialize products that contain 3D229 as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in mainland China, Taiwan region, Hong Kong and Macau.
December 2020	We obtained the BLA acceptance from NMPA for envafolimab in the treatment of advanced solid tumors with MSI-H/dMMR.  We entered into a license agreement with SELLAS Life Sciences Group, Inc., a company listed on Nasdaq, and its subsidiary (collectively “SELLAS”) for license of certain intellectual property owned or controlled by SELLAS for the purpose of developing, manufacturing and commercializing our 3D189 and 3D059 for all therapeutic and other diagnostic uses in mainland China, Hong Kong, Macau and Taiwan region.  We entered into a license agreement with Y-Biologics with respect to license of 3D057 (also known as YBL-013), a T cell bi-specific engager, pursuant to which we will obtain the exclusive right to develop, manufacture and commercialize 3D057 in therapeutic, palliative, prophylactic and diagnostic applications for all therapeutic areas based on Y-Biologics’ Antibody Like Cell Engager (ALiCE) platform technology in China, Hong Kong, Macau and Taiwan region.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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<u>Time</u>	<u>Milestone</u>
January 2021	<p>We received the IND approval for 3D011 from NMPA.</p> <p>Our envafolimab was publicly announced to be accepted for priority review by NMPA.</p>
March 2021	<p>We filed the IND for 3D229 in China.</p> <p>We entered into a license agreement with ImmuneOncia Therapeutics, Inc. for an exclusive license for the development, manufacturing and commercialization of 3D197 (also known as IMC-002) in mainland China, Hong Kong, Macau and Taiwan region in respect of oncology indications.</p>
May 2021	<p>We received approval from NMPA to initiate clinical trial for 3D229.</p> <p>The first-in-human study of envafolimab was published on the Oncologist.</p>
June 2021	<p>The Phase II pivotal clinical trial result of our envafolimab was published on the Journal of Hematology &amp; Oncology.</p>
July 2021	<p>We received the IND approval for 3D229 for a Phase III clinical trial in patients with PROC in China to participate in the MRCT.</p>
November 2021	<p>Our envafolimab received BLA approval for previously treated microsatellite instability-high (MSI-H)/mismatch repair deficiency (dMMR) advanced solid tumors from the NMPA.</p>
March 2022	<p>We obtained the IND approval for 3D189 in China.</p>
May 2022	<p>We completed a Phase I clinical trial for 3D229 in healthy volunteers in China.</p>

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### OUR MATERIAL SUBSIDIARIES

As of the Latest Practicable Date, we had eleven subsidiaries and one branch. We set forth below certain information on our subsidiaries which made material contribution to our results of operations during the Track Record Period and up to the Latest Practicable Date:

<u>Name</u>	<u>Date and place of incorporation</u>	<u>Percentage of equity attributable to our Company</u>	<u>Share capital/ Registered capital</u>	<u>Principal business activities</u>
3D Medicines	September 10, 2015; PRC	89.46%	US\$119,735,390	Research and development
3DMed Beijing	December 22, 2014; PRC	89.46%	RMB200,000,000	Research and development
3DMed Shanghai	April 13, 2017; PRC	89.46%	RMB50,000,000	Research and development
3DMed Sichuan	March 16, 2016; PRC	89.46% <sup>(1)</sup>	RMB50,000,000	Research and development
3DMed Xuzhou	November 26, 2020; PRC	100%	US\$150,000,000	Manufacturing

*Note:*

- (1) Although 3DMed Sichuan is owned as to 51% and 49% by 3DMed Beijing and the Alphamab Group respectively, 3DMed Beijing is entitled to 100% economic interests and nomination right of the director(s), supervisor(s) and senior management, and retains 100% voting rights. For more details, please refer to paragraphs “History – Corporate Development – Major Shareholding Changes in Our Material Subsidiaries – 3DMed Sichuan” and note 1 to the Accountants’ Report set out in Appendix I to this document.

For details of our subsidiaries, please refer to note 1 to the Accountants’ Report set out in Appendix I to this document.

### CORPORATE DEVELOPMENT

#### Restructuring of our Group

The following sets forth the major corporate history of our Company and subsidiaries in our Group.

#### 1. Incorporation of Our Company

Our Company was incorporated in the Cayman Islands on January 30, 2018 as the holding company of our Group.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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### 2. *Incorporation of the BVI subsidiaries*

#### *Full Goal*

On January 30, 2018, Full Goal Trading Limited (“**Full Goal**”) was incorporated in the British Virgin Islands with limited liability and was authorized to issue a maximum of 50,000 shares of a single class with a par value of US\$1.00 each. On the same day, Full Goal allotted and issued one ordinary share at par value to Tong Chi Ho, an Independent Third Party, who subsequently transferred the one ordinary share to our Company on April 24, 2018. Since then, Full Goal has been a wholly-owned subsidiary of our Company.

#### *Integral Lane*

On April 17, 2018, Integral Lane Holdings Limited (“**Integral Lane**”) was incorporated in the British Virgin Islands with limited liability and was authorized to issue a maximum of 50,000 shares of a single class with a par value of US\$1.00 each.

On April 17, 2018, Integral Lane allotted and issued one ordinary share to Dr. Gong, who subsequently transferred the one ordinary share to Li Fugen, an investor and an Independent Third Party, on May 2, 2018.

On December 18, 2018, Li Fugen transferred the one ordinary share of Integral Lane to 3D Medicines (Hong Kong) Co., Limited (“**3DMed Hong Kong**”) at nominal consideration. The nominal consideration of the foregoing transfer was determined with reference to the unpaid consideration of RMB211,400 due to the Predecessor Holdco when Integral Lane acquired 5% equity interest in 3D Medicines held by Integral Lane from Predecessor Holdco. The payable of RMB211,400 from Integral Lane to Predecessor Holdco was subsequently settled in January 2019. For details, please refer to the subsection headed “Major Shareholding Changes in Our Material Subsidiaries – 3D Medicines” below.

Upon completion of the above transfers and as of the Latest Practicable Date, Integral Lane is an indirect wholly-owned subsidiary of our Company.

### 3. *Incorporation of the Hong Kong subsidiary*

On February 8, 2018, 3DMed Hong Kong was incorporated in Hong Kong with limited liability. On the same day, 3DMed Hong Kong allotted and issued 10,000 ordinary shares at par value to the initial subscriber, Tong Chi Ho, an Independent Third Party, who subsequently transferred the same shares to Full Goal on April 27, 2018. Upon completion of the above transfers and as of the Latest Practicable Date, 3DMed Hong Kong is an indirect wholly-owned subsidiary of our Company.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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### 4. *Acquisition of 3D Medicines*

Pursuant to an equity transfer agreement dated August 7, 2018, 3DMed Hong Kong acquired 93% and 2% equity interest in 3D Medicines from the Predecessor Holdco and Shanghai 3DMed Biopharm Technology Co., Ltd. (上海思路迪生物技術有限公司) (“**3DMed Biopharm Technology**”), an affiliate of the Predecessor Holdco, at a consideration of RMB3,933,500 and RMB200,000, respectively. The consideration of the above equity transfer was fully settled in December 2020. Please refer to the paragraph headed “Corporate Development – Major Shareholding Changes in Our Material Subsidiaries – 3D Medicines” for more details.

For the corporate structure of our Group subsequent to the above restructuring and the shareholding changes as set out in the paragraphs headed “– Corporate Development – Major Shareholding Changes,” please refer to the chart in “– Our Structure Immediately Prior to the [REDACTED]” below.

### **Major Shareholding Changes in Our Company**

#### *Our Company*

Subsequent to the completion of the Business Restructuring, we received three rounds of Pre-[REDACTED] Investments, please refer to the paragraphs headed “– Pre-[REDACTED] Investments” in this section for more details.

Concurrently with the Pre-[REDACTED] Investments, some of the Pre-[REDACTED] Investors acquired certain shares from the then shareholders of the Company. The consideration of such secondary transfers were determined through arms’ length negotiation and settled between the relevant parties. Among these secondary transfers, other than the sale and purchase transactions conducted directly between the exiting shareholders and new investors, to facilitate certain transactions, the Company repurchased certain shares and made repurchase payment to the exiting shareholders and issued the same number of shares to new investors at a consideration equal to the repurchase payment paid to the exiting shareholders. All the exiting shareholders and new investors are Independent Third Party of the Company. Please refer to the paragraphs headed “– Capitalization of our Company” for capitalization of the Company upon completion of the Pre-[REDACTED] Investments and the secondary transfers.

On June 25, 2021, immediately prior to the completion of 2021 Financing, each of our issued and unissued shares of par value of HK\$0.01 was subdivided into 10 shares of par value of HK\$0.001 (the “**Share Subdivision**”).

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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[REDACTED]

Pursuant to the resolutions passed by our shareholders on [●], our Directors were authorized to allot and issue on the [REDACTED] a total of [REDACTED] Shares credited as fully paid at par to the shareholders whose name is registered on the register of members of our Company as at the date of the shareholders’ resolutions in proportion to their respective shareholdings in our Company (as nearly as possible without fractions) by capitalizing the sum of HK\$[REDACTED] standing to the credit of the share premium account of our Company, and the Shares to be allotted and issued shall rank *pari passu* in all respects with the then existing issued Shares.

For other changes in the authorized share capital of our Company within two years immediately preceding the date of this document, please refer to the paragraphs headed “A. Further Information about our Group – 2. Changes in the Share Capital of our Company.” For capitalization of our Company as of the date of this document, please refer to the paragraphs headed “– Capitalization of our Company” in this section for more details.

### Major Shareholding Changes in Our Material Subsidiaries

#### *3D Medicines*

3D Medicines was incorporated in the PRC on September 10, 2015 as a domestic enterprise wholly-owned by the Predecessor Holdco with an initial registered capital of RMB1,000,000, which was increased to RMB10,000,000 in December 2015.

As part of the Business Restructuring, pursuant to an equity transfer agreement dated May 28, 2018, the Predecessor Holdco transferred 5% and 2% equity interest in 3D Medicines to Integral Lane and 3DMed Biopharm Technology at a consideration of RMB211,400 and RMB200,000, respectively. The considerations were determined through arms’ length negotiation amongst the parties. 3D Medicines was converted to a Sino-foreign joint venture with limited liability as the result of Integral Lane’s acquisition.

Pursuant to an equity transfer agreement dated August 7, 2018, 3DMed Hong Kong acquired 93% and 2% equity interest in 3D Medicines from the Predecessor Holdco and 3DMed Biopharm Technology at a consideration of RMB3,933,500 and RMB200,000, respectively. The consideration of the foregoing transfers were determined through arms’ length negotiation amongst the parties.

On March 19, 2019, Integral Lane and 3DMed Hong Kong resolved to increase the registered capital of 3D Medicines from RMB10,000,000 to US\$100,000,000 and 3DMed Hong Kong subscribed for the increased registered capital of US\$98,508,800.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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On June 17, 2020, as part of the Pre-[REDACTED] Investments, the registered capital of 3D Medicines was increased from US\$100,000,000 to US\$121,768,707 to reflect Simcere Group’s subscription of an increased registered capital of US\$21,768,707 at a consideration of US\$40 million (the “**Simcere Investment**”).

According to a capital increase agreement entered into by, among others, Dr. Gong and 3D Medicines on August 31, 2020, Dr. Gong’s subscribed registered capital of US\$7,118,583 at a consideration of RMB100,000,000 (the “**Dr. Gong’s Investment**”). The equity interest representing registered capital of 3D Medicines of US\$7,118,583 was subsequently transferred to 3D Med Hong Kong at a consideration of RMB100,000,000 pursuant to an equity transfer agreement dated December 18, 2020 entered into by and between Dr. Gong and 3D Med Hong Kong. To reflect Dr. Gong’s Investment, our Company allotted 785,073 Series D Preferred Shares with par value HK\$0.01, which is equivalent to RMB100 million, to Dr. Gong’s holding vehicle, Dragon Prosper Holdings Limited (“**Dragon Prosper**”).

On January 14, 2021, the shareholders of 3D Medicines resolved to reduce the registered capital of 3D Medicines from US\$128,887,290 to US\$107,118,583 to reflect Simcere Group’s conversion of its equity interest in 3D Medicines to 2,304,730 Series D Preferred Shares with par value HK\$0.01 of our Company in March 2021. Please refer to the paragraphs headed “– Pre-[REDACTED] Investments – 2019 Financing” in this section for more details of the Simcere Investment and Dr. Gong’s Investment.

Pursuant to a capital increase agreement dated December 31, 2020, as supplemented on the same day and further supplemented on May 24, 2021, Qingdao Hainuo Investment Development Co., Ltd. (青島海諾投資發展有限公司) (“**Qingdao Hainuo**”) subscribed for an increased registered capital of 3D Medicines of US\$12,616,807, representing 10.54% equity interest in 3D Medicines at a consideration of RMB332,780,000. The consideration was determined with reference to a pre-money valuation of 3D Medicines at US\$424,507,482. The investment from Qingdao Hainuo was fully settled in May 2021. Qingdao Hainuo is a limited liability company incorporated in the PRC and wholly-owned by the Financial Department of Southern District of Qingdao (青島市市南區財政局). To the best of our Directors’ knowledge, save for being a substantial shareholder of 3D Medicines, Qingdao Hainuo is independent from our Group. Qingdao Hainuo does not have any special right in 3D Medicines or any other members of our Group.

Upon completion of the above equity transfers and changes in registered capital and as of the Latest Practicable Date, 3D Medicines was held as to 89.40%, 0.06% and 10.54% by 3D Med Hong Kong, Integral Lane and Qingdao Hainuo, respectively.

### ***3D Med Beijing***

3D Med Beijing was incorporated in the PRC on December 22, 2014 as a limited liability company wholly-owned by the Predecessor Holdco with an initial registered capital of RMB1,000,000, which was increased to RMB50,000,000 in October 2015.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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As part of the Business Restructuring, pursuant to an equity transfer agreement dated February 27, 2018, the Predecessor Holdco transferred 100% equity interest in 3DMed Beijing to 3D Medicines. On August 7, 2020, 3D Medicines resolved to increase the registered capital from RMB50,000,000 to RMB200,000,000 and subscribed for the increased registered capital of RMB150,000,000.

Upon completion of the above equity transfer and as of the Latest Practicable Date, 3DMed Beijing is wholly-owned by 3D Medicines.

### *3DMed Shanghai*

3DMed Shanghai was incorporated in the PRC on April 13, 2017 as a limited liability company owned as to 98% and 2% by 3DMed Beijing and 3DMed Biopharm Technology, respectively.

Pursuant to an equity transfer agreement dated May 3, 2018, 3DMed Biopharm Technology transferred 2% equity interest in 3DMed Shanghai to 3D Medicines as part of the Business Restructuring.

Upon completion of the above equity transfer and as of the Latest Practicable Date, 3DMed Shanghai is owned as to 98% and 2% by 3DMed Beijing and 3D Medicines, respectively.

### *3DMed Sichuan*

3DMed Sichuan was incorporated in the PRC on March 16, 2016 as a limited liability company owned as to 68% and 32% by the Predecessor Holdco and Gong Zhaoxing (龔兆興), respectively, with registered capital of RMB50,000,000. Gong Zhaoxing is Dr. Gong’s brother.

For the purpose of the concentration of the equity interests in 3DMed Sichuan and along with the Business Restructuring, Gong Zhaoxing transferred 32% equity interest in 3DMed Sichuan to the Predecessor Holdco on January 31, 2018 at nil consideration, which was determined with reference to the 32% equity interest subscribed but not paid up at the time of the equity transfer. On March 20, 2018, the Predecessor Holdco subsequently transferred 100% equity interest in 3DMed Sichuan to 3D Medicines at the consideration of RMB1,491,771.11, which was determined through arms’ length negotiation amongst the parties. Pursuant to an equity transfer agreement dated August 20, 2020 entered into between 3D Medicines and 3DMed Beijing, 3D Medicines transferred 100% equity interest in 3DMed Sichuan to 3DMed Beijing to further streamline the corporate structure.

To reflect our collaboration with the Alphamab Group and to prepare for future manufacturing and commercialization of envafolimab, pursuant to an equity transfer agreement dated April 29, 2021, 3DMed Beijing transferred 49% equity interest in 3DMed Sichuan to the Alphamab Group at a nominal consideration. Upon completion of the aforementioned equity transfer and pursuant to the articles of association currently in effect of 3DMed Sichuan,



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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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3DMed Beijing retains 100% voting right at shareholders’ meetings and is entitled to 100% economic interests and nomination right of the director(s), supervisor(s) and senior management. Accordingly, 3DMed Sichuan remains a subsidiary of 3DMed Beijing as of the Latest Practicable Date. Please refer to the paragraphs headed “Business – Our Research and Development – Collaboration with Alphamab Group for Envafolimab” in this document for more details of the collaboration between our Group and the Alphamab Group.

### *3DMed Xuzhou*

3DMed Xuzhou was incorporated in the PRC on November 26, 2020 as a limited liability company. Since its incorporation and as of the Latest Practicable Date, 3DMed Xuzhou is wholly-owned by 3DMed Hong Kong.

## SHARE INCENTIVE SCHEME

In order to facilitate the administration of share incentives granted to the employees and for future grant, our Company adopted a restricted share unit scheme (the “**RSU Scheme**”) on June 22, 2021, pursuant to which restricted share units (“**RSU**”) representing no more than 20% of the total number of Shares in issue on the [REDACTED] may be delivered to the eligible participants.

On June 24, 2021, our Company established three trusts (the “**ESOP Trusts**”) by entering into trust deeds with Kastle Limited (the “**Trustee**”). As of the Latest Practicable Date, 38,337,760 Shares were allotted and issued to three BVI entities wholly-owned by the Trustee, namely Immunal Medixin US Limited, Immunal Medixin Cino L. Limited and Immunal Medixin Cino Limited (collectively, the “**Share Incentive Platforms**”).

Pursuant to the trust deeds of the ESOP Trusts, the Trustee shall procure each of the Share Incentive Platforms to exercise its voting rights attached to the Shares in accordance with Dr. Gong’s instructions. As such, Dr. Gong is deemed to be interested in the Shares held by the Share Incentive Platforms.

As of the Latest Practicable Date, 26,068,462 RSUs have been granted under the RSU Scheme. For details, please refer to the paragraph headed “Statutory and General Information – D. Share Incentive Schemes – 1. Share Incentive Scheme” in Appendix IV to this document.

## PRE-[REDACTED] INVESTMENTS

Our Company received three rounds of Pre-[REDACTED] Investments, including the 2019 Financing, the 2020 Financing and the 2021 Financing as set out below.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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### 2019 Financing

Pursuant to a capital increase agreement dated December 23, 2019, Simcere Group subscribed for an increased registered capital of 3D Medicines of US\$21,768,707 at a consideration of US\$40,000,000 which were then converted to 2,304,730 Preferred Shares with par value of HK\$0.01 in our Company. Pursuant to a capital increase agreement dated August 31, 2020, Dr. Gong through Dragon Prosper subscribed for registered capital of US\$7,118,583 in 3D Medicines at a consideration of RMB100,000,000, which were then converted to 785,073 Series D Preferred Shares with par value of HK\$0.01 of our Company. Please refer to the paragraph headed “– Major Shareholding Changes in Our Material Subsidiaries – 3D Medicines” in this section for more details of the Simcere Investment and Dr. Gong’s Investment.

In addition to the Simcere Investment and Dr. Gong’s Investment, 15 other investors subscribed for 4,869,055 Series D Preferred Shares with par value of HK\$0.01 at an aggregate consideration of US\$90,642,711.

The investment amount of the 2019 Financing was primarily determined based on the post-money valuation of our Group of US\$340,642,711 and was fully settled on June 23, 2021. For details of share subscription of the 2019 Investors, please refer to the paragraphs headed “– Principal terms of the Pre-[REDACTED] Investments” and “– Capitalization of our Company” below.

### 2020 Financing

Pursuant to an agreement dated November 11, 2020 as supplemented on December 31, 2020 and further supplemented on February 22, 2021, the 2020 Investors subscribed for 1,136,305 Preferred Shares with par value of HK\$0.01 at a consideration of US\$24,507,482. The investment amount of the 2020 Financing was determined with reference to the post-money valuation of 3D Medicines at US\$424,507,482 and was fully settled on April 21, 2021. For details of share subscription of the 2020 Investors, please refer to the paragraphs headed “– Principal terms of the Pre-[REDACTED] Investments” and “– Capitalization of our Company” below.

### 2021 Financing

Pursuant to a series of share purchase agreements entered into by, among others, our Company, Dr. Gong and the 2021 Investors in April and June 2021, the 2021 Investors subscribed for 18,921,712 Preferred Shares with par value HK\$0.001 of our Company immediately upon the Share Subdivision at a consideration of US\$60,180,500 in aggregate. The investment was legally completed and the investment amount of the 2021 Financing was fully settled. For more details of share subscription of the 2021 Investors, please refer to the paragraphs headed “– Principal terms of the Pre-[REDACTED] Investments” and “– Capitalization of our Company” below.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### Principal Terms of the Pre-[REDACTED] Investments

Principal terms of the 2019 Financing, 2020 Financing and 2021 Financing are set forth below:

	<u>2019 Financing</u>	<u>2020 Financing</u>	<u>2021 Financing</u>
<b>Date of Investments</b>	December 2019	November 2020	From April to June 2021
<b>Date of Full Settlement</b>	June 23, 2021	April 21, 2021	June 28, 2021
<b>Cost per Share paid<sup>(1)</sup></b>	US\$1.83	US\$2.16	US\$3.18
<b>Discount to the [REDACTED]<sup>(2)</sup></b>	[REDACTED]%	[REDACTED]%	[REDACTED]%
<b>Amount of consideration paid</b>	US\$145,257,680	US\$24,507,482	US\$60,180,500
<b>Number of Preferred Shares<sup>(1)</sup></b>	79,588,580	11,363,050	18,921,712
<b>Post-money valuation of our Company</b>	US\$340,642,711	US\$424,507,482	US\$700,177,630
<b>Lock-up Period</b>	The equity interest of our Company acquired by the Pre-[REDACTED] Investors in the Pre-[REDACTED] Investments will be subject to a lock-up period of six months from the [REDACTED].		
<b>Use of proceeds from the Pre-[REDACTED] Investments</b>	The proceeds have been used to support the research and development activities of our Group and the working capital needs of our Group. As of the Latest Practicable Date, approximately [67.07]% of the net proceeds from the Pre-[REDACTED] Investments by the Pre-[REDACTED] Investors were utilized. We intend to utilize the remaining net proceeds from the Pre-[REDACTED] Investments after the [REDACTED].		
<b>Strategic benefits of the Pre-[REDACTED] Investors brought to our Company</b>	At the time of the Pre-[REDACTED] Investments, our Directors were of the view that our Company could benefit from the additional capital that would be provided by the Pre-[REDACTED] Investors’ investments in our Company and the Pre-[REDACTED] Investors’ knowledge and experience.		

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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*Notes:*

- (1) The 2019 Financing and the 2020 Financing took place prior to the Share Subdivision. For illustration purpose, the number of Preferred Shares issued and the cost per share paid of the 2019 Financing and the 2020 Financing are based on number of Preferred Shares of par value of HK\$0.001 held by our 2019 Investors and 2020 Investors subsequent to the Share Subdivision.
- (2) The discount to the [REDACTED] is calculated based on (i) the [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the [REDACTED] range, (ii) the exchange rate of US\$1.00 to HK\$7.8483 as of July 18, 2022 and (iii) the conversion of Preferred Shares into Shares on 1:1 basis.

The increase from the post-money valuation of the 2019 Financing to the pre-money valuation of the 2020 Financing was due to (i) the anticipated filing to NMPA for application of BLA acceptance for envafolimab for treatment of previously treated MSI-H/dMMR advanced solid tumors in November 2020 and (ii) the expanded product portfolio of our Group after licensing in 3D229 November 2020. The significant increase from the post-money valuation of the 2020 Financing to the pre-money valuation of the 2021 Financing was due to (i) the IND approval for 3D011 obtained from NMPA in January 2021, (ii) our envafolimab being accepted to priority review by NMPA in January 2021, (iii) the commencement of construction of new manufacturing facilities in Xuzhou in February 2021, and (iv) three new products introduced to our Group product portfolio after licensing in 3D189 in December 2020, 3D057 in December 2020 and 3D197 in March 2021 which further increased the valuation of our Group. These developments have significantly reduced the development risks in relation to our product candidates and increased the probability of success, which reflect the likelihood of our products being approved and the attainability of future cash flow, and in turn boost the Company’s valuation.

### **Pre-[REDACTED] Exchangeable Loan**

Pursuant to a facility agreement and a series of ancillary documents dated December 31, 2020 entered into among Dr. Gong, Dragon Prosper, CNCB (Hong Kong) Investment Limited (“CNCB”) and our Company, CNCB provided a loan to Dragon Prosper (the “**Pre-[REDACTED] Exchangeable Loan**”), in consideration of which Dragon Prosper provided CNCB with a right to exchange a fixed monetary amount (the “**Exchange Amount**”), in full or in part, to certain Shares owned by Dragon Prosper (the “**Exchanged Shares**”) at the [REDACTED].

CNCB is a subsidiary of China CITIC Bank, a commercial bank listed on the Stock Exchange (stock code: 0998) and is primarily engaged in debt and equity investments. To the best of our Directors’ knowledge, CNCB is an Independent Third Party of the Company, CSCI (one of the Pre-[REDACTED] Investors) and China Securities (International) Corporate Finance Company Limited (one of the Joint Sponsors).

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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Principal terms of the Pre-[REDACTED] Exchangeable Loan are set forth below:

<b>Principal amount of the Pre-[REDACTED] Exchangeable Loan</b>	US\$20 million
<b>Date of facility agreement</b>	December 31, 2020
<b>Final Repayment Date of Pre-[REDACTED] Exchangeable Loan</b>	24 months from the first utilization date of the Pre-[REDACTED] Exchangeable Loan, or any other extended final repayment date
<b>Exchange Amount</b>	The lesser of (i) 20% of the total outstanding principal amount as of the last utilization date of the Pre-[REDACTED] Exchangeable Loan or (ii) US\$4 million (or its equivalent in other currencies)
<b>Exercise Period of the Exchange Right</b>	After six months upon the [REDACTED] and until 36 months from the first utilization date of the Pre-[REDACTED] Exchangeable Loan
<b>Exchangeable Shares</b>	Number of Shares equivalent to the Exchange Amount divided by [REDACTED]
<b>Utilization of the Pre-[REDACTED] Exchangeable Loan</b>	Dragon Prosper primarily used the proceeds of the Pre-[REDACTED] Exchangeable Loan for further subscription of 785,073 shares of our Company.  The capital raised by our Company from such subscription will be used for our working capital and general corporate purposes, research and development, and general and administrative expenses.

As of the Latest Practicable Date, US\$[15,600,000] was drawn down and the total outstanding principal amount was US\$15,600,000. As such, as of the Latest Practicable Date, the Exchange Amount is US\$3,120,000, being the lesser of (i) 20% of the total outstanding principal amount as of the last utilization date of the Pre-[REDACTED] Exchangeable Loan or (ii) US\$4,000,000. Based on the Exchange Amount as of the Latest Practicable Date, and assuming (i) CNCB elects to exercise its Exchange Right in full within the Exchange Period and (ii) the [REDACTED] is HK\$[REDACTED] per Share (being the mid-point of the [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED]) and based on the exchange rate of US\$1.00 to HK\$7.8483 as of July 18, 2022, [REDACTED] shares held by Dragon Prosper will be transferred to CNCB.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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As Dragon Prosper relied on the Pre-[REDACTED] Exchangeable Loan as financing to further invest in our Company and CNCB is interested in the shares of our Company through its Exchange Right, CNCB is regarded as one of our Pre-[REDACTED] Investors. Save for the Exchangeable Right which is only exercisable upon the [REDACTED] subject to the lock-up requirement imposed on Dr. Gong under Listing Rules, the terms of the Pre-[REDACTED] Exchangeable Loan did not grant any special right to CNCB.

### Information about the Pre-[REDACTED] Investors

Save as disclosed below, each of our Pre-[REDACTED] Investors, including their respective general partner(s) and limited partner(s) where applicable, is an Independent Third Party. The background information of our Pre-[REDACTED] Investors who either holds 1% or more of the Shares as at the Latest Practicable Date, or are our sophisticated investors, is set out below:

<b>Name of Pre-[REDACTED] Investors</b>	<b>Background</b>
Hangzhou Tigermed Consulting Co., Ltd. (杭州泰格醫藥科技股份有限公司) (“Tigermed”)	Hangzhou Tiger Equity Investment Partnership (Limited Partnership) (杭州泰格股權投資合夥企業(有限合夥)) is a limited partnership established in the PRC and its general partner is Shanghai Tiger Medicine Technology Co., Ltd. (上海泰格醫藥科技有限公司) (“Shanghai Tiger”), a wholly-owned subsidiary of Tigermed. Tigermed is a China-based provider of comprehensive biopharmaceutical R&D services which is listed on the ChiNext market of the Shenzhen Stock Exchange (stock code: 300347) and the Stock Exchange (stock code: 3347). As of June 30, 2020, Tigermed has invested in 57 innovative companies and other companies in the healthcare industry, as well as a limited partner in 39 investment funds. Hongkong Tigermed Co., Limited is a company incorporated in Hong Kong with limited liability. It is wholly owned by Tigermed. Tigermed is a sophisticated investor.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name of Pre-[REDACTED] Investors	Background
Shenzhen Efung Ruishi Investment Enterprise (Limited Partnership) (深圳市倚鋒睿實投資企業(有限合夥)) (“ <b>Shenzhen Efung</b> ”)	Shenzhen Efung invested in our Company through its affiliate, Shanghai Zhenlu Enterprise Management Consulting Partnership (Limited Partnership) (上海甄路企業管理諮詢合夥企業(有限合夥)). Shenzhen Efung is principally engaged in business consulting. It is a limited partnership incorporated in the PRC whose executive partner is Shenzhen Efung Investment Management Enterprise (L.P.) (深圳市倚鋒投資管理企業(有限合夥)), which is in turn owned as to 51%, 24%, 15% and 10% by Shenzhen Efung Holding Co., Ltd. (深圳市倚鋒控股集團有限公司) (“ <b>Shenzhen Efung Holding</b> ”), Mr. Zhu Jinqiao (朱晉橋), Shenzhen Galaxy Start-up Investment Centre Limited Partnership (L.P.) (深圳市格拉斯創業投資中心合夥企業(有限合夥)) and Shenzhen Efung Capital Co., Ltd. (深圳市倚鋒創業投資有限公司), respectively. Shenzhen Efung Holding is in turn owned as to 54%, 23% and 23% by Mr. Zhu Jinqiao (朱晉橋), Mr. Zhu Pai (朱湃) and Ms. Zhu Chen (朱晨), respectively. Mr. Zhu Jinqiao is the father of Mr. Zhu Pai, who is our non-executive Director, while Ms. Zhu Chen (朱晨) is an Independent Third Party. Mr. Zhu Jinqiao and Mr. Zhu Pai shall act in concert in relation to the exercising of their voting rights in Shenzhen Efung Holding. Shenzhen Efung Investment Management Enterprise (L.P.) is a sophisticated investor with more than RMB3 billion of assets under management and has invested in 56 companies as of June 30, 2021, including Chipscreen Biosciences, a company listed on the Shanghai Stock Exchange (stock code: 688321) and Ascentage Pharma, a company listed on the Stock Exchange (stock code: 6855).

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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Name of Pre-[REDACTED] Investors	Background
Advantech Capital Investment XVIII Limited (“ <b>Advantech</b> ”)	Advantech is an exempted limited company registered in the Cayman Islands and an affiliate of Advantech Capital II L.P. (“ <b>Advantech Capital II</b> ”). Advantech Capital II is a growth capital fund focusing on innovation-driven private equity investments primarily in China. As of June 30, 2021, Advantech Capital II has a capital commitment of approximately US\$867 million. Advantech Capital II pursues investment opportunities in the healthcare, technology and innovation sectors, particularly companies providing innovative products, solutions or services. Within the biotech sector, Advantech Capital II’s portfolio investments mainly comprise pharmaceutical companies specializing in anti-tumor or anti-inflammatory drugs and developers of innovative medical equipment or software solutions.
Sincere	Sincere Pharmaceutical Group Limited (“ <b>Sincere</b> ”, together with its subsidiaries, the “ <b>Sincere Group</b> ”) is a rapidly transitioning to an innovation and R&D-driven pharmaceutical company has listed on the Stock Exchange (stock code: 2096). Sincere Group is engaged in the R&D, production and commercialization of pharmaceuticals with the national key laboratory of translational medicine and innovative pharmaceuticals. Sincere Group has a diversified product portfolio in strategically focused therapeutic areas, including, (i) oncology, (ii) central nervous system diseases and (iii) autoimmune diseases, with leading positions in their respective therapeutic segments and/or established track record. As of March 24, 2022 (being the date of Sincere’s 2021 annual report), Sincere Group has developed a diversified product portfolio of over 60 innovative pharmaceuticals in its R&D pipelines, and is conducting 20 registration clinical studies for 17 potential innovative pharmaceuticals. In 2021, Sincere’s proportion of sales revenue from innovative pharmaceuticals contributed to 62.4% of its total revenue. Sincere as a major pharmaceutical company is a sophisticated investor. Other than investment in our Group, Sincere also invested in other companies engaging in the R&D of innovative pharmaceutical products, e.g. Bioheng Therapeutics Limited, Ruichu Pharm Co., Ltd., etc. As of December 31, 2021, the assets relating to investments held by Sincere amounted to approximately RMB2.24 billion.



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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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<b>Name of Pre-[REDACTED] Investors</b>	<b>Background</b>
GSUM VIII Holdings Limited	GSUM VIII Holdings Limited is ultimately managed and controlled by Hillhouse Capital Management, Ltd. (“ <b>Hillhouse</b> ”), an exempted company incorporated under the laws of Cayman Islands. Founded in 2005, Hillhouse is a global firm of investment professionals and operating executives who are focused on building and investing in high quality business franchises that achieve sustainable growth. Independent proprietary research and industry expertise, in conjunction with world-class operating and management capabilities, are key to Hillhouse’s investment approach. Hillhouse partners with exceptional entrepreneurs and management teams to create value, often with a focus on enacting innovation and technological transformation. Hillhouse invests in the healthcare, consumer, TMT, consumer technology, financial and business services sectors in companies across all equity stages. Hillhouse and its group members manage assets on behalf of global institutional clients. Hillhouse is a sophisticated investor.
China Securities (International) Finance Company Limited (中信建投(國際)財務有限公司) (“ <b>CSCI</b> ”)	CSCI is ultimately owned as to 100% by CSC Financial Co., Ltd. (中信建投證券股份有限公司) (“ <b>CSC Financial</b> ”) (Stock Code: 6066.HK/601066.SH), and is mainly engaged in investment of equity and financial instruments covering emerging industries such as healthcare, AI and pan-TMT, etc. Both CSCI and China Securities (International) Corporate Finance Company Limited (one of the Joint Sponsors) are subsidiaries of CSC Financial and are therefore the connected persons of each other.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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<b>Name of Pre-[REDACTED] Investors</b>	<b>Background</b>
Smilegate Global Unicorn 1st Venture Fund and Smilegate Pathfinder Fund	Smilegate Global Unicorn 1st Venture Fund and Smilegate Pathfinder Fund are managed by Smilegate Investment, a venture capital firm based in Korea, and specializes in investing in seed, early stage and growth companies. Smilegate Investment has approximately US\$1 billion of assets under management and has invested in 550 portfolio companies, including more than 80 biotech and healthcare companies. Mr. Chang Heung-Sun is the vice president of Smilegate Investment with focus on both life science and artificial intelligence sector. He has led the KOSDAQ initial public offering of Syntekabio, Inc., an AI-based drug development company listed on KOSDAQ (stock code: 226330) and MiCo BioMed Co Ltd, a company listed on KOSDAQ (stock code: 214610) focusing on COVID-19 diagnostics based on semiconductor technologies.
Xuzhou Zhenxin Venture Capital Co., Ltd. (徐州臻心創業投資有限公司)	Xuzhou Zhenxin Venture Capital Co., Ltd. (徐州臻心創業投資有限公司) is a limited liability company established in the PRC. It is wholly owned by Xuzhou Jinlonghu Holding Group Co., Ltd. (徐州金龍湖控股集團有限公司), which is ultimately owned by the Xuzhou Economic and Technological Development Zone Management Committee (徐州經濟技術開發區管理委員會).

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name of Pre-[REDACTED] Investors	Background
Guofeng Precision Medicine Capital Limited (“ <b>Guofeng</b> ”)	Guofeng is an exempted company incorporated in the Cayman Islands, wholly owned by Shenzhen Yifeng Investment Partnership (Limited Partnership) (深圳屹峰投資合夥企業(有限合夥)) (“ <b>Shenzhen Yifeng</b> ”). It is principally engaged in investment holding. The general partner of Shenzhen Yifeng is China Reform Venture Capital Investment Management (Shenzhen) Ltd. (國新風險投資管理(深圳)有限公司), which is wholly owned by Guoxin Science and Technology Fund Management Co., Ltd. (國新科創基金管理有限公司). Guoxin Science and Technology Fund Management Co., Ltd. is in turn held as to 40% by China Reform Fund Management Co., Ltd. (中國國新基金管理有限公司), a wholly owned subsidiary of China Reform Holdings Corporation Ltd. (中國國新控股有限責任公司) (“ <b>CRHC</b> ”). CRHC is controlled by the State Council. Shenzhen Yifeng has five limited partners, with 98.64% of the partnership interest held by China Venture Capital Fund Corporation Limited (中國國有資本風險投資基金股份有限公司), in which the State Council holds more than 35% interest. Guofeng is a sophisticated investor.
Wuhu Boquan Yifei Equity Investment Partnership (Limited Partnership) (蕪湖博 荃逸飛股權投資合夥 企業(有限合夥))	Wuhu Boquan Yifei Equity Investment Partnership (Limited Partnership) (蕪湖博荃逸飛股權投資合夥企業(有限合夥)), a limited partnership established in the PRC, is principally engaged in investing in the healthcare sector. Its general partner is Shanghai Boquan Equity Investment Management Co., Ltd. (上海博荃股權投資管理有限公司), which is ultimately owned by Wu Yaqiu (吳亞秋), Ge Weidong (葛衛東), Liu Leilei (劉蕾蕾), Zhou Yijun (周逸君), and Shang Haijin (尚海金). Wuhu Boquan Yifei Equity Investment Partnership (Limited Partnership) (蕪湖博荃逸飛股權投資合夥企業(有限合夥)) has three limited partners, with Huang Jiamei (黃嘉眉) holding 89.98% of the partnership interest.
Pavilion Soar Limited	Pavilion Soar Limited is a company incorporated in the British Virgin Islands with limited liability. It is solely owned by Mr. Yu Mingfang (于明芳).

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name of Pre-[REDACTED] Investors	Background
U-Tiger Global Strategic International Placement Fund S.P.	U-Tiger Global Strategic International Placement Fund S.P. is a segregated portfolio created by U-Tiger SPC. U-Tiger SPC is a segregated portfolio company incorporated with limited liability and registered as a segregated portfolio company under the laws of the Cayman Islands. It is wholly owned by Prosperous Investment Management Limited, a company with limited liability incorporated in the Cayman Islands indirectly wholly owned by UP Fintech Holding Limited, a company listed on the NASDAQ (stock code: TIGR).
Lucion VC 3 Limited and Lucion VC 5 Limited	Lucion VC 3 Limited is an exempted company incorporated in the Cayman Islands with limited liability. It is indirectly wholly owned by Luxin Venture Capital Group Co., Ltd. (魯信創業投資集團股份有限公司) (“ <b>Luxin Venture</b> ”), a company listed on the Shanghai Stock Exchange (stock code: 600783). Luxin Venture is in turn owned as to 69.57% by Shandong Luxin Investment Holding Group Co., Ltd. (山東省魯信投資控股集團有限公司), an investment platform under the Shandong Provincial Department of Finance (山東省財政廳). Lucion VC 5 Limited is an exempted company incorporated in the Cayman Islands with limited liability. It is wholly owned by Yunnan Huaxin Runcheng Biopharmaceutical Industry Venture Investment Fund (Limited Partnership) (雲南華信潤城生物醫藥產業創業投資基金合夥企業(有限合夥)) (“ <b>Yunnan Huaxin</b> ”). Yunnan Huaxin’s general partner is Yunnan Huaxin Runcheng Equity Investment Fund Management Co., Ltd. (雲南華信潤城股權投資基金管理有限公司), a limited liability company whose ultimate beneficial owners are Shandong Provincial Department of Finance, Yu Wenxue (于文學), Du Lin (杜霖), Bao Haiping (暴海平) and Shandong SASAC. Yunnan Huaxin has five limited partners, with Luxin Venture being the largest holding 37.05%.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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Name of Pre-[REDACTED] Investors	Background
Shenzhen Bo Rong Gong Ying No.3 Investment Corporation (Limited Partnership) (深圳博 榮共盈三號投資企業 (有限合夥))	Shenzhen Bo Rong Gong Ying No.3 Investment Corporation (Limited Partnership) (深圳博榮共盈三號投資企業(有限合夥)) is a limited liability partnership established in the PRC. Its general partner, Hainan Ruiming Investment Partnership (Limited Partnership) (海南睿明投資合夥企業(有限合夥)) (“ <b>Hainan Ruiming</b> ”), also owns 99% of the partnership interest. Hainan Ruiming’s general partner is Deng Yuehui (鄧躍輝), and it has nine limited partners. None of the beneficial owners or limited partners of Hainan Ruiming holds 30% or more interest in the partnership.
Rainbow Beauty International Limited	Rainbow Beauty International Limited is a company incorporated in the British Virgin Islands with limited liability. It is wholly owned by Mr. Zhang Zhixiang (張志祥).
JAS Investment Group Limited	JAS Investment Group Limited is a company incorporated in the British Virgin Islands with limited liability. It is wholly owned by Jiang Nanchun (江南春).
Aves Capital Holdings Limited	Aves Capital Holdings Limited is a company incorporated in the British Virgin Islands with limited liability. Each of Minghua Xiong and Rong Hu owns 50% of Aves Capital Holdings Limited.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Name of Pre-[REDACTED] Investors	Background
Shanghai Xing Zhi Mang Information Technology Partners LP (上海星之芒信息科技合夥企業(有限合夥)), Charm City Enterprises Limited, Rich Full Enterprises Limited, and Cosmic Star Ventures Limited	Shanghai Xing Zhi Mang Information Technology Partners LP (上海星之芒信息科技合夥企業(有限合夥)) is a limited partnership established in the PRC. Its general partner is Zhang Zhiyao (張志耀) (“ <b>Mr. Zhang</b> ”). It has three limited partners, with Wanzai Hongding Enterprise Management Center (Limited Partnership) (萬載鴻鼎企業管理中心(有限合夥)) holding 94.12% of the partnership interest. Mr. Zhang and Chen Xiaoyun (陳小雲) (“ <b>Mr. Chen</b> ”) hold 80% and 20% of the partnership interest in Wanzai Hongding Enterprise Management Center (Limited Partnership) (萬載鴻鼎企業管理中心(有限合夥)) respectively. Charm City Enterprises Limited, wholly owned by Mr. Zhang, and Rich Full Enterprises Limited, wholly owned by Mr. Chen, are both companies incorporated in the British Virgin Islands with limited liability. Cosmic Star Ventures Limited is a company incorporated in the British Virgin Islands with limited liability and wholly owned by Skycore Holdings Limited, a company directly wholly owned by Vistra Trust as trustee of a discretionary trust established by Mr. Zhang (as the settlor and beneficiary) for the benefit of Mr. Zhang and his family.
DH International Capital Partners Limited	DH International Capital Partners Limited is a limited liability company incorporated in Hong Kong. Its beneficial owner is Hua Feng Mao (華風茂), who owns 95.1% of its shares.
CEG Beaux Associated Co., Ltd.	CEG Beaux Associated Co., Ltd. is a company incorporated in the British Virgin Islands with limited liability. It is wholly owned by Shanghai Laishuo Investment Limited Partnership (上海來碩投資合夥企業(有限合夥)) (“ <b>Shanghai Laishuo</b> ”), whose general partner is Beijing Xinzhongli Equity Investment Management Co., Ltd. (北京信中利股權投資管理有限公司), a company indirectly owned by Chen Chunmei (陳春梅). Shanghai Laishuo has 11 limited partners, with Bohai Life Insurance Co., Ltd. (渤海人壽保險股份有限公司) and Lee On Life Insurance Co., Ltd. (利安人壽保險股份有限公司) each holding 25.53% of the partnership interest. None of the beneficial owner or limited partners of Shanghai Laishuo holds 30% or more interest in the partnership.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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<b>Name of Pre-[REDACTED] Investors</b>	<b>Background</b>
Grow Lighthouse Project Company Limited	Grow Lighthouse Project Company Limited is a company incorporated in the Cayman Islands. Its majority shareholder is K11 Investment Company Limited, which is in turn wholly owned by New World Development Company Limited, a company listed on the Stock Exchange (stock code: 0017). New World Development is a HongKong-based conglomerate with businesses spanning across numerous sectors, including property investment, management and development, infrastructure and services, healthcare, insurance, hospitality and other strategic businesses.
Golden Sail Ventures Limited	Golden Sail Ventures Limited is a company incorporated in the Cayman Islands. Each of Liu Guailin and Chen Ming Hao holds 80% and 20% respectively.
Smart Viotory Limited	Smart Viotory Limited is a company incorporated in the British Virgin Islands with limited liability. Each of Liao Hai Bing and Ma Qing Xiong owned 36.06% and 63.94% respectively.

### **Rights of the Pre-[REDACTED] Investors**

All Preferred Shares shall be converted into Shares of our Company immediately before the completion of the [REDACTED] on a ratio of 1:1. All the existing shareholders (including the Pre-[REDACTED] Investors) of our Company are bound by the shareholders’ agreement dated June 25, 2021 (as amended from time to time) (the “SHA”), which superseded all previous agreements among the contracting parties in respect of the shareholders’ rights in our Company, and the current articles of association of our Company.

The principal special rights granted to the Pre-[REDACTED] Investors under the SHA include the customary protective provisions, redemption rights, information rights, right of first refusal, right to elect directors, inspection rights etc. The certain special rights including redemption rights under the SHA are automatically terminated prior to the date of the first submission of the [REDACTED] by the Company. All remaining special rights together with the second amended and restated shareholders agreement are expected to terminate upon the closing of an initial [REDACTED].

### **Compliance with Interim Guidance and Guidance Letters**

On the basis that (i) the consideration for the Pre-[REDACTED] Investments (apart from the investment by 2021 Investors in June 2021) was settled more than 28 clear days before the date of our first submission of the [REDACTED] to the Stock Exchange in relation to the [REDACTED], (ii) the consideration for the investment by 2021 Investors in June 2021 was settled no less than 120 clear days before the [REDACTED], and (iii) all special rights granted

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

to the Pre-[REDACTED] Investors have been terminated or will cease to be effective prior to the [REDACTED], in particular, redemption rights under the SHA have been automatically terminated prior to the date of the first submission of the [REDACTED] by the Company, the Joint Sponsors have confirmed that the Pre-[REDACTED] Investments are in compliance with the Interim Guidance on Pre-[REDACTED] Investments issued by the Stock Exchange on 13 October 2010, as updated in March 2017, the Guidance Letter HKEX-GL43-12 issued by the Stock Exchange in October 2012, as updated in July 2013 and March 2017, and the Guidance Letter HKEX-GL44-12 issued by the Stock Exchange in October 2012, as updated in March 2017.

### CAPITALIZATION OF OUR COMPANY

The following table illustrates the capitalizations of the Company as of the Latest Practicable Date and immediately upon completion of the [REDACTED] and the [REDACTED] (assuming that (i) all the Preferred Shares have been converted to Ordinary Shares on 1:1 basis, (ii) the [REDACTED] is not exercised and (iii) CNCB does not elect to exercise its Exchange Right):

Shareholders	As of the Latest Practicable Date			Upon completion of the [REDACTED] and the [REDACTED]	
	Number of Ordinary Shares	Number of Preferred Shares	Ownership percentage	Number of Ordinary Shares	Ownership percentage
Dragon Prosper Holdings Limited	22,357,900	13,634,200	15.04%	[REDACTED]	[REDACTED]%
Immunal Medixin US Limited	19,143,220	-	8.00%	[REDACTED]	[REDACTED]%
Immunal Medixin Cino L. Limited	9,571,610	-	4.00%	[REDACTED]	[REDACTED]%
Immunal Medixin Cino Limited	9,622,930	-	4.02%	[REDACTED]	[REDACTED]%
Simcere Pharmaceutical Group Limited	-	23,047,300	9.63%	[REDACTED]	[REDACTED]%
Shanghai Zhenlu Enterprise Management Consulting Partnership (Limited Partnership)	-	13,817,280	5.77%	[REDACTED]	[REDACTED]%
Xuzhou Zhenxin Venture Capital Co., Ltd.	-	9,273,130	3.88%	[REDACTED]	[REDACTED]%
Hopeway Development Limited	8,446,660	-	3.53%	[REDACTED]	[REDACTED]%
Guofeng Precision Medicine Capital Limited	-	7,335,360	3.07%	[REDACTED]	[REDACTED]%



## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shareholders	As of the Latest Practicable Date			Upon completion of the [REDACTED] and the [REDACTED]	
	Number of Ordinary Shares	Number of Preferred Shares	Ownership percentage	Number of Ordinary Shares	Ownership percentage
	Wuhu Boquan Yifei Equity Investment Partnership (Limited Partnership)	-	6,444,680	2.69%	[REDACTED]
China Securities (International) Finance Company Limited	-	5,371,700	2.24%	[REDACTED]	[REDACTED]%
Pavilion Soar Limited	-	5,240,250	2.19%	[REDACTED]	[REDACTED]%
U-Tiger Global Strategic International Placement Fund S.P.	-	4,716,240	1.97%	[REDACTED]	[REDACTED]%
Lucion VC 3 Limited	-	4,297,360	1.80%	[REDACTED]	[REDACTED]%
Shenzhen Bo Rong Gong Ying No. 3 Investment Corporation (Limited Partnership)	-	3,925,360	1.64%	[REDACTED]	[REDACTED]%
Rainbow Beauty International Limited	-	3,788,050	1.58%	[REDACTED]	[REDACTED]%
JAS Investment Group Limited	-	3,350,640	1.40%	[REDACTED]	[REDACTED]%
Aves Capital Holdings Limited	-	3,350,640	1.40%	[REDACTED]	[REDACTED]%
Shanghai Xing Zhi Mang Information Technology Partners LP	-	3,280,890	1.37%	[REDACTED]	[REDACTED]%
Advantech Capital Investment XVIII Limited	-	3,144,160	1.31%	[REDACTED]	[REDACTED]%
Hangzhou Tigermed Equity Investment Partnership (Limited Partnership)	-	3,140,290	1.31%	[REDACTED]	[REDACTED]%
DH International Capital Partners Limited	-	3,083,250	1.29%	[REDACTED]	[REDACTED]%
CEG Beaux Associated Co., Ltd.	-	2,718,630	1.14%	[REDACTED]	[REDACTED]%
Grow Lighthouse Project Company Limited	-	2,685,850	1.12%	[REDACTED]	[REDACTED]%
Golden Sail Ventures Limited	-	2,685,850	1.12%	[REDACTED]	[REDACTED]%
Smilegate Global Unicorn 1st Venture Fund	-	2,672,536	1.12%	[REDACTED]	[REDACTED]%
Smart Victory Limited	-	2,556,630	1.07%	[REDACTED]	[REDACTED]%
Charm City Enterprises Limited	-	2,518,230	1.05%	[REDACTED]	[REDACTED]%

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shareholders	As of the Latest Practicable Date			Upon completion of the [REDACTED] and the [REDACTED]	
	Number of Ordinary Shares	Number of Preferred Shares	Ownership percentage	Number of Ordinary Shares	Ownership percentage
Rui Xia Investment Holding Limited	-	2,355,220	0.98%	[REDACTED]	[REDACTED]%
Lucion VC 5 Limited	-	2,223,050	0.93%	[REDACTED]	[REDACTED]%
Gongqingcheng Hyde Dingchuang Investment Partnership (Limited Partnership)	-	2,158,950	0.90%	[REDACTED]	[REDACTED]%
Ng Shan Shan	-	2,148,230	0.90%	[REDACTED]	[REDACTED]%
Able Legend Development Limited	-	2,119,946	0.89%	[REDACTED]	[REDACTED]%
Zhuhai Hengqin Xingrui Yuanhang Investment Center (Limited Partnership)	-	2,089,920	0.87%	[REDACTED]	[REDACTED]%
Saint Seiya Co., Ltd.	-	1,903,470	0.80%	[REDACTED]	[REDACTED]%
GSUM VIII Holdings Limited	-	1,572,080	0.66%	[REDACTED]	[REDACTED]%
Hongkong Tigermed Co., Limited	-	1,572,080	0.66%	[REDACTED]	[REDACTED]%
CHARIOT SPC FUND – WANHAI BALANCE FUND SP	-	1,572,080	0.66%	[REDACTED]	[REDACTED]%
Manyee Engineering Limited	-	1,568,500	0.66%	[REDACTED]	[REDACTED]%
HONG JINXIU	-	1,157,490	0.48%	[REDACTED]	[REDACTED]%
Smilegate Pathfinder Fund	-	1,074,340	0.45%	[REDACTED]	[REDACTED]%
Cosmic Star Ventures Limited	-	1,000,000	0.42%	[REDACTED]	[REDACTED]%
Raderwo Limited	-	1,000,000	0.42%	[REDACTED]	[REDACTED]%
Coast Town Limited	-	943,248	0.39%	[REDACTED]	[REDACTED]%
Glory Gain Engineering Limited	-	899,650	0.38%	[REDACTED]	[REDACTED]%
Rising Capital Holdings Limited	-	823,990	0.34%	[REDACTED]	[REDACTED]%
Weifang Datron CNC Equipment Co., Ltd	-	785,070	0.33%	[REDACTED]	[REDACTED]%
Star Union Industries Limited	-	754,970	0.32%	[REDACTED]	[REDACTED]%
Sheenway International Limited	-	690,890	0.29%	[REDACTED]	[REDACTED]%
Rich Full Enterprises Limited	-	644,010	0.27%	[REDACTED]	[REDACTED]%
JMC Capital HK LIMITED	-	628,832	0.26%	[REDACTED]	[REDACTED]%
Powerful Kirin Limited	-	537,170	0.22%	[REDACTED]	[REDACTED]%
Tao Qiling	-	537,170	0.22%	[REDACTED]	[REDACTED]%
Unite Choice Holdings Limited	-	506,660	0.21%	[REDACTED]	[REDACTED]%

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

	As of the Latest Practicable Date			Upon completion of the [REDACTED] and the [REDACTED]	
	Number of Ordinary Shares	Number of Preferred Shares	Ownership percentage	Number of Ordinary Shares	Ownership percentage
<b>Shareholders</b>					
Hong Kong Anchengda Investments Co., Limited	–	460,600	0.19%	[REDACTED]	[REDACTED]%
Regal Sky Enterprises Limited	–	180,830	0.08%	[REDACTED]	[REDACTED]%
Max Gain Engineering Limited	–	160,980	0.07%	[REDACTED]	[REDACTED]%
<b>Subtotal</b>	<b>69,142,320</b>	<b>170,147,932</b>	<b>100.00%</b>	<b>[REDACTED]</b>	<b>[REDACTED]%</b>
Investors taking part in the [REDACTED]	–	–	–	[REDACTED]	[REDACTED]%
<b>Total</b>	<b>69,142,320</b>	<b>170,147,932</b>	<b>100.00%</b>	<b>[REDACTED]</b>	<b>100.00%</b>

[REDACTED]

Upon completion of the [REDACTED] (assuming that no Shares will be allotted and issued under the [REDACTED]), the Shares held by our core connected persons will not count towards the [REDACTED]. The Shares held by Dragon Prosper, the Share Incentive Platforms and Shenzhen Efung will not count towards the [REDACTED].

Save as disclosed above, to the best of our Directors’ knowledge, all other investors and shareholders of our Company are not core connected persons of our Company. As a result, our other existing Shareholders will aggregately hold a total of approximately [REDACTED]% of the Shares (upon completion of the [REDACTED] and the [REDACTED] without taking into account (i) the Shares which may be allotted and issued under the [REDACTED] and (ii) the Exchangeable Shares to be transferred from Dragon Prosper to CNCB if the Exchange Right is exercised) which will count towards the [REDACTED]. Assuming the [REDACTED] are allotted and issued to public shareholders, over 25% of our Company’s total issued Shares will be held by the public upon completion of the [REDACTED] in accordance with 8.08(1)(a) of the Listing Rules.

### PRC LEGAL COMPLIANCE

Our PRC Legal Advisers advised that the transfer of 5% equity interests in 3D Medicines to Integral Lane (the “**First Transfer**”) on May 28, 2018 is subject to the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (Revised in 2009, the “**M&A Rules**”) (關於外國投資者併購境內企業的規定) and Interim Administrative Measures for the Record-filing of the Incorporation and Change of Foreign-invested Enterprises (Revised in 2017, the “**2017 Measures**”) (外商投資企業設立及變更備案管理暫行辦法(2017年修訂)), which became invalid from June 30, 2018 due to the implementation of the Interim

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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Administrative Measures for the Record-filing of the Incorporation and Change of Foreign-invested Enterprises (Revised in 2018, the “**2018 Measures**”) (外商投資企業設立及變更備案管理暫行辦法(2018年修訂)), and 3D Medicines has obtained the record-filing receipt for the incorporation of foreign-invested enterprise (外商投資企業設立備案回執) and the new business license pursuant to the M&A Rules and 2017 Measures. After the First Transfer, 3D Medicines became a sino-foreign joint venture enterprise. For the transfer of 93% equity interests held by Predecessor Holdco, 2% equity interests held by 3D Med Biopharm Technology in 3D Medicines to 3D Med Hong Kong (the “**Second Transfer**”) on August 7, 2018, our PRC Legal Advisers advised that since 3D Medicines has converted into a sino-foreign joint venture enterprise, the Second Transfer is the equity transfer in a foreign-invested enterprise, thus the Rules on the Changes of Shareholding of Foreign-invested Enterprise Investor (外商投資企業投資者股權變更的若干規定, the “**Rules**”) and the 2018 Measures, shall apply. 3D Medicines has obtained the record-filing receipts for the change of foreign-invested enterprise (外商投資企業變更備案回執) and the new business license pursuant to the Rules and 2018 Measures for the Second Transfer. Our PRC Legal Advisers are of the view that the First Transfer has been completed in accordance with the M&A Rules and 2017 Measures, the Second Transfer has been completed in accordance with the Rules and the 2018 Measures.

As confirmed by our PRC Legal Advisers, we have obtained and completed all necessary approvals and/or registrations in all material aspects from the relevant PRC regulatory authorities as to PRC laws in relation to our PRC subsidiaries as described above.

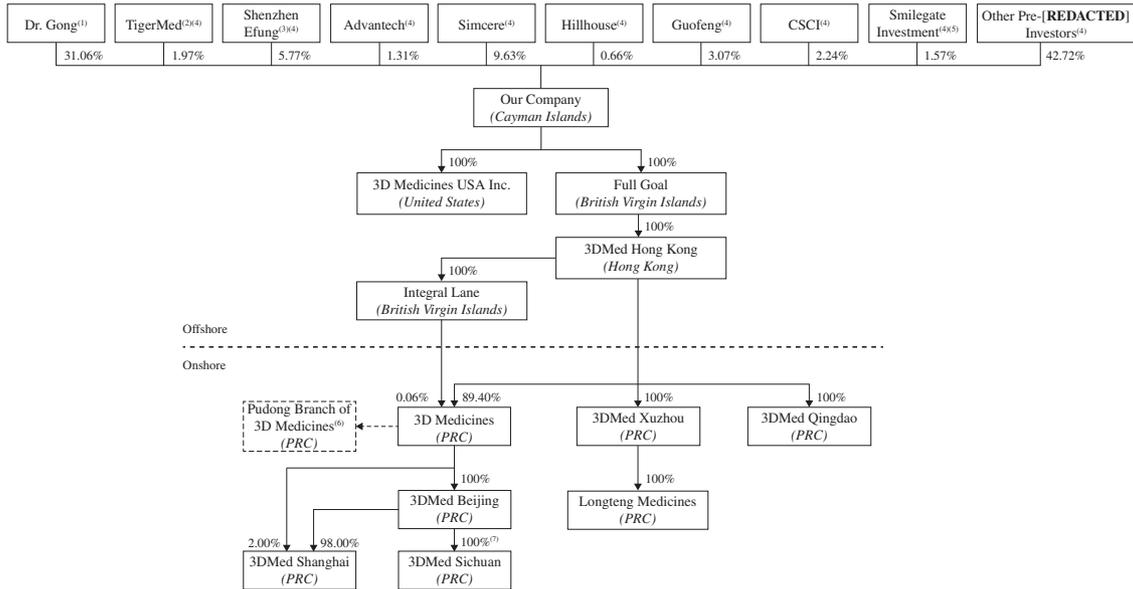
Pursuant to the SAFE Circular 37 promulgated by SAFE and which became effective on July 1, 2014, (a) a PRC resident must register with the local SAFE branch before he or she contributes assets or equity interests in an overseas special purpose vehicle (the “**Overseas SPV**”) that is directly established or indirectly controlled by the PRC resident for the purpose of conducting investment or financing, and (b) following the initial registration, the PRC resident is also required to register with the local SAFE branch for any major change, in respect of the Overseas SPV, including, among other things, a change of Overseas SPV’s PRC resident shareholder(s), the name of the Overseas SPV, terms of operation, or any increase or reduction of the Overseas SPV’s capital, share transfer or swap, and merger or division.

Pursuant to the Circular of SAFE on Further Simplification and Improvement in Foreign Exchange Administration 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) (the “**SAFE Circular 13**”), promulgated by SAFE and which became effective on June 1, 2015, initial foreign exchange registration under SAFE Circular 37 was delegated from local SAFE to local banks where the assets or interest in the local entity was located.

As of the Latest Practicable Date, none of the direct shareholder of the Company was PRC citizen or was subject to the registration under SAFE Circular 37.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### OUR STRUCTURE IMMEDIATELY PRIOR TO THE [REDACTED]

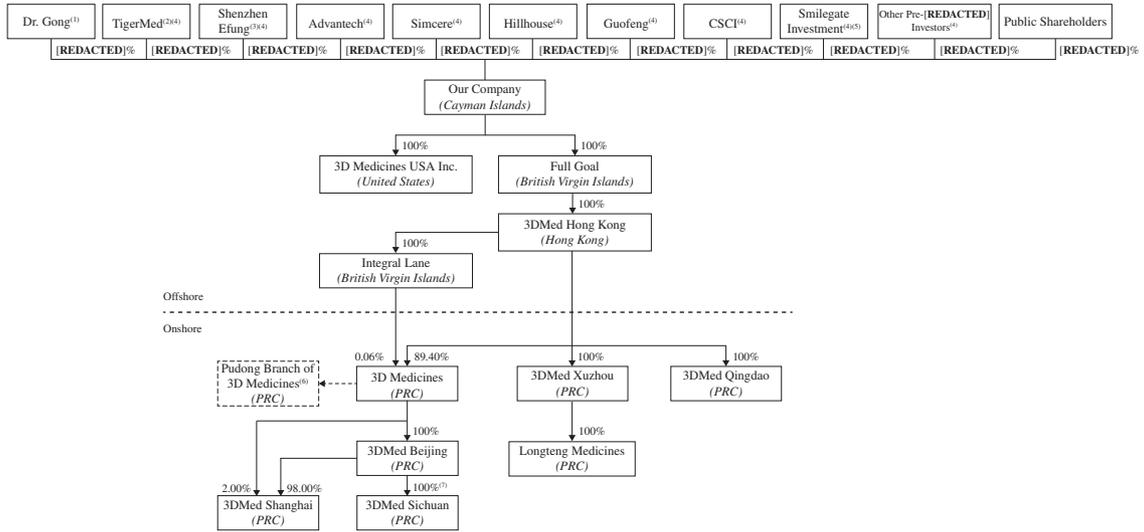


#### Notes:

- (1) Dr. Gong controls Shares of our Company through Dragon Prosper and the Share Incentive Platforms. For more details, please refer to the paragraph headed “– Share Incentive Scheme” in this section.
- (2) TigerMed is interested in our Shares through Hangzhou Tigermed Equity Investment Partnership (Limited Partnership) and Hongkong Tigermed Co., Limited. Each of Hangzhou Tigermed Equity Investment Partnership (Limited Partnership) and Hongkong Tigermed Co., Limited is an Independent Third Party.
- (3) Shenzhen Efung is interested in our Shares through Shanghai Zhenlu Enterprise Management Consulting Partnership (Limited Partnership) (上海甄路企業管理諮詢合夥企業(有限合夥)). Mr. Zhu Jinqiao and Mr. Zhu Pai, who are connected persons of the Company, control 54% and 23% of Shenzhen Efung Holding respectively, which in turn holds 51% of Shenzhen Efung Investment Management Enterprise (L.P.) (深圳市倚鋒投資管理企業(有限合夥)), the executive partner of Shenzhen Efung. Mr. Zhu Jinqiao and Mr. Zhu Pai shall act in concert in relation to the exercising of their voting rights in Shenzhen Efung Holding.
- (4) To the best of knowledge of our Directors, save for Shenzhen Efung, each of the Pre-[REDACTED] Investors is an Independent Third Party. Please refer to “– Pre-[REDACTED] Investments – Information about the Pre-[REDACTED] Investors” for more information of some of the Pre-[REDACTED] Investors.
- (5) Smilegate Investment is interested in our Shares through Smilegate Global Unicorn 1st Venture Fund and Smilegate Pathfinder Fund. Each of Smilegate Global Unicorn 1st Venture Fund and Smilegate Pathfinder Fund is an Independent Third Party.
- (6) The Pudong branch of 3D Medicines was incorporated on March 29, 2021.
- (7) Please refer to Note (1) in the paragraph headed “– Our Material Subsidiaries” in this section.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### OUR STRUCTURE IMMEDIATELY FOLLOWING THE [REDACTED] AND [REDACTED]



Note: Please refer to the notes to “– Our Structure Immediately Prior to the [REDACTED]” in this section.

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## BUSINESS

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### OVERVIEW

Founded in 2014, we are a bio-pharmaceutical company with research and development capabilities. We are committed to the development and commercialization of oncology therapies differentiated clinical profile in response to the trend of treating cancer as a chronic disease.

Our core business model is to discover, research, develop and commercialize oncology products and drug candidates by building a pipeline of innovative products and drug candidates with a potential to create significant synergy as combination therapies to address an unmet medical needs through a combination of in-house discovery, co-development and in-licensing. Our management team has extensive industry experience at organizations including FDA and pharmaceutical companies, and has led us to build capabilities from discovery to commercialization with proven track record.

With the increasing incidence and prevalence of cancer patients as well as the increase of the 5-year overall survival rate of cancer in the U.S. and China (67.1% in the U.S. and 40.5% in China), treating cancer as a chronic disease has become a major trend in oncology treatment. Due to the unmet medical needs to prevent progression, recurrence and metastasis of cancer and to improve the quality of life, treating cancer as a chronic disease will further drive the growth of the oncology drug market in China. In addition, there has been recent evolution of oncology treatment from in-hospitals to out-hospitals, which will potentially make oncology drugs more accessible for patients. Leveraging our deep understanding of the oncology market and unmet medical needs across tumor types as well as our business development, clinical development and registration capabilities and scientific insights of mechanism of actions of candidate drug molecules, we are able to identify and secure compounds and proceed with the discovery, research, development, clinical and regulatory processes. Through both in-house discovery and external collaboration, we have assembled and are developing a portfolio of therapies to treat cancer as a chronic disease.

Focusing on the trend of treating cancer as a chronic disease, we have strategically carried out a forward-looking plan for our product and drug candidate pipeline. We have built a pipeline consisting of one Core Product and 11 drug candidates, including a fully validated immuno-oncology monotherapy, innovative drug candidates with mechanisms of action amenable to combination within the pipeline, and pain management assets. Among our product and drug candidates, the Core Product envafolimab (brand name: ENWEIDA, 恩維達®), as our backbone, was approved in November 2021 and commercialized in December 2021, and seven are in clinical stage. Three of these product and clinical-stage drug candidates have entered into Phase II/III pivotal trials, two of which are conducted by our collaboration partners.

Our Core Product envafolimab is a subcutaneously-injectable PD-L1 antibody that has the potential to address an unmet medical need for the treatment of cancer as a chronic disease. We spent only four years moving envafolimab, a new molecular entity, from the IND stage to the BLA stage. On November 24, 2021, we received BLA approval for envafolimab for previously treated microsatellite instability-high (MSI-H)/mismatch repair deficiency (dMMR) advanced

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solid tumors from the NMPA and we are the marketing authorization holder (MAH). It has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Furthermore, envafolimab has potential to drive the technological advancement in the field of immunotherapy by offering PD-L1 inhibitor with a more convenient, cost-effective and generally preferred injection method. Compared with the currently approved PD-1/PD-L1 inhibitors, envafolimab is smaller with better stability and higher solubility, which enables high concentration formulation suitable for subcutaneous injection. Due to its subcutaneous formulation, it has the potential to have better patient compliance with increased convenience, wider patient coverage and huge market potential. Envafolimab has been well acknowledged by the Chinese clinical oncology community and recommended by three updated Chinese Society of Clinical Oncology (CSCO) 2022 Guidelines, including: (1) CSCO Guidelines for Gastric Cancer 2022 Version (Class I recommendation, Level 2A evidence); (2) CSCO Guidelines for Colorectal Cancer 2022 Version (Class II recommendation, Level 2A evidence), and (3) CSCO Guidelines for Clinical Application of Immune Checkpoint Inhibitors 2022 Version (Class I recommendation, Level 2A evidence). As of the Latest Practicable Date, our Core Product was approved for the indication of previously treated MSI-H/dMMR advanced solid tumors only, the incidence of which in China reached approximately 146,100 in 2021 and is expected to reach approximately 186,000 in 2030. We may face fierce competition from existing products and potential drug candidates in the entire oncology market and the market opportunities in respect of the Core Product may be small as it targets late line treatment, i.e., second line or later stage of treatment, for most of its targeted indications.

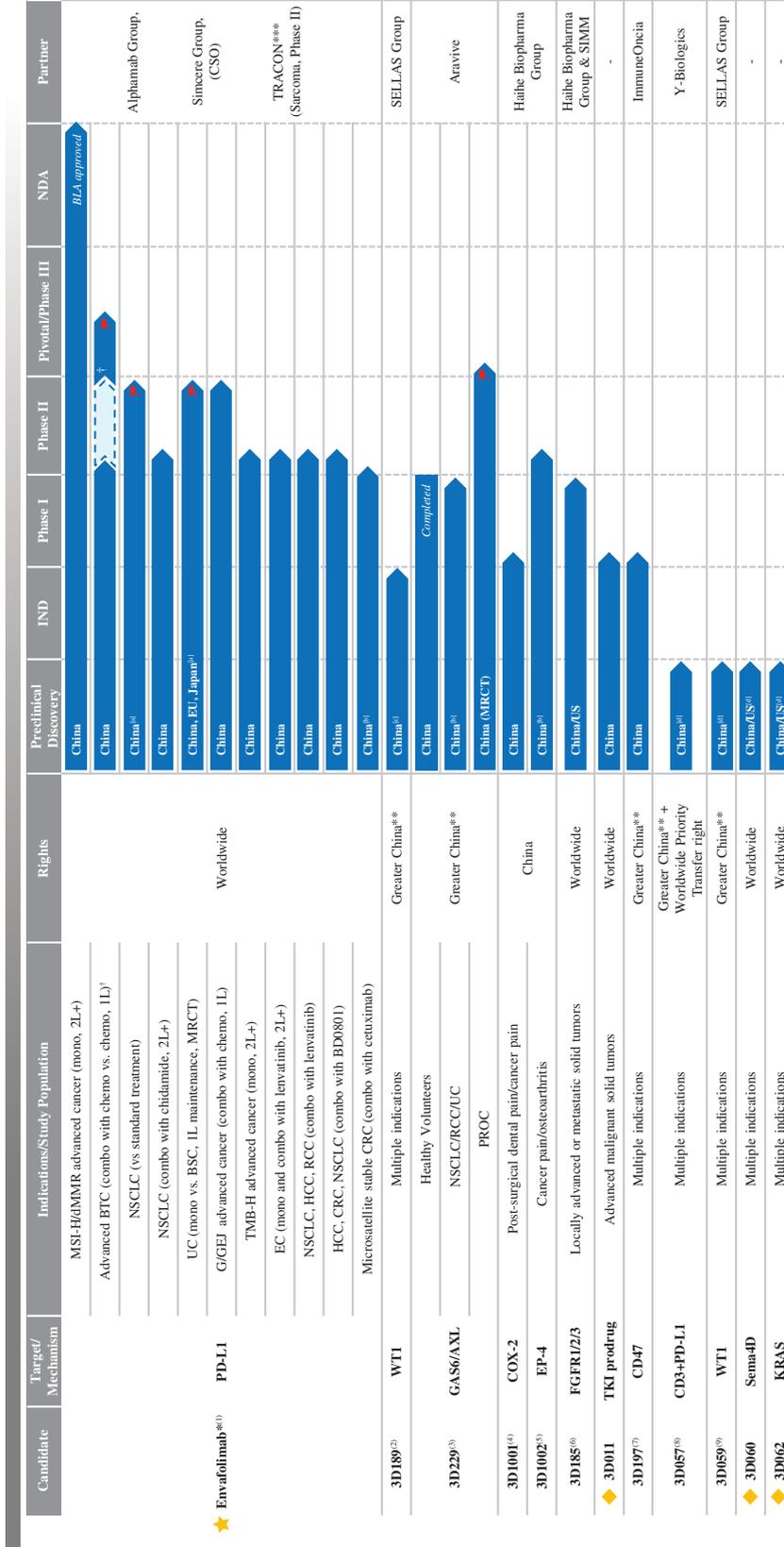
Our peptide cancer vaccine 3D189 (also known as Galinpepimut-S) is currently being evaluated by our partner SELLAS Group in an ongoing Phase III pivotal trial in the U.S. and Europe for the treatment of acute myeloid leukemia (AML). We obtained the IND approval for 3D189 in China in March 2022. Our GAS6 decoy receptor 3D229 (also known as batiraxcept, AVB-500) is being evaluated by our partner Aravive in a Phase III pivotal trial in the U.S. and Europe for the treatment of platinum resistant ovarian cancer (PROC). We completed a Phase I clinical trial in healthy volunteers in China in May 2022 and we obtained the IND approval for a Phase Ib/II clinical trial in patients with NSCLC, RCC and UC in April 2022. We obtained the IND approval for a Phase III clinical trial in patients with PROC in China in July 2021 to participate in the MRCT, and initiated this Phase III clinical trial in China in February 2022. We plan to join both aforementioned advanced trials to expedite our development and commercialization process in China.

We are focused on and have contributed to the development of immuno-oncology therapies. Employing a combination approach, immuno-oncology therapies have improved therapeutic efficacy and life expectancy of patients with a variety of cancer types and have stood out as particularly influential in recent years. Envafolimab can be used in combination with other treatments, including chemotherapy, targeted therapies, and other immunotherapies, which would potentially benefit more patients. Other drug candidates in our pipeline have promising potential to synergize with envafolimab through varied complementary mechanism of actions.



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The following chart summarizes the development status of our product, clinical-stage drug candidates and selected pre-clinical stage drug candidates as of the Latest Practicable Date:



★ Co-owned Asset    ◆ Proprietary Asset    🚩 Pivotal Trial

\* Denotes our Core Product  
 \*\* Greater China includes China, Hong Kong, Macau and Taiwan region.  
 \*\*\* TRACON is a licensee of envafolimab for the U.S., Canada and Mexico.  
 [a] Preparing for Phase III clinical trial  
 [b] Preparing for Phase II clinical trial  
 [c] Preparing for IND filing  
 [d] Pre-clinical stage

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*Abbreviations:* MSI-H/dMMR = microsatellite instability-high/mismatch repair deficiency; BTC = biliary tract cancer; NSCLC = non-small cell lung cancer; UC = urothelial cancer; BSC = best supportive care; MRCT = multi-regional clinical trial; G/GEJ = gastric or gastroesophageal junction; TMB-H = tumor mutational burden-High; EC = endometrial cancer; HCC = hepatocellular carcinoma; RCC = renal cell carcinoma; CRC = colorectal cancer; PROC = platinum resistant ovarian cancer; IND = investigational new drug application; BLA = biologics license application; 1L = first-line; 2L+ = second-line or later

### *Notes:*

- (1) We maintain the rights to develop envalfolimab globally in oncology field through our co-development agreement with Alphasab Group. On December 17, 2020, the NMPA accepted the BLA for envalfolimab for previously treated MSI-H/dMMR advanced solid tumors, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for envalfolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors. On January 16, 2020, the FDA granted envalfolimab with orphan drug designation for the treatment of advanced BTC. On June 28, 2021, the FDA granted envalfolimab with orphan drug designation for the treatment of soft tissue sarcoma. The commencement of each of the clinical trials for the treatment of previously treated MSI-H/dMMR advanced solid tumors, advanced BTC and G/GEJ cancer were based on the initial safety and efficacy data across multiple dose levels from the three then-ongoing Phase I clinical trials in advanced solid tumors in China, the U.S., and Japan.
- (2) We own the exclusive rights to develop, manufacture and commercialize 3D189 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses through our exclusive license agreement with SELLAS Group. We obtained the IND approval for 3D189 in China in March 2022 and we plan to join the MRCT with our partner SELLAS Group. 3D189 has been granted fast track and orphan drug designations by the FDA for the treatment of AML.
- (3) We own the exclusive rights to develop, manufacture and commercialize products that contain 3D229 as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in China, Hong Kong, Macau and Taiwan region through our collaboration and license agreement with Aravive. Stanford licensed the technology that is used by Aravive to develop 3D229 and Aravive licensed 3D229 to us. We completed the Phase I clinical trial in healthy volunteers in China in May 2022. In addition, we received the IND approval for 3D229 for a Phase III clinical trial in patients with PROC in China in July 2021 to participate in the MRCT, and we initiated this Phase III clinical trial in China in February 2022.
- (4) We own the exclusive rights to develop, manufacture and commercialize 3D1001 in China in the pain indication field through our license agreement with Haihe Biopharma Group.
- (5) We own the exclusive rights to develop, manufacture and commercialize 3D1002 in China in the pain indication field through our license agreement with Haihe Biopharma Group.
- (6) We own the exclusive rights to develop, manufacture and commercialize 3D185 globally in the oncology and pulmonary fibrosis treatment through our patent license agreements with Haihe Biopharma and Shanghai Institute of Materia Medica, Chinese Academy of Sciences.
- (7) We own the exclusive rights to develop, manufacture and commercialize 3D197 in China, Hong Kong, Macau and Taiwan region in respect of oncology indications through our exclusive license agreement with ImmuneOncia.
- (8) We own the exclusive rights to develop, manufacture and commercialize 3D057 in China, Hong Kong, Macau and Taiwan region for all therapeutic areas through our license agreement with Y-Biologics.
- (9) We own the exclusive rights to develop and commercialize 3D059 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses through our exclusive license agreement with SELLAS Group. MSK licensed certain know-how relating to 3D059 to SELLAS, which in turn sub-licensed the same to us.  
† The study included an interim analysis after the first 100 patients were enrolled (considered to be equivalent to a Phase II clinical trial) in the pivotal Phase III clinical trial for the treatment of advanced BTC, which has been designed with reference to the sufficient regulatory basis as described below. As advised by our PRC Legal Advisers, according to the Technical Guiding Principles of Clinical Trials of Anti-tumor Drugs (抗肿瘤药物临床试验技术指导) effective as of May 15, 2012, the clinical studies of anti-tumor drugs are generally divided into phase I, phase II and phase III clinical trials. The primary objectives of a phase I clinical trial include the preliminary studies of the tolerability and pharmacokinetics profile of the drugs, which provides data support to the dosage regimen design of subsequent studies. A phase II clinical trial is typically an exploratory study, such as the exploration of administration dosage, the exploration of dosage regimen and the exploration of efficacy, and includes the observation of safety. A phase III clinical trial further confirms the benefits for cancer patients on top of the results of the phase II clinical trial, and provide adequate evidence for obtaining marketing approval. However, the phases of the aforementioned clinical studies are not necessarily fixed. For instance, an exploratory study (i.e. phase II clinical trial) may also be a part of a phase III clinical trial. Specifically, a phase III clinical trial requires to generate efficacy data, of clinical benefit and the duration of the phase III trial is relatively long. Therefore, a phase III clinical trial may include an element of exploratory research allowing the adjustments of its clinical trial protocol or conduct pursuant to the interim analysis and accumulated information. In the field of oncology clinical research, the objectives of a traditional phase II study are increasingly commonly achieved through an expanded Phase I study design or by introducing an interim analysis in the phase III study. This approach has enabled a more efficient clinical development of oncology drugs in recent years.

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- **Envafolelimab (KN035):** Our envafolimab (brand name: ENWEIDA, 恩維達®) is a subcutaneously-injectable PD-L1 inhibitor for the treatment of tumor-agnostic indications, and it has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Envafolelimab is a fusion protein of single domain PD-L1 antibody and we are solely responsible for, and are conducting its clinical development in the oncology field. We initially focused on the indication of MSI-H/dMMR for envafolimab. As it has the potential to create significant synergies with other drug candidates as a result of its broad activity across multiple tumor types, we adopt a forward-looking approach to choose to focus on other indications, some of which have high risk for recurrence and metastasis such as hepatocellular carcinoma (HCC), urothelial carcinoma (UC) and renal cell carcinoma (RCC), which have significant potential for combination therapy. On December 17, 2020, the NMPA accepted the BLA for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for this indication from the NMPA. In addition, envafolimab has undergone an exploratory Phase II clinical trial in China in advanced gastric or gastroesophageal junction (G/GEJ) cancer, and is currently being evaluated in two ongoing pivotal clinical trials including a Phase III clinical trial in patients with advanced biliary tract carcinoma (BTC) in China, and a Phase II clinical trial in selected types of advanced sarcoma (SC) in the U.S. sponsored by our partner TRACON. On January 16, 2020, the FDA granted envafolimab with orphan drug designation for the treatment of advanced BTC. On June 28, 2021, the FDA granted envafolimab with orphan drug designation for the treatment of soft tissue sarcoma.
- **Galinpepimut-S (3D189):** Our 3D189 is a peptide cancer vaccine with potential to create synergies in combination with PD-1/PD-L1 therapies including with our envafolimab. 3D189 is currently being evaluated by our partner SELLAS Group in an ongoing Phase III pivotal trial in the U.S. and Europe for the treatment of AML, and has been granted fast track and orphan drug designations by the FDA for the treatment of AML. 3D189 targets the Wilms Tumor 1 (WT1) protein which is present and over-expressed in an array of hematological malignancies and solid tumors. Through combination therapies, 3D189 has potential to target over 20 types of cancers (including lung cancer and CRC) that over-express WT1 and, due to its ability to induce strong T-cell immune response, is designed to prevent or delay relapses (by prolonging the progression-free interval) and potentially prolong survival in these patients. We obtained the IND approval for 3D189 in China in March 2022 and plan to join the MRCT with our partner SELLAS Group.
- **3D229:** Our 3D229 is a GAS6 decoy receptor that is being evaluated by our partner Aravive in a Phase III pivotal trial in the U.S. and Europe for the treatment of PROC. We received the IND approval for Phase I clinical trial in healthy volunteers in China in May 2021 and completed this Phase I clinical trial in May 2022. We obtained the IND approval for a Phase Ib/II clinical trial in patients with NSCLC, RCC and UC in April 2022. We plan to join Aravive’s Phase III pivotal trial to

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enable BLA submissions across multiple jurisdictions including China, and we obtained the IND approval for 3D229 for a Phase III clinical trial in patients with PROC in China in July 2021 to participate in the MRCT, and we initiated this Phase III clinical trial in China in February 2022. Research has shown GAS6-AXL signaling to be a key molecular pathway that promotes tumor invasion and metastasis, as well as development of resistance to chemotherapy, targeted therapy and immuno-therapy. Through combination therapies including with envafolimab, 3D229 has the potential to address unmet medical needs to treat multiple tumor types including lung cancer, ovarian cancer (OC), renal cell carcinoma (RCC) and UC.

- **3D011:** Our 3D011 is an in-house discovered tyrosine kinase inhibitor (TKI) prodrug that will be developed as monotherapy and in combination with other agents for the treatment of solid tumors. In pre-clinical studies, 3D011 has demonstrated a better safety profile compared to its parent drug while maintaining efficacy, justifying its clinical development in advanced prostate cancer, HCC, and RCC. We received the IND approval from the NMPA in January 2021, and we initiated this Phase I clinical trial in February 2022.
- **3D185:** Our 3D185 is a fibroblast growth factor receptors (FGFR) 1-3 and colony stimulating factor 1 receptor (CSF1R) inhibitor that is expected to both inhibit tumor cells and remodel the tumor microenvironment to synergistically antagonize tumors and delay the development of resistance to FGFR inhibitors alone. The IND approval was obtained from the NMPA in January 2018. We received the IND approval from the FDA in September 2019. We completed the Phase I clinical trial in patients with advanced solid tumors in China and the U.S. in August 2021. As of the Latest Practicable Date, a new formulation of 3D185 was being studied in a Phase I clinical trial. 3D185 has the potential to be used in combination with our envafolimab.
- **3D1001:** Our 3D1001 is a third-generation cyclooxygenase-2 (COX-2) inhibitor with rapid onset of action and prolonged pain relief to patients with post-surgical dental pain in clinical study attributable to a favorable PK profile. The IND approval was obtained from the NMPA in February 2019. We plan to develop 3D1001 for the treatment of post-surgical dental pain and potentially other pain indications, including cancer pain management. We are preparing for a Phase I/II clinical trial for 3D1001 oral solution.
- **3D1002:** Our 3D1002 is an E-type prostanoid receptor 4 (EP4) inhibitor that has the potential for improved safety profile compared to COX1/2 inhibitors. 3D1002 has demonstrated favorable safety profile and promising efficacy results in phase I/II clinical studies. The IND approval was obtained from the NMPA in July 2018. We plan to develop 3D1002 for the treatment of cancer pain and osteoarthritis.

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- **3D197:** Our 3D197 is a next-generation fully human anti-CD47 IgG4 monoclonal antibody with potentially better safety profile that is expected to treat hematological malignancies and solid tumors. We obtained the IND approval for 3D197 in China in January 2022.
- **Our Pre-Clinical Stage Drug Candidates:** In addition to our clinical-stage drug candidates, we are also evaluating a number of promising pre-clinical stage drug candidates in our rich pipeline, including, (a) 3D057, our bispecific antibody drug which targets CD3 receptor of T-cells and PD-L1 of tumor cells, (b) 3D059, our next-generation immunotherapeutic which targets the WT1 protein in hematological malignancies and solid tumors, (c) 3D060, our in-house developed monoclonal antibody which targets Semaphorin 4D (Sema4D) of tumor cells, and (d) 3D062, our in-house developed small molecule for patients with KRAS mutation.

We are led by an experienced management team with a proven track record of leadership responsibilities and successful performance at international drug regulatory agencies, pharmaceutical and biotech companies. Our management team has an average of over 20 years of industry and regulatory experience at reputable organizations such as the FDA, BMS, AstraZeneca and Celgene. Our founder, CEO and Chairman, Dr. Gong, has more than 30 years of industry and academic experience leading and participating in the entire process of new drug development at regulatory agency, various pharmaceutical and biotech companies, and institutions. Led by our management team and supported by our full team with strong execution capabilities, we have adopted a highly systematic approach to the process of screening, identifying, evaluating and developing drug candidates that enhances our comprehensive portfolio for chronic cancer treatment. Our pre-clinical and clinical teams work collaboratively to ensure a seamless transition from discovery to clinical development. We apply efficient clinical study design and disciplined trial execution to achieve shortened timeline in a more cost-effective manner.

We plan to continue to accelerate the development and commercialization of our pipeline products, and further promote our comprehensive competitive capabilities. We have been establishing our internal manufacture capability and sales force, and further enhancing our in-house innovative R&D capability. We believe that these efforts will allow us to reinforce our position in innovative pharmaceutical industry. Our continuous R&D commitments will enhance our competitive advantages in the race to discover, develop and commercialize innovative cancer therapies and help us create and capture more opportunities in the chronic cancer market.

### OUR STRENGTHS

We believe that the following core competitive strengths form the foundation of our past success and will continue to help us solidify and enhance our position in a rapidly-growing chronic cancer treatment market:

#### **A major market player in the treatment of cancer as a chronic disease**

Due to the increase in chronic cancer patients and the rapid development of continued advances in innovative cancer treatment therapies, the size of the chronic cancer treatment market is expected to grow, which is evidenced by the increasing market size and proportion

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of oncology drugs sold outside hospital. According to Frost & Sullivan, the market size of oncology drugs sold outside hospital in China increased from RMB8.3 billion in 2016 to RMB30.8 billion in 2020, representing 6.6% and 15.6% of the China oncology pharmaceutical market, respectively. It is expected to further grow to RMB165.7 billion in 2025 and to RMB379.2 billion in 2030, representing 39.8% and 55.5% of the China oncology pharmaceutical market, respectively.

Significant scientific and clinical advances have been made in the oncology therapeutic area so that many types of cancers can now be controlled and managed as chronic diseases for an extended period of time, thus growing a chronic cancer treatment market that abounds with significant needs and opportunities. A strong evidence to show the trend of treating cancer as a chronic disease is the increase of the overall survival rate of cancer patients in China. For example, according to Frost & Sullivan, the 5-year survival rate of cancer patients in China has reached 40.5% in 2015 from 30.9% in 2005. In the early treatment phase of chronic cancer patients, generally during the first to sixth month after initial diagnosis, patients tend to seek and undergo treatment in tertiary hospitals to improve their survival rate. Due to the distribution of medical resources in China, long-distance treatment could incur significant indirect cost. According to Frost & Sullivan, the indirect costs of cancer treatments including transportation expenses, accommodation expenses is more than twice as the direct costs of cancer treatment in 2019, and increasing indirect costs of cancer treatments shifts cancer patients to choose local hospitals instead of famous tertiary hospitals to the extent possible. According to Frost & Sullivan, the annual growth rate of patients with chronic diseases transferring from tertiary and secondary hospitals to community healthcare institutions has been over 10% since 2017.

We are a major market player in the chronic cancer treatment market, according to Frost & Sullivan. Leveraging the insightful understanding by our management team of the trend of treating cancer as a chronic disease, we have built a complementary pipeline of innovative product and drug candidates to cover all different stages of cancer treatment. Our Core Product envafolimab is a subcutaneously-injectable PD-L1 antibody that has the potential to address an untapped and unmet medical need for the treatment of cancer as a chronic disease. In contrast to all of the marketed PD-1/PD-L1 inhibitors that are required to be administered intravenously, our subcutaneously-injectable envafolimab offers the following advantages:

- *Favorable safety and consistent efficacy.* Based on available clinical data, compared to other marketed PD-1/PD-L1 inhibitors, envafolimab has shown favorable safety profile and consistent efficacy results in clinical trials. Based on available clinical data, envafolimab has a low immune-related pneumonitis rate and no infusion-related reactions.
- *Better patient compliance with increased convenience.* According to the phase III HannaH study of Roche’s Herceptin Hylecta, intravenous infusion takes a long time, usually 30-60 minutes, with large dose, potential for irritation and increased adverse reactions, while the subcutaneous injection time is much shorter, usually 2-5 minutes for conventional antibodies formulated for subcutaneous injection. In the

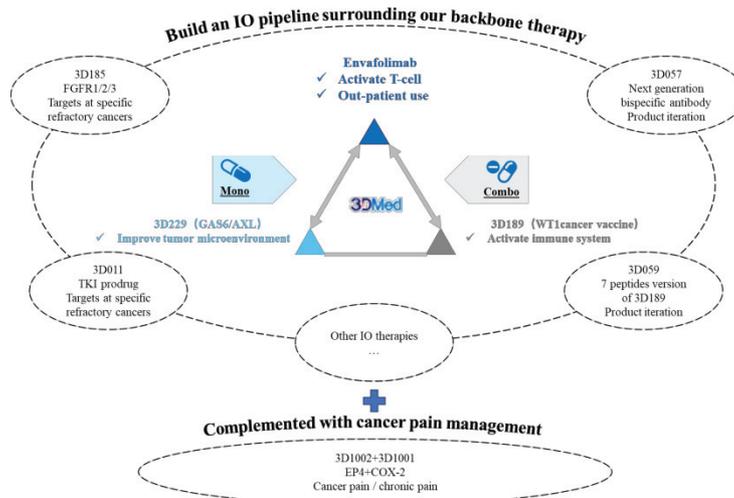
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case of envafohimab, the subcutaneous injection takes less than 30 seconds to inject 0.75ml (150 mg). In addition, the observation time for subcutaneous injection is also shorter than for intravenous infusion. Furthermore, while intravenous infusion is usually operated in tertiary hospitals, the subcutaneous injection method allows patients to be injected in outpatient departments and county-level hospitals or community clinics.

- *Wider patient coverage.* According to Ann Emerg Med. 2005 Nov;46(5):456-61. and J Clin Nurs. 2019 Jun;28(11-12):2206-2213, around 10% cancer patients may not be eligible for intravenous formulation due to limited vein access caused by long-term and numerous drug treatments, and subcutaneous injections could be used in patients who are not eligible for intravenous administration to address the unmet medical need.
- *More cost-effective.* In addition to lower production costs, patients would also benefit from lower transportation and accommodation costs as subcutaneous injections can be administered at a wider range of facilities and institutions nearby, such that envafohimab may result in lower indirect cancer treatment cost as a whole.

Therefore, safe and convenient administration of PD-1/PD-L1 subcutaneously is expected to expand application scenarios and further increase the penetration rate among cancer patients, with the potential to expand to the market of oncology drugs sold outside of hospital. Our Core Product envafohimab gives us first mover advantage in the market. Furthermore, we have been building deep entry barriers in the chronic cancer treatment market by focusing on combinational therapies that treat cancer through complementary mechanisms with potential for substantial synergistic effects. We believe this approach will allow us to systemically and effectively tackle tumors, and to significantly improve the response and survival rates of cancer patients.

### A multi-mechanism and highly synergetic pipeline of innovative drugs



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Our vibrant chronic cancer treatment ecosystem focuses on immuno-oncology therapies which is supported by cancer-related pain management solutions. As we strive to explore and capture oncology market opportunities, through both in-house discovery and external licensing of highly innovative products, we have assembled and are developing a portfolio of therapies for the treatment of cancer as a chronic disease. Over the years since our inception, we have maintained tremendous R&D investment, adopted a forward-looking multi-stream strategy and built cutting-edge technological expertise, thus culminating in a deep pipeline of product and drug candidates that cover multiple therapeutic targets/pathways and employ diverse mechanisms of actions for chronic cancer treatment. In 2020 alone, we have had one BLA accepted, seven clinical trials ongoing, six IND applications submitted, and six drug candidates in-licensed. Our pipeline products not only show differentiated properties in pre-clinical and/or clinical studies, but also have potential for synergy when used in combination with each other, promising broad clinical application prospects and market potential.

Our pipeline is pillared by our fusion protein of single domain PD-L1 antibody envafolimab. Led by envafolimab, our innovative therapeutic pipeline consists of products that are designed and being developed to address critical therapeutic targets and employ diverse validated mechanisms for the treatment of a broad spectrum of cancer indications, and each product and drug candidate can potentially be utilized both as a monotherapy and in combination with other therapies that together may unleash potentially breakthrough efficacy. Our other drug candidates have promising potential to synergize with envafolimab to better guide the human immune system to fight cancer and prolong the survival of cancer patients. 3D189 may potentially create good synergy with envafolimab by increasing the proportion of patients who develop an immune response against their cancer and prolonging the duration of such a response by induction of memory T cells. 3D229 may also potentially achieve good synergy with PD-1/PD-L1 antibodies including envafolimab as it has the potential to treat invasive cancers that are outside the treatment scope of PD-1/PD-L1 and may overcome resistance to PD-1/PD-L1 antibodies. In addition, our in-house developed 3D011 also has the potential to be used in combination with our envafolimab for the treatment of solid tumors.

Furthermore, our R&D investment in safe and effective cancer-related pain management solutions, including 3D1001 and 3D1002, is expected to help us achieve the goal of helping cancer patients live better with reduced cancer related symptom burden.

### **Successful exploration of innovative oncology therapies with resources consolidation, business development, clinical development and registration capabilities**

The global oncology drug market has expanded significantly in the past several years, and is expected to further expand at an accelerated pace. To strategically expand our business in an effective and efficient manner, we have selectively integrated industry resources by exploring innovative oncology therapies through collaboration with strategic partners with complementary resources, and acquired innovative drug candidates that are complementary to our existing product and drug candidates with significant clinical and commercial potential. Leveraging our outstanding R&D capabilities, we have formed collaborations with reputable domestic and multinational pharmaceutical and biotech companies such as Alphamab Group,



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Sincere Group, TRACON, SELLAS Group, Aravive, Haihe Biopharma Group, Y-Biologics and ImmuneOncia, and we have also become their trusted partner with respect to research and clinical development. The collaboration with our partners has also allowed us to save costs, minimize risks and strengthen R&D capabilities, which further enables us to deploy sufficient resources to our R&D process.

To ensure maximized commercial value of our product and drug candidates, we have also sought strategic collaboration opportunities worldwide. We have established long-term relationships with industry experts, scholars and regulators through years of endeavors in the R&D of innovative drugs, which enable us to closely follow the latest development in scientific research and clinical practices and the latest changes in applicable regulatory policies. We have worked with reputable PIs to carry out various clinical trials to realize the clinical and commercial value of our product and drug candidates. We have pursued business collaborations with our partners in terms of joint development and commercialization of our product and drug candidates in international markets. For example, we have collaborated with TRACON to carry out clinical trials for envafolimab in patients with soft tissue sarcoma in the U.S., Canada and Mexico, with the majority of the development activities expected to occur in the U.S. Such collaboration is a validation of envafolimab’s development strategy as we leverage TRACON’s local expertise and efficiently facilitate our market entry in the U.S. While focusing on the Chinese market, we have been committed to realizing the clinical and market potential of our product and drug candidates.

We have carefully considered patient needs as a starting point of our R&D efforts, evaluated the commercialization potential of drug candidates and made product screening decisions based on the mission to treat cancer as a chronic disease. Since inception, we have maintained long-term and effective R&D investment. In 2020, 2021 and for the five months ended May 31, 2022, our R&D expenses reached RMB264.0 million, RMB371.2 million and RMB138.3 million, respectively. As of the Latest Practicable Date, our patent portfolio consisted of 87 patents/patent applications that were owned/co-owned by or licensed to us (including 57 outside of China), including 26 for our Core Product envafolimab. In addition, a large number of publications had been published for our pipeline assets, including 16 publications for our Core Product envafolimab.

### **Full research and clinical development capabilities with proven track record from discovery to NDA stage**

We have a proven track record from discovery to NDA stage, which demonstrates our full research and clinical development capabilities. Our R&D platform has strong molecule screening and design capabilities that increase the possibility of success of moving molecules from pre-clinical studies to market, enable innovative therapeutic approaches and support rich pipeline assets built around key pathways and targets. Our R&D centers in Shanghai and Beijing include large and small molecule platforms, complete cell line screening platforms, high-throughput compound screening platforms and comprehensive animal models. Our strong R&D capabilities can be demonstrated by our in-house developed 3D011 which received the IND approval in January 2021. During the clinical development stage, we manage clinical

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trials and carry out a comprehensive suite of clinical development activities in-house, supplemented by CROs as needed, including clinical trial design, medical monitoring, operation, data management, statistics, programming, and pharmacovigilance. As of the Latest Practicable Date, we had obtained 16 IND approvals and implemented 12 Phase II/III clinical studies. We have accumulated comprehensive experience and strong ability to independently complete the entire drug development process from pre-clinical research to clinical development and to NDA/BLA filings.

Our R&D team works collaboratively to ensure a seamless transition from pre-clinical discovery to clinical development. We apply efficient clinical study design and disciplined trial execution to achieve shortened timeline while reducing overall costs. For example, we spent only four years moving envafolimab from the IND stage to the NDA/BLA stage. Historically, innovative oncology drugs like envafolimab took approximately five to six years to move from the IND stage to the NDA/BLA stage, according to Frost & Sullivan. Leveraging trial management and technological expertise of our clinical team, we have successfully enrolled nearly a thousand patients in clinical trials in multiple countries and regions. We are also one of the early pioneers to apply advanced drug discovery and development technologies to minimize false starts and optimize the structure of lead compounds in drug discovery.

### **Internationally skilled management and R&D team**

We are led by an experienced management team with successful performance in the fields of international drug regulatory agencies, pharmaceutical and biotech companies. We specialize in the entire drug R&D process from pre-clinical research to clinical development and to commercialization. Our management team has an average of 20 years of industry experience at reputable organizations such as the FDA, BMS, AstraZeneca and Celgene. Led by Dr. Gong, CEO and Chairman, our outstanding management team has attracted a large number of professionals. As of Latest Practicable Date, our R&D team has a total of 151 employees, 82 of which have a master's degree or higher, including 17 with doctor's degrees. Our drug discovery and translational research function is led by Dr. Yihui Lin, our Head of Translational Medicine Center, and our clinical development team is led by Dr. Dongfang Liu, our Chief Medical Officer. The two functions have been working seamlessly to drive our R&D process.

Our founder, Chairman and CEO, Dr. Gong, has more than 30 years of experience leading and participating in the entire process of new drug development at various pharmaceutical and biotech companies and institutions, including 10 years working at the FDA as a new drug reviewer. Dr. Gong has extensive experience in new drug R&D, including strategic planning, pre-clinical and clinical trial design, Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) regulations, new drug project evaluation, coordination in advancing pre-clinical trials and clinical trials, and risk control and management throughout drug development programs.

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Dr. Dongfang Liu, our Chief Medical Officer, has more than 20 years of experience in clinical oncology practice and R&D and has led several clinical development programs resulting in approvals in the U.S., China and Europe, including the approval of nivolumab in China for second-line treatment of non-small cell lung cancer (NSCLC), and the approval of Revlimid plus rituximab (R2) in China, the U.S. and Europe for the treatment of previously treated follicular lymphoma or marginal zone lymphoma.

Dr. Shen Xiao, our Chief Strategic Officer, is responsible for directing and overseeing company strategies and regulatory affairs. He has around 20 years of experiences in FDA where he was primarily responsible for the review and approval of new drug applications. He had led the review of various development stages of hundreds of new drugs and approved more than ten new drugs. Dr. Xiao holds a Ph.D. in kidney physiology and cell biology from West Virginia University in the U.S.

Dr. Yihui Lin, our Head of Translational Medicine Center, has more than 10 years of experience in biomarker validation and translational medicine. Dr. Lin holds a Ph.D. from the Center for Excellence in Molecular Cell Science of Chinese Academy of Sciences.

Led by our management team and supported by our team members, we have adopted a highly systematic approach to the process of screening, identifying, evaluating and developing drug candidates that enhance our comprehensive portfolio for chronic cancer treatment. With the management team’s deep industry insights and sound judgment, we have built a synergetic pipeline of innovative product and drug candidates to fully tap the chronic cancer treatment market.

### OUR STRATEGIES

We are committed to the discovery, development, and commercialization of safe and effective innovative drugs for chronic cancer treatment, and will further strengthen our position in this market by implementing the following strategies:

#### **Further expand the commercial potential of envafolimab and explore market opportunities**

As we already received BLA approval for the treatment of previously treated MSI-H/dMMR advanced solid tumors from NMPA on November 24, 2021, we are leveraging our commercialization resources to quickly penetrate the market and increase our market share, through our collaboration with Simcere Group in connection with the promotion of envafolimab in China. Meanwhile, we will continue to carry out additional clinical studies to expand the addressable indications for envafolimab, such as NSCLC, EC, UC and RCC.

Furthermore, we plan to continue maximizing the commercial value of envafolimab by conducting clinical trials both independently and in collaboration with partners outside of China.

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### **Accelerate the product development to commercialization and further enrich our pipeline**

We intend to continue advancing the development of our pipeline drug candidates and fully explore the opportunities for combinational use of pipeline assets in the chronic cancer market. For 3D229, 3D189, and other drug candidates at late clinical stage, we will leverage the clinical data from our partners sponsored clinical trials to advance clinical programs and communicate with regulatory authorities to expedite BLA/NDA submission opportunities in China. For early clinical stage assets, we plan to apply innovative clinical trial designs and efficient clinical strategies to speed up the development process.

Furthermore, our strong business development team will continue conducting foresighted market analysis to seek innovative products that have potential combination synergies with our current pipeline through in-house discovery, licensing or other collaboration arrangements. We also plan to find the most suitable and resourceful partners for strategic collaboration on R&D and commercialization to maximize the clinical and commercial value of innovative therapies and our product and drug candidates.

### **Further enhance our in-house innovative R&D capability**

We intend to further invest in in-house discovery to capture market opportunities and treat cancer patients around the world. The development of novel cancer therapeutics requires industry-leading technologies and know-how that are rapidly upgrading and evolving. Therefore, we will continue to strengthen and optimize our drug discovery and development platforms that integrate cutting-edge technologies and deep know-how in drug design and development, particularly our large molecule platform, small molecule platform and cell line screening platform, which aid our efforts to accelerate the timeline from discovery to approval of innovative products and drug candidates. We currently cooperate with XtalPi and plan to further cooperate with other third parties to further integrate AI-enabled digital drug R&D infrastructure for drug development and efficiency enhancement. We will also continue to leverage our experience from the collaboration with reputable partners to further strengthen our R&D capabilities.

In addition, we will also continue to invest in pre-clinical R&D to identify pipeline assets that cover a wider spectrum of cancer indications, and actively conduct research to evaluate the combination effects of our pipeline candidates. We will continue to screen and design innovative molecules with differentiated characteristics to meet clinical needs by focusing on key targets, pathways and mechanisms of actions. We believe that these R&D commitments will enhance our competitive advantages in the race to discover, develop and commercialize innovative cancer therapies and help us capture more opportunities in the chronic cancer market.

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### **Further establish GMP manufacturing capability and strengthen commercialization capability**

We are establishing our internal manufacture capability and continue optimizing management processes to strengthen the operational capabilities of our platform. We have been building manufacturing system and facilities throughout the drug development process, including chemical drugs and biologics, in Xuzhou, Jiangsu Province in compliance with cGMP-standards that cover an area of 65,637.97 square meters. We have obtained the construction permit and started construction of new manufacturing facilities in Xuzhou. We believe optimization of our management process and expansion of our manufacture capabilities will prepare us better for the manufacturing and commercialization of our product and drug candidates.

In addition, we plan to adopt a localized commercial approach, focus on medical-driven promotion strategies, and intend to establish suitable commercialization strategy based on each product or drug candidate’s characteristics and market coverage to quickly and efficiently achieve commercial success. For sales of drug candidates in niche but underserved markets, we plan to build our in-house commercial team by recruiting experienced senior-level sales and marketing personnel to support and facilitate the commercialization of our drug candidates. For sales of multi-indication drug candidates in highly competitive markets and drug candidates with extensive patient coverage, we will work with most suitable collaboration partners such as contract sales organizations (CSOs) to leverage their sales and marketing expertise, well-established business networks and experienced teams. For sales of drug candidates outside China, we also intend to seek strategic collaboration opportunities with local expertise for commercialization. We believe these strategic collaborations could expedite commercialization process of potential products and help us capture a substantial share of the chronic cancer treatment market.

### **Continue to attract, cultivate and retain talents**

Our employees are key to our strategy and ability to develop and commercialize innovative drugs, and hence we will continue to recruit, train, promote and retain talents with relevant background and experience in the pharmaceutical and biotech industries. We have established R&D centers in Shanghai and Beijing, and will establish in the U.S. in the future to execute our development strategy and to tap the talent pool of well-trained talents. To fully support our continued growth, we will continue to invest in attracting and retaining top talent in various aspects of our operations around the world, including discovery, research and development, manufacture and commercialization. In addition, in order to ensure our compliance with various standards, such as GLP, GCP and GMP regulations, we will continue to invest in enhancing our talent pool in terms of regulatory compliance.

To attract and retain talent, we are committed to the continued development of a collegial and vibrant corporate culture that inspires and encourages innovation. We will continue to provide our employees with various internal and external training opportunities to help them stay abreast of industry developments and further improve their technical skills. In addition, we

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will continue to utilize and optimize our employee incentive schemes to attract and retain highly talented professionals with a passion for building a career in the pharmaceutical and biotech industry. Meanwhile, we will identify leadership talents from an early stage and cultivate them to take on greater responsibilities along with their personal growth through internal training, promotion programs and initiatives. With these measures, we plan to further expand our sustainable talent pool to support our future development.

### OUR CORE PRODUCT AND OTHER DRUG CANDIDATES

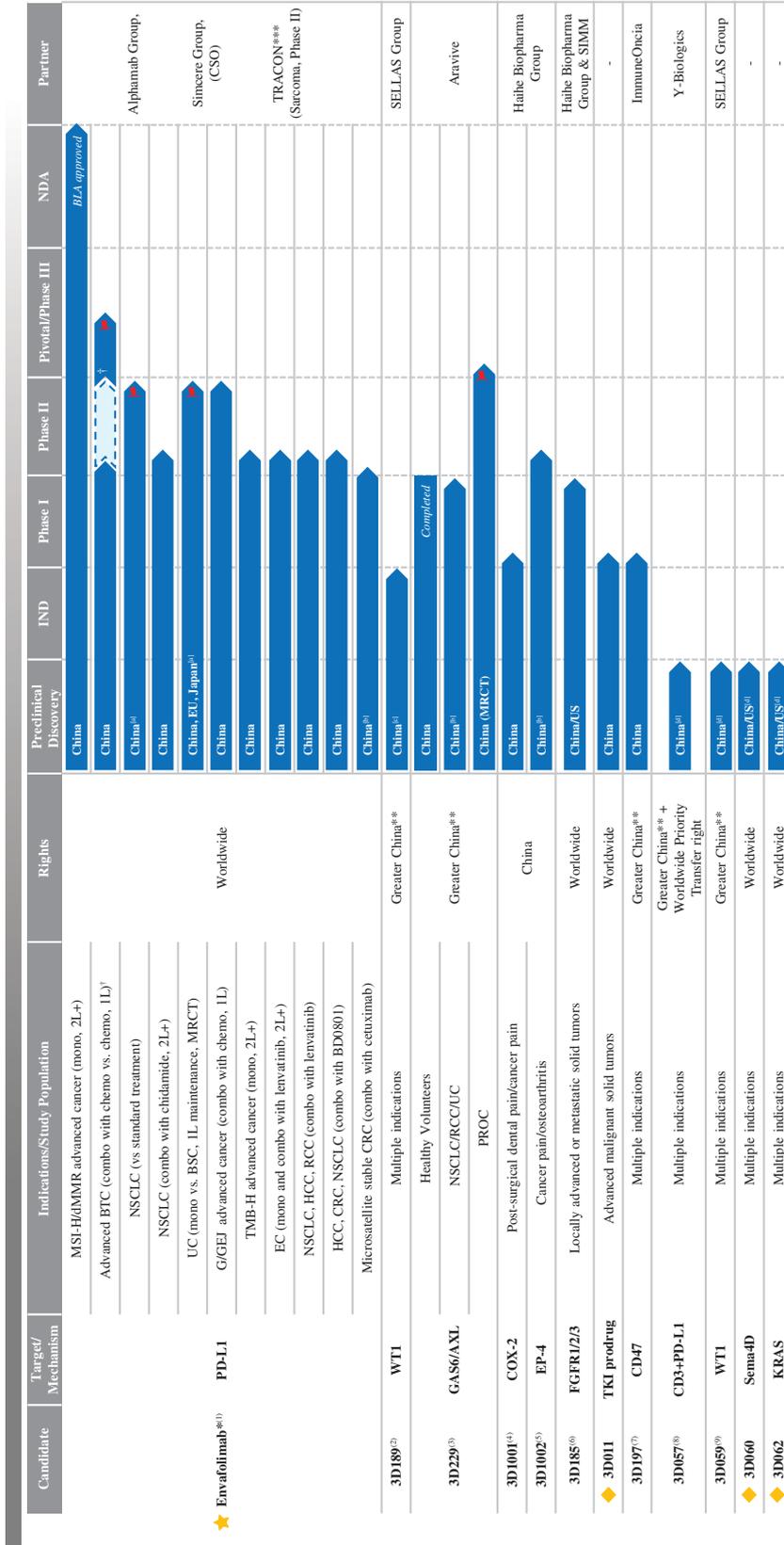
Our core business model is to discover, research, develop and commercialize oncology products and drug candidates by building a differentiated pipeline of innovative products and drug candidates with a potential to create significant synergy as combination therapies to address global unmet medical needs through a combination of in-house discovery, co-development and in-licensing. Leveraging our strong capabilities in drug discovery, clinical research and development, we have built a pipeline consisting of one Core Product and 11 drug candidates. Among our product and drug candidates, the Core Product envafolimab (brand name: ENWEIDA, 恩維達<sup>®</sup>), as our backbone, was approved in November 2021 and commercialized in December 2021, and seven are in clinical stage. Three of these product and clinical-stage drug candidates have entered into Phase II/III pivotal trials, two of which are conducted by our collaboration partners. Our Core Product envafolimab, a fusion protein of single domain PD-L1 antibody and fragment crystallizable (Fc), is a subcutaneously injectable single domain PD-L1 antibody. We spent only four years moving envafolimab from the IND stage to the BLA stage. In December 2020, the NMPA accepted our BLA for envafolimab as a monotherapy in the treatment of previously treated MSI-H/dMMR advanced solid tumors based on results from our completed pivotal trials in China, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for this indication from the NMPA, and we are the marketing authorization holder (MAH). It has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Envafolimab is currently being evaluated in two other ongoing pivotal clinical trials including a randomized Phase III clinical trial in combination with gemcitabine and oxaliplatin in patients with advanced biliary tract carcinoma (BTC) in China, and a Phase II clinical trial as monotherapy and in combination with ipilimumab in selected types of advanced sarcoma (SC) in the U.S. sponsored by our partner TRACON.

Our peptide cancer vaccine 3D189 (also known as Galinpepimut-S) is currently being evaluated by our partner SELLAS Group in an ongoing Phase III pivotal trial in the U.S. and Europe for the treatment of acute myeloid leukemia (AML) and we obtained the IND approval in China in March 2022. Our GAS6 decoy receptor 3D229 (also known as batiraxcept, AVB-500) was submitted the IND in March 2021 and received the IND approval in China in May 2021 and is being evaluated by our partner Aravive in a Phase III pivotal trial in the U.S. and Europe for the treatment of platinum resistant ovarian cancer (PROC). We plan to join both aforementioned advanced trials to expedite our development and commercial process in China.

With technologies and industry know-how accumulated by our management team over 20 years, we have established a pharmaceutical discovery and clinical R&D platform which serves as the foundation of our continuous innovations. Leveraging such platform, we have developed a synergetic pipeline of product and drug candidates.

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The following chart summarizes the development status of our product, clinical-stage drug candidates and selected pre-clinical stage drug candidates as of the Latest Practicable Date:



★ Co-owned Asset    ◆ Proprietary Asset    ▲ Pivotal Trial

\* Denotes our Core Product  
 \*\* Greater China includes China, Hong Kong, Macau and Taiwan region.  
 \*\*\* TRACON is a licensee of envafolimab for the U.S., Canada and Mexico.  
 [a] Preparing for Phase III clinical trial  
 [b] Preparing for Phase II clinical trial  
 [c] Preparing for IND filing  
 [d] Pre-clinical stage

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*Abbreviations:* MSI-H/dMMR = microsatellite instability-high/mismatch repair deficiency; BTC = biliary tract cancer; NSCLC = non-small cell lung cancer; UC = urothelial cancer; BSC = best supportive care; MRCT = multi-regional clinical trial; G/GEJ = gastric or gastroesophageal junction; TMB-H = tumor mutational burden-high; EC = endometrial cancer; HCC = hepatocellular carcinoma; RCC = renal cell carcinoma; CRC = colorectal cancer; PROC = platinum resistant ovarian cancer; IND = investigational new drug application; BLA = biologics license application; 1L = first-line; 2L+ = second-line or later

### *Notes:*

- (1) We maintain the rights to develop envalfolimab globally in oncology field through our co-development agreement with Alphamab Group. On December 17, 2020, the NMPA accepted the BLA for envalfolimab for previously treated MSI-H/dMMR advanced solid tumors, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for envalfolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors. On January 16, 2020, the FDA granted envalfolimab with orphan drug designation for the treatment of advanced BTC. On June 28, 2021, the FDA granted envalfolimab with orphan drug designation for the treatment of soft tissue sarcoma. The commencement of each of the clinical trials for the treatment of previously treated MSI-H/dMMR advanced solid tumors, advanced BTC and G/GEJ cancer were based on the initial safety and efficacy data across multiple dose levels from the three then-ongoing Phase I clinical trials in advanced solid tumors in China, the U.S., and Japan.
- (2) We own the exclusive rights to develop, manufacture and commercialize 3D189 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses through our exclusive license agreement with SELLAS Group. We obtained the IND approval for 3D189 in China in March 2022 and we plan to join the MRCT with our partner SELLAS Group. 3D189 has been granted fast track and orphan drug designations by the FDA for the treatment of AML.
- (3) We own the exclusive rights to develop, manufacture and commercialize products that contain 3D229 as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in China, Hong Kong, Macau and Taiwan region through our collaboration and license agreement with Aravive. Stanford licensed the technology that is used by Aravive to develop 3D229 and Aravive licensed 3D229 to us. We completed the Phase I clinical trial in healthy volunteers in China in May 2022. In addition, we received the IND approval for 3D229 for a Phase III clinical trial in patients with PROC in China in July 2021 to participate in the MRCT, and we initiated this Phase III clinical trial in China in February 2022.
- (4) We own the exclusive rights to develop, manufacture and commercialize 3D1001 in China in the pain indication field through our license agreement with Haihe Biopharma Group.
- (5) We own the exclusive rights to develop, manufacture and commercialize 3D1002 in China in the pain indication field through our license agreement with Haihe Biopharma Group.
- (6) We own the exclusive rights to develop, manufacture and commercialize 3D185 globally in the oncology and pulmonary fibrosis treatment through our patent license agreements with Haihe Biopharma and Shanghai Institute of Materia Medica, Chinese Academy of Sciences.
- (7) We own the exclusive rights to develop, manufacture and commercialize 3D197 in China, Hong Kong, Macau and Taiwan region in respect of oncology indications through our exclusive license agreement with Y-Biologics.
- (8) We own the exclusive rights to develop, manufacture and commercialize 3D057 in China, Hong Kong, Macau and Taiwan region for all therapeutic areas through our license agreement with Y-Biologics.
- (9) We own the exclusive rights to develop and commercialize 3D059 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses through our exclusive license agreement with SELLAS Group. MSK licensed certain know-how relating to 3D059 to SELLAS, which in turn sub-licensed the same to us.  
† The study included an interim analysis after the first 100 patients were enrolled (considered to be equivalent to a Phase II clinical trial) in the pivotal Phase III clinical trial for the treatment of advanced BTC, which has been designed with reference to the sufficient regulatory basis as described below. As advised by our PRC Legal Advisers, according to the Technical Guiding Principles of Clinical Trials of Anti-tumor Drugs (抗肿瘤药物临床试验技术指导) effective as of May 15, 2012, the clinical studies of anti-tumor drugs are generally divided into phase I, phase II and phase III clinical trials. The primary objectives of a phase I clinical trial include the preliminary studies of the tolerability and pharmacokinetics profile of the drugs, which provides data support to the dosage regimen design of subsequent studies. A phase II clinical trial is typically an exploratory study, such as the exploration of administration dosage, the exploration of dosage regimen and the exploration of efficacy, and includes the observation of safety. A phase III clinical trial further confirms the benefits for cancer patients on top of the results of the phase II clinical trial, and provide adequate evidence for obtaining marketing approval. However, the phases of the aforementioned clinical studies are not necessarily fixed. For instance, an exploratory study (i.e. phase II clinical trial) may also be a part of a phase III clinical trial. Specifically, a phase III clinical trial requires to generate efficacy data, of clinical benefit and the duration of the phase III trial is relatively long. Therefore, a phase III clinical trial may include an element of exploratory research allowing the adjustments of its clinical trial protocol or conduct pursuant to the interim analysis and accumulated information. In the field of oncology clinical research, the objectives of a traditional phase II study are increasingly commonly achieved through an expanded Phase I study design or by introducing an interim analysis in the phase III study. This approach has enabled a more efficient clinical development of oncology drugs in recent years.



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### 1. Our Core Product

#### a. *Envafolimab*

Envafolimab (brand name: ENWEIDA, 恩維達<sup>®</sup>), also known as KN035, a fusion protein of single domain PD-L1 antibody and Fc, is a subcutaneously injectable PD-L1 antibody, and it has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Compared with the other approved PD-1/PD-L1 antibodies, our envafolimab has demonstrated favorable clinical safety profile and consistent clinical efficacy results, and it potentially has better patient compliance with increased convenience, wider patient coverage and may reduce indirect cancer treatment cost for patients. Envafolimab has been well acknowledged by the Chinese clinical oncology community and recommended by three updated Chinese Society of Clinical Oncology (CSCO) 2022 Guidelines, including: (1) CSCO Guidelines for Gastric Cancer 2022 Version (Class I recommendation, Level 2A evidence); (2) CSCO Guidelines for Colorectal Cancer 2022 Version (Class II recommendation, Level 2A evidence), and (3) CSCO Guidelines for Clinical Application of Immune Checkpoint Inhibitors 2022 Version (Class I recommendation, Level 2A evidence). Envafolimab was in pre-clinical stage when the Co-Development Agreements were first entered into between the Company and Alphamab Group in February 2016. Since then, we have independently completed and been independently conducting a number of clinical trials in relation to envafolimab and achieved a number of major R&D milestones on our own and at our own cost, which amounted to approximately RMB614.9 million as of May 31, 2022, and we have significantly increased our R&D team to 151 members as of the Latest Practicable Date. Pursuant to our Co-Development Agreements with Alphamab Group, we are solely responsible for, and are conducting, global clinical development of envafolimab, which has undergone clinical trials for multiple tumor indications in the U.S., China and Japan.

We have completed a Phase II pivotal trial with single agent envafolimab for the treatment of previously treated MSI-H/dMMR advanced cancer and the results of this trial provided data for the initial BLA submission in China. On December 17, 2020, the NMPA accepted the BLA for envafolimab in the treatment of previously treated MSI-H/dMMR advanced solid tumors, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for this indication from the NMPA. In addition, we have completed an exploratory Phase II clinical trial in China with envafolimab in combination with chemotherapy as a first-line treatment in advanced gastric or gastroesophageal junction (G/GEJ) cancer and three Phase I trials with single agent envafolimab conducted in China, the U.S. and Japan, respectively.

We are currently evaluating envafolimab in late-stage clinical trials covering three tumor indications, in an attempt to address the significantly unmet or underserved medical needs in treating cancer, including (i) a randomized Phase III pivotal clinical trial in China as a first-line therapy in combination with chemotherapy for advanced BTC, (ii) a Phase II pivotal trial in the U.S. as monotherapy and in combination with ipilimumab in selected types of advanced SC sponsored by TRACON, and (iii) a Phase II clinical trial in China for the treatment of TMB-H advanced solid tumors. On January 16, 2020, the FDA granted envafolimab with orphan drug designation for the treatment of advanced BTC. On June 28, 2021, the FDA granted

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envafolimab with orphan drug designation for the treatment of soft tissue sarcoma. In addition, a number of new clinical studies investigating single agent envafolimab or envafolimab in combination with other agents for a variety of indications are being initiated or ongoing, including non-small cell lung cancer (NSCLC), urothelial carcinoma (UC), endometrial cancer (EC), hepatocellular carcinoma (HCC), renal cell carcinoma (RCC), and colorectal cancer (CRC).

The commencement of each of the clinical trials for the treatment of previously treated MSI-H/dMMR advanced solid tumors, advanced BTC and G/GEJ cancer (the “**Phase II/III Clinical Trials**”) were based on the initial safety, efficacy and PK data across multiple dose levels from Phase I clinical trials in advanced solid tumors in China, the U.S., and Japan (the “**Phase I Clinical Trials**”).

### *Clinical Basis*

We had sufficient clinical basis to commence the Phase II/III Clinical Trials based on the initial safety, efficacy and PK data of the Phase I Clinical Trials.

The Phase I Clinical Trials were single-arm, open-label, dose escalation and dose expansion Phase I studies of envafolimab as monotherapy. The Phase I Clinical Trials enrolled various tumor types that served as basis for indication selection in subsequent phase II/III studies including but not limited to the previously treated MSI-H/dMMR advanced solid tumors, advanced BTC and G/GEJ. In other words, the previously treated MSI-H/dMMR advanced solid tumors, advanced BTC, and G/GEJ are types of “advanced solid tumors” already covered by the extensive Phase I Clinical Trials in advanced solid tumors. According to the clinical trial protocols of the Phase I Clinical Trials, the primary endpoints of these trials were safety and tolerability and the secondary endpoints of these trials included PK, efficacy, immunogenicity and recommended phase II dose. As of March 20, 2018 (before the commencement of each of the Phase II/III Clinical Trials), 61 subjects were enrolled in these three Phase I Clinical Trials with dose level ranging from 0.01 mg/kg QW to 10.0 mg/kg QW and the follow-up time of the first patient had reached 57 weeks. Prior to the commencement of the Phase II/III Clinical Trials, the initial safety, efficacy and PK data of the Phase I Clinical Trials were as follows:

- **Safety:** The safety data across the Phase I Clinical Trials were consistent. No dose limiting toxicity (DLT) occurred and no unexpected safety signal was observed. The occurrence of treatment emergent adverse event (TEAE) were consistent with other marketed PD-1/PD-L1 inhibitors and there was no clear dose-response relationship on safety.
- **Efficacy:** Among 25 subjects who received at least one post-treatment efficacy assessment, 4 subjects achieved partial response (1 subject in 0.3 mg/kg QW, 1 subject in 1.0 mg/kg QW and 2 subjects in 2.5 mg/kg QW). In particular, 1 subject treated at 2.5 mg/kg QW was subject with MSI-H prostate cancer, which served as the basis for our choice of indication.

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- PK Profile: The data generated from the trial in China and the U.S. showed favorable PK profile, which supported the dose level of 2.5 mg/kg QW, 150 mg QW and 5.0 mg/kg Q2W were reasonable dosing regimens, which could be used in these subsequent clinical studies.

After obtaining the initial safety, efficacy and PK data of the Phase I Clinical Trials, we had in-depth discussions with principal investigators regarding such initial safety, efficacy and PK data. We and principal investigators were of the view that, based on above initial safety, efficacy and PK data of the Phase I Clinical Trials, the primary and secondary endpoints had been verified in accordance with the study design requirements of clinical trial protocols. Specifically, envafolimab had showed favorable safety and tolerability profile, promising anti-tumor activities and efficacy signal on specific indications. Therefore, we and principal investigators were of the view that such initial safety, efficacy and PK data could support the commencement of next phase of studies of envafolimab.

Accordingly, the following Phase II/III Clinical Trials were proposed and their protocols were well prepared and signed off by us and principal investigators and approved by the respective ethics committees:

- MSI-H/dMMR (pivotal Phase II): Based on initial safety, efficacy and PK data of the Phase I Clinical Trials, we selected 150 mg QW dose regimen (equivalent of 2.5 mg/kg assuming 60 kg body weight) for the pivotal Phase II clinical trial for the treatment of previously treated MSI-H/dMMR advanced solid tumors. On April 17, 2018, the leading principal investigator signed off the protocol (1.0st version) of this trial. On May 15, 2018, this trial was approved by the ethics committee. On July 25, 2018, this trial was duly registered on the registration and information announcement platform for clinical trials of drugs (the "**Information Platform**", <http://www.chinadrugtrials.org.cn/>) as required under the relevant NMPA regulations. On August 22, 2018, we enrolled the first patient for this trial.
- Advanced BTC (pivotal Phase III): Based on initial safety, efficacy and PK data of the Phase I Clinical Trials, we selected a dose level of 2.5 mg/kg QW for the pivotal Phase III clinical trial for the treatment of advanced BTC. On December 13, 2017, the leading principal investigator signed off the protocol (1.0st version) of this trial. On December 28, 2017, this trial was approved by the ethics committee. On April 9, 2018, this trial was duly registered on the Information Platform as required under the relevant NMPA regulations. On April 23, 2018, we enrolled the first patient for this trial.
- G/GEJ cancer (Phase II): Based on initial safety, efficacy and PK data of the Phase I Clinical Trials, we selected a dose level of 5.0 mg/kg Q2W for the exploratory Phase II clinical trial for the treatment of G/GEJ cancer. On June 6, 2018, the leading principal investigator signed off the protocol (1.0st version) of this trial. On

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June 29, 2018, this trial was approved by the ethics committee. On July 24, 2018, this trial was duly registered on the Information Platform as required under the relevant NMPA regulations. On August 31, 2018, we enrolled the first patient for this trial.

### *Industry Practice*

According to Frost & Sullivan, for PD-1/PD-L1 inhibitors, it is a common industry practice to commence the next phase of clinical studies once the primary endpoints of Phase I studies, being safety and tolerability are verified. Specifically, the Phase I dose escalation studies of marketed PD-1/PD-L1 had studied a series of dose levels ranging from 0.1 mg/1.0 mg/kg to 10.0 mg/kg Q2W and the results had shown that the safety and efficacy profile of PD-1/PD-L1 inhibitors would not change significantly once certain dose level (i.e. 0.3 mg/kg) have been reached, which showed a flat exposure-response (E-R) characteristic on both safety and efficacy. Based on this flat E-R characteristic of PD-1/PD-L1 inhibitors, certain marketed PD-1/PD-L1 inhibitors in the industry commenced their phase II/III studies based on the initial results of their Phase I studies.

### *The Competent Authority had no objection for us to commence each of the Phase II/III Clinical Trials based on the initial safety, efficacy and PK data from the Phase I Clinical Trials*

As advised by our PRC Legal Advisers, according to the laws and regulations in relation to drug clinical trials applicable to the development of the Core Product, prior to commencing a clinical trial, an applicant who has obtained an IND approval shall formulate a drug clinical trial protocol and obtain approval from the ethics committee, and the applicant shall also submit the protocol and supporting documents through the Information Platform. The applicable laws and regulations do not require the applicant who has obtained an umbrella IND approval to submit any additional clinical trial application prior to the commencement of phase II or phase III clinical trial, which means that the applicant does not need to obtain any additional IND approval and there is no additional requirement for such applying for such approval.

Prior to obtaining no objection from CDE to commence the Phase II/III Clinical Trials, neither NMPA nor CDE has raised any additional requirements in relation to the Phase I Clinical Trial in China. We have obtained approvals from ethics committee for each of the Phase II/III Clinical Trials (the “**Ethics Committee Approvals**”) and have duly registered each of the Phase II/III Clinical Trials on the Information Platform. Neither the Ethics Committee Approvals nor the information registered on the Information Platform contained any additional requirements raised by the ethics committee or the CDE. Furthermore, in the Regulatory Interview, NMPA/CDE did not raise any additional requirements in relation to the Phase I Clinical Trials in China.

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As advised by our PRC Legal Advisers, on the basis that (i) the Umbrella IND Approval granted by the NMPA in December 2016 was a one-time umbrella approval for the clinical trials of envafolimab including all phases of Phase I, Phase II and III, which was confirmed by Frost & Sullivan with reference to the industry practice; (ii) we had consulted CDE regarding the Phase I Clinical Trials and each of the Phase II/III Clinical Trials; (iii) each of the Phase II/III Clinical Trials were duly registered on the Information Platform as required by the relevant PRC rules and regulations; (iv) the consents from ethics committees in relation to each of the Phase II/III Clinical Trials were granted; and (v) the interview with a senior officer of NMPA conducted on February 21, 2022 with the attendance of professional parties (the “**Regulatory Interview**”) reconfirms, amongst others, that based on the initial safety, efficacy and PK data across multiple dose levels from the Phase I Clinical Trials, that NMPA had no objection for us to commence each of the Phase II/III Clinical Trials, we have obtained all required approvals from the NMPA to proceed with each of the Phase II/III Clinical Trials and no further approval from the NMPA is required for us to commence each of the Phase II/III Clinical Trials.

In the view of our legal advisers as to intellectual property law, we are exclusively entitled to use the patent in the field of oncology or tumor therapy. Besides, we maintain the rights to develop envafolimab globally in oncology field and obtained all the intellectual property rights relating to envafolimab under the Co-Development Agreements. Please refer to the paragraphs headed “Our Collaboration Arrangements – Collaboration with Alphamab Group for Envafolimab” in this section. Under the Co-Development Agreements, with respect to research and development, we are solely responsible for the clinical stage R&D activities in relation to envafolimab. Since the Co-Development Agreements were first entered into in February 2016, we have independently achieved the following major R&D milestones on our own and at our own costs:

- In November 2016, we received the IND approval for envafolimab from FDA for solid tumors;
- In December 2016, we received an umbrella IND approval for Phase I, II and III trials for envafolimab from NMPA;
- In February 2017, we launched (i.e. the first patient was enrolled) a first-in-human Phase I clinical trial of envafolimab in subjects with advanced solid tumors in the U.S.;
- In March 2017, we launched (i.e. the first patient was enrolled) a Phase I clinical trial of envafolimab in subjects with advanced solid tumors in China;
- In May 2017, we received the IND approval for envafolimab from PMDA for solid tumors;
- In October 2017, we launched (i.e. the first patient was enrolled) a Phase I clinical trial of envafolimab in subjects with advanced solid tumors in Japan;

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- In April 2018, we launched (i.e. the first patient was enrolled) a randomized Phase III clinical trial of envafolimab for the treatment of advanced BTC in China;
- In August 2018, we launched (i.e. the first patient was enrolled) a pivotal Phase II clinical trial of envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors;
- In August 2018, we launched (i.e. the first patient was enrolled) an exploratory Phase II clinical trial of envafolimab in combination with chemotherapy for the treatment of advanced G/GEJ cancer in China;
- In January 2020, we received orphan drug designation from FDA for envafolimab for the treatment of advanced BTC;
- In April 2020, we completed the Phase I clinical trial of envafolimab in subjects with advanced solid tumors in China;
- In July 2020, we completed the pivotal Phase II clinical trial of envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors;
- In December 2020, we obtained the BLA acceptance from NMPA for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors;
- In January 2021, the BLA for envafolimab in the treatment of previously treated MSI-H/dMMR advanced solid tumors was publicly announced to be accepted for priority review by NMPA;
- In February 2021, we completed the exploratory Phase II clinical trial of envafolimab in combination with chemotherapy for the treatment of advanced G/GEJ cancer in China;
- In March 2021, we completed the Phase I clinical trial of envafolimab in subjects with advanced solid tumors in Japan;
- In June 2021, we received the IND approval for envafolimab from NMPA for a Phase Ib/II clinical trial in combination with lenvatinib for the treatment of advanced solid tumors;
- In July 2021, we received the IND approval for envafolimab from NMPA for a Phase II clinical trial in combination with chidamide for the treatment of NSCLC;
- In July 2021, we received the IND approval for envafolimab from FDA for a Phase II clinical trial for the treatment of advanced BTC;

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- In July 2021, we received the IND approval for envafolimab from NMPA for a Phase II clinical trial in combination with BD0801 for injection with or without chemotherapy for the treatment of advanced solid tumors;
- In September 2021, we received the IND approval for envafolimab from NMPA for a Phase II clinical trial for the treatment of EC;
- In October 2021, we completed the Phase I clinical trial of envafolimab in subjects with advanced solid tumors in the U.S.; and
- In November 2021, we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors.

The table below shows the indications for which we are currently evaluating envafolimab in clinical trials:

Indication <sup>(1)</sup>	Status				
	IND	Phase I	Phase II	Phase III	NDA/BLA (Approved)
<b>China</b>					
Advanced solid tumors <sup>(2)</sup>	●	●			
MSI-H/dMMR	●		● (pivotal)		●
Advanced BTC <sup>(3)</sup>	●			⓪ (pivotal)	
G/GEJ	●		●		
NSCLC (combination with chidamide)	●		⓪		
NSCLC, HCC, RCC (combination with lenvatinib)	●		⓪		
EC (combination with lenvatinib)	●		⓪		
TMB-H	●		⓪		
HCC, CRC, NSCLC (combination with BD0801)	●		⓪		
<b>U.S.</b>					
Advanced solid tumors <sup>(2)</sup>	●	●			
SC (sponsored by TRACON)	●		⓪ (pivotal)		
<b>Japan</b>					
Advanced solid tumors <sup>(2)</sup>	●	●			

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*Abbreviations:* MSI-H/dMMR = microsatellite instability-high/mismatch repair deficiency; NSCLC = non-small cell lung cancer; BTC = biliary tract cancer; HCC = hepatocellular carcinoma; RCC = renal cell carcinoma; EC = endometrial cancer; G/GEJ = gastric or gastroesophageal junction cancer; TMB-H = tumor mutational burden-high; CRC = colorectal cancer; SC = sarcoma.

Symbols: ● = complete; ○ = in progress (a clinical trial is deemed to have been initiated when the first study site is activated)

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*Notes:*

- (1) Some indications may not require every phase of the clinical trials indicated on this chart to be completed in the same tumor type prior to the filing of an NDA/BLA.
- (2) The Phase I clinical trials for advanced solid tumors in China, the U.S., and Japan covered various solid tumor types including the tumor types studied by subsequent clinical trials.
- (3) The study included an interim analysis after the first 100 patients were enrolled (considered to be equivalent to a Phase II clinical trial) in the pivotal Phase III clinical trial for the treatment of advanced BTC, which has been designed with reference to the sufficient regulatory basis as described below. As advised by our PRC Legal Advisers, according to the Technical Guiding Principles of Clinical Trials of Anti-tumor Drugs (抗腫瘤藥物臨床試驗技術指導) effective as of May 15, 2012, the clinical studies of anti-tumor drugs are generally divided into phase I, phase II and phase III clinical trials. The primary objectives of a phase I clinical trial include the preliminary studies of the tolerability and pharmacokinetics profile of the drugs, which provides data support to the dosage regimen design of subsequent studies. A phase II clinical trial is typically an exploratory study, such as the exploration of administration dosage, the exploration of dosage regimen and the exploration of efficacy, and includes the observation of safety. A phase III clinical trial further confirms the benefits for cancer patients on top of the results of the phase II clinical trial, and provide adequate evidence for obtaining marketing approval. However, the phases of the aforementioned clinical studies are not necessarily fixed. For instance, an exploratory study (i.e. phase II clinical trial) may also be a part of a phase III clinical trial. Specifically, a phase III clinical trial requires to generate efficacy data of clinical benefit and the duration of the phase III trial is relatively long. Therefore, a phase III clinical trial may include an element of exploratory research allowing the adjustments of its the clinical trial protocol or conduct pursuant to the interim analysis and accumulated information. In the field of oncology clinical research, the objectives of a traditional phase II study are increasingly commonly achieved through an expanded Phase I study design or by introducing an interim analysis in the phase III study. This approach has enabled a more efficient clinical development of oncology drugs in recent years.

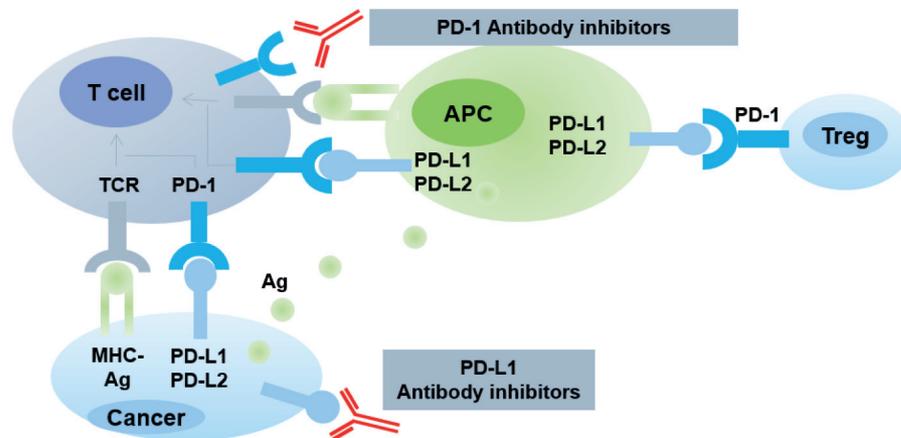
*i. Mechanism of Action*

Under normal conditions, T cells are activated in response to foreign antigens (Ag). Antigen-presenting cells (APCs) process and present Ag to activate T cells through T-cell receptor (TCR) and major histocompatibility complex (MHC) binding. Activated T cells play critical roles in regulating immune response of human body, including recognizing and killing cancer cells. To prevent activated T cells from attacking healthy body tissues, regulatory T cells (Treg) express immune checkpoint receptors, such as PD-1, on their surface to limit overstimulation of the immune system after antigen encounter.



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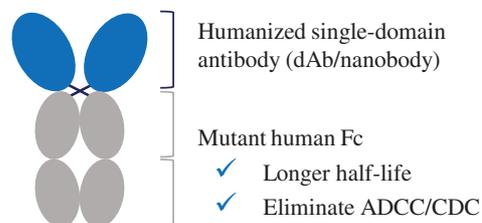
PD-L1 is an important ligand protein that can engage PD-1. The binding of PD-L1, expressed on the surface of normal cells, to PD-1 on the surface of T cells can deliver a negative signal to T-cells, leading to inhibition on immune response. However, it has been found that tumor cells can overexpress PD-L1 to protect themselves from being detected and killed by T cells. A PD-L1 antibody binds to PD-L1 and blocks PD-L1 from binding to PD-1, which allows T cells to kill tumor cells. The diagram below shows the mechanism of action of a PD-L1 antibody:



*Abbreviations:* Ag = antigen; APC = antigen-presenting cells; TCR = T-cell receptor; MHC = major histocompatibility complex; Treg = regulatory T cell.

*Source: American Cancer Society, Front Cell Dev Biol. 2020; 8: 672., Frost & Sullivan Report*

Envafolelimab is a novel fusion protein consisting of a single-domain antibody (sdAb) fused with a human fragment crystallizable (Fc) region that binds to PD-L1 and blocks PD-L1 from binding to PD-1. As illustrated by the diagram below, as a recombinant fusion protein, envafolelimab consists of two identical polypeptide chains linked via a pair of disulfide bonds. Each chain contains a human IgG1 Fc fragment and sdAb, which are obtained from a focused phage library, derived from peripheral blood mononuclear cells (PBMC) of human PD-L1 immunized camel, and humanized afterwards.



*Source: Company data*

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Due to the sdAb format, envafolimab has about half the molecular weight of a full-length conventional antibody with better stability, which enables it to have enhanced tissue penetrability while possessing a full antigen-binding capacity as compared with conventional PD-L1 antibodies. Envafolimab is also more water soluble than a conventional antibody, enabling a convenient subcutaneous injection. In addition, the Fc mediated effector functions are muted in envafolimab to minimize unwanted adverse immune responses.

### ii. Market Opportunities and Competition

PD-1/PD-L1 is a clinically-validated immune checkpoint for immuno-oncology therapies. To date, all of the immune checkpoint inhibitors on the market are conventional antibodies administered by intravenous infusion. The introduction of immune checkpoint inhibitors offers breakthrough treatment for certain cancer indications that previously lacked effective therapies. In 2020, the global sales of PD-1/PD-L1 inhibitors reached US\$28.6 billion, according to Frost & Sullivan.

As of the Latest Practicable Date, there were a total of 17 approved PD-1/PD-L1 monoclonal antibodies inhibitors in the global market, of which 11 target PD-1 and five target PD-L1. 16 of them are conventional antibodies administered by intravenous infusion. As of the Latest Practicable Date, there were 13 PD-1/PD-L1 inhibitors approved by the NMPA, including nine PD-1 inhibitors and four PD-L1 inhibitors, and seven PD-1/PD-L1 inhibitors approved by the FDA. The following table sets out details of the FDA approved PD-1/PD-L1 inhibitors for MSI-H/dMMR cancer in the U.S. as of the Latest Practicable Date.

Product	Drugs	Company	Immune Checkpoint	2021 Revenue (million)	Price (USD)	2020	Patent Expiration Date	FDA Approved Indications	Injection Methods	Date of Approval
						Annual Cost (thousand)				
Keytruda	Pembrolizumab	MSD	PD-1	\$17,186	25mg/ml 4ml: 5,264.7 8ml: 10,519.8	\$168.3	2037-07-18	MSI-H/dMMR solid tumors  First-line MSI-H/dMMR CRC	Intravenous	May 2017  June 2020
Opdivo	Nivolumab	Bristol Myers Squibb	PD-1	\$7,523	10mg/ml 4ml: 1,171.7 10ml: 2,914.9 24ml: 6,982.5	\$181.5	2037-06-01	MSI-H/dMMR CRC	Intravenous	August 2017
Jemperli	Dostarlimab-gxly	GlaxoSmithKline	PD-1	\$7	500mg/10ml: 10,835.1	\$184.2	2036-02-03	dMMR endometrial cancer  dMMR recurrent or advanced solid tumor	Intravenous	April 2021  August 2021

Abbreviations: MSI-H/dMMR = microsatellite instability-high/mismatch repair deficiency; CRC = colorectal cancer

Note: 2021 Revenue indicates sales revenue for all indications

Source: FDA, Annual Reports of Listed Pharmaceutical Companies, Company Official Websites, NRDL, Frost & Sullivan

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Prior to the BLA approval of envafolimab, all of the approved PD-1/PD-L1 inhibitors were required to be administered intravenously. However, intravenous formulation is inconvenient for patients because it requires frequent infusion services and some patients experience infusion reactions. In addition, around 10% cancer patients may not be eligible for intravenous formulation due to limited vein access caused by long-term and numerous drug treatments. Compared to all these approved PD-1/PD-L1 inhibitors, envafolimab can be subcutaneously administered, which is a more convenient administration form for patients that enables improved patient compliance and wider patient coverage. With the indication for previously treated MSI-H/dMMR advanced solid tumors, envafolimab is the first subcutaneously injectable PD-1/PD-L1 inhibitor to receive priority review for a tissue agnostic indication in China and it has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors.

Subcutaneous formulation is challenging for conventional antibodies due to limited solubility while requiring formulation development. Subcutaneous formulation has been developed for several conventional antibodies by adding hyaluronidase to facilitate subcutaneous absorption. However, these formulations typically require relatively large volume (over 2 mL) and take several minutes to administer. In contrast, full therapeutic dose of envafolimab of 0.75 mL (150 mg) is administered by a single injection in volume less than 1 mL that takes less than 30 seconds to administer. For subcutaneous formulation, the volume for each injection is typically under 2 mL, which is technically challenging for conventional antibodies formulated for subcutaneous injection.

### *iii. Competitive Advantages*

#### (1) A marketed subcutaneously injectable PD-L1 antibody

Envafolimab is a single-domain antibody with a molecular weight of about 80 kDa, which is smaller compared to other approved PD-1/PD-L1 antibodies. Benefitting from such unique molecular structure, envafolimab has about half the molecular weight of a full-length conventional antibody with better stability and higher solubility, which enables the development of high concentration formulation suitable for subcutaneous injection. Envafolimab is a subcutaneously injectable PD-L1 antibody, and it has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Compared with the other approved PD-1/PD-L1 antibodies, our envafolimab potentially has the following advantages as a result of its subcutaneous injection method:

- (a) Envafolimab may achieve better patient compliance with increased convenience. Subcutaneous formulation enables quicker administration and potential for self-injection in the future, which is more convenient for patients in long-term care and enables better patient compliance with the

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treatment regimen. It generally only takes less than 30 seconds to subcutaneously inject 0.75 mL (150 mg) of envafolimab. In addition, the observation time for subcutaneous injection is shorter than for intravenous infusion.

- (b) Envafolimab may achieve a wider patient coverage. Our envafolimab could be used in patients who are not eligible for intravenous administration, such as elderly patients who are vulnerable to complications of intravenous fluid overload, patients who are heavily treated with chemotherapy resulting in vein shrinkage, or other medical reasons making repeated intravenous infusions not feasible or desired. In addition, envafolimab provides an alternative for patients under the circumstance of public health crisis when they have limited access to hospitals.
  - (c) Envafolimab may be more cost-effective and better-received by patients. In addition to lower production costs, patients would also benefit from lower transportation and accommodation costs as subcutaneous injections can be administered at a wider range of facilities and institutions nearby, such that envafolimab may result in lower indirect cancer treatment cost as a whole.
  - (d) Envafolimab may have great potential to expand to the market of oncology drugs sold outside of hospital as a result of its safe and convenient subcutaneous administration method.
- (2) First PD-1/PD-L1 inhibitor under priority review for a tissue-agnostic indication in China

In December 2020, the NMPA accepted our BLA for envafolimab as a monotherapy for the treatment of previously treated MSI-H/dMMR advanced solid tumors based on results from our completed pivotal trial in China, and our BLA was granted priority review. On November 24, 2021, we received BLA approval for this indication from the NMPA. Our envafolimab is the first PD-1/PD-L1 inhibitor to receive priority review for a tissue agnostic indication in China, and it has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Therefore, it potentially has substantial competitive advantage and commercial potential in the market, with the potential to create significant synergies with the clinical development of other drug candidates.

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(3) Favorable clinical safety profile compared to other marketed PD-1/PD-L1 inhibitors

Based on data collected from our clinical studies, envafolimab has demonstrated a favorable safety profile, compared to other marketed PD-1/PD-L1 inhibitors, in addition to the benefit of no infusion-related reactions. As further illustrated in the table below, a low incidence of immune related pneumonitis (0.5%) and no immune-related colitis was observed based on pooled analyses of our pivotal clinical trial in previously treated MSI-H/dMMR advanced cancer and the Phase I clinical trial in China for envafolimab, and no infusion-related reaction was observed in these studies. Also, due to subcutaneous route of administration of envafolimab, injection site reactions can be observed, and the incidence of injection site reactions with envafolimab is low (~10%) and of mild to moderate severity. Please refer to the paragraphs headed “Our Core Product and Other Drug Candidates – 1. Our Core Product – a. Envafolimab – iv. Summary of Clinical Trials – (1) Pivotal Clinical Trial to Treat Previously Treated MSI-H/dMMR Advanced Cancer in China” in this section. Although these are not head-to-head studies, we believe that helpful insights can nonetheless be obtained from the comparison.

All level AE rate	Anti-PD-1 inhibitors					Anti-PD-L1 inhibitors			
	Nivolumab <sup>(1)</sup> (N=1994)	Pembrolizumab <sup>(2)</sup> (N=2799)	Sintilimab <sup>(3)</sup> (N=540)	Toripalimab <sup>(4)</sup> (N=598)	Camrelizumab <sup>(5)</sup> (N=986)	Avelumab <sup>(6)</sup> (N=1738)	Durvalumab <sup>(7)</sup> (N=1889)	Atezolizumab <sup>(8)</sup> (N=2616)	Envafolimab <sup>(9)</sup> (N=390)
<b>IR-Pneumonitis</b>	3.1%	3.4%	6.9%	1.8%	2.7%	1.2%	5%	2.5%	0.5%
<b>IR-Colitis</b>	2.9%	1.7%	0%	0%	0.2%	1.5%	-	1.0% <sup>(10)*</sup>	0%
<b>IR-Endocrine disease</b>									
Hypothyroidism	9%	8.5%	8.5%	12.9%	20.5%	5%	11%	4.6%	13.6%
Hyperthyroidism	2.7%	3.4%	4.3%	4.8%	6.7%	0.4%	7%	1.6%	9.0%
<b>IR-Myocarditis</b>	<1%	<1%	0.6%	-	0.3%	<1%	<1%	<1%	0.5%
<b>IR-Hepatitis</b>	1.8%	0.7%	3.5%	3.5%	9.1%	0.9%	12%	9%	3.6%
<b>Infusion reaction</b>	6.4%	3.0% <sup>(11)*</sup>	-	-	-	25%	2.2%	1.3%	0

\* Atezolizumab IR-colitis (1.0%; n=729); Pembrolizumab infusion reaction (3.0%; n=495)

*Notes:*

The above comparisons are not based on head-to-head clinical trials. The major limitation of the comparisons that are not based on head-to-head clinical trials is that it is not possible to determine if any differences noted between the efficacy measures of different drugs can solely be attributable to the drugs themselves. Instead, the differences may reflect differences in other aspects of the various clinical trials, such as populations, comparators and outcomes. As such, you are cautioned not to place undue reliance on the above cross-trial comparison results.

- (1) Nivolumab. HIGHLIGHTS OF PRESCRIBING INFORMATION, Reference ID: 4400635
- (2) Pembrolizumab. HIGHLIGHTS OF PRESCRIBING INFORMATION, Reference ID: 4492828
- (3) Center for Drug Evaluation of NMPA, Drug Application Technical Review Report of Sintilimab Injection (信迪利单抗注射液申請上市技術審評報告) (March 2019)
- (4) Center for Drug Evaluation of NMPA, Drug Application Technical Review Report of Toripalimab Injection (特瑞普利单抗注射液申請上市技術審評報告) (March, 2019)
- (5) Center for Drug Evaluation of NMPA, Drug Application Technical Review Report of Camrelizumab for Injection (注射用卡瑞利珠单抗申請上市技術審評報告) (July, 2019)
- (6) Avelumab. HIGHLIGHTS OF PRESCRIBING INFORMATION Reference ID: 4433254

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- (7) Durvalumab. HIGHLIGHTS OF PRESCRIBING INFORMATION Reference ID: 4465139
- (8) Atezolizumab. HIGHLIGHTS OF PRESCRIBING INFORMATION Reference ID: 4527935
- (9) From KN035-CN-006 (cut-off date: June 19, 2020) and KN035-CN-001 (Sep 2, 2019) studies.
- (10) Wang DY, et al, Onco 2017; 6; e1344805
- (11) Garon E B, et al, N Engl J Med, 2015, 372 (21)

*Source: Company data*

- (4) Consistent clinical efficacy results compared to other marketed PD-1/PD-L1 inhibitors

In our pivotal clinical trial to evaluate its treatment of previously treated MSI-H/dMMR advanced cancer, envafolimab achieved a confirmed objective response rate (ORR) of 42.7% per BIRC and a 12-month OS of 74.6%, and its efficacy is highly consistent with pembrolizumab and nivolumab. Please refer to the paragraphs headed “– Our Core Product and Other Drug Candidates – 1. Our Core Product – a. Envafolimab – iv. Summary of Clinical Trials – (1) Pivotal Clinical Trial to Treat Previously Treated MSI-H/dMMR Advanced Cancer in China” in this section. Although these are not head-to-head studies, we believe that helpful insights can nonetheless be obtained from the comparison.

*iv. Summary of Clinical Trials*

As of the Latest Practicable Date, we had evaluated the safety and efficacy profiles of envafolimab in five completed clinical trials and seven ongoing clinical trials, and three clinical studies being initiated with either pre-IND or IND submission completed. We have completed the pivotal trial for the treatment of previously treated MSI-H/dMMR advanced cancer in China, and we have two other ongoing pivotal trials respectively for the treatment of advanced BTC and selected types of advanced SC.

- (1) Pivotal Clinical Trial to Treat Previously Treated MSI-H/dMMR Advanced Cancer in China

We have completed a single-arm, multi-center, Phase II pivotal clinical trial to evaluate the efficacy and safety of envafolimab in subjects with previously treated MSI-H/dMMR advanced cancer in China. MSI-H/dMMR results in exceptionally high number of mutations and neoantigens and predicts sensitivity to PD-L1/PD-L1 inhibitor regardless of cancers’ tissue of origin. Patients with advanced MSI-H/dMMR cancer who failed standard of care have no satisfactory alternative treatment options and poor prognosis. Pembrolizumab and nivolumab have been approved for the treatment of patients with previously treated MSI-H/dMMR advanced colorectal cancer (CRC). Pembrolizumab was also approved for the treatment of other previously treated advanced tumor types (tissue agnostic

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indication). Pembrolizumab was recently approved for first-line treatment of MSI-H/dMMR advanced CRC. JEMPERLI (dostarlimab) was also recently approved by the FDA for the treatment of previously treated advanced dMMR solid tumors.

The efficacy and safety data of this trial was presented at the 2020 European Society for Medical Oncology Asia Virtual Congress in November, 2020. According to the data presented in the 2020 ESMO Asia Virtual Congress (the “**2020 ESMO Asia Presentation**”), 103 subjects with previously treated MSI-H/dMMR advanced cancer were enrolled in this trial from August 22, 2018 to December 5, 2019.

*Study purpose.* The primary endpoint of this trial was ORR per RECIST v1.1 by blinded independent radiology review (BIRC). The secondary endpoints of this trial were duration of response (DOR), disease control rate (DCR), progression free survival (PFS) and overall survival (OS).

*Study design.* This trial enrolled subjects who (i) were 18 years or older, (ii) had locally advanced or metastatic solid tumors, (iii) had centrally confirmed MSI-H for CRC, GC and locally confirmed dMMR for other tumors, (iv) had one or more prior line of systemic therapy, (v) ECOG PS between 0 and 1, and (vi) had measurable disease per RECIST v1.1.

Subjects received envafolimab at 150 mg on weekly basis with a single subcutaneous injection at a volume of 0.75 mL using a 1 c.c. syringe. Safety and tolerability would be assessed by monitoring treatment emergent adverse events (TEAEs), physical exams, and laboratory tests. Tumor assessments would be performed every eight weeks based on RECIST version v1.1.

According to the 2020 ESMO Asia Presentation, 103 subjects with previously treated MSI-H/dMMR advanced cancers were enrolled at 25 centers, including 65 subjects with CRC (41 failed  $\geq 2$  lines of prior therapies including fluoropyrimidine, oxaliplatin and irinotecan and 24 failed 1 line prior therapy including fluoropyrimidine and oxaliplatin or fluoropyrimidine and irinotecan), 18 subjects with GC and 20 subjects with other tumor types. As of June 19, 2020, the median follow-up was 11.5 month in the overall population (N=103).

*Efficacy.* The confirmed ORR per BIRC was 42.7% (95%CI: 33.0%-52.8%) in the overall population, 43.1% (95%CI: 30.8%-56.0%) in CRC, 44.4% (95%CI: 21.5%-69.2%) in GC and 40.0% (95%CI: 19.1%-63.9%) in other tumors. ORRs per investigators were consistent with BIRC assessment.

The median PFS per BIRC was 7.2 months (95% CI: 3.5, NE) for CRC population, and 11.1 months (95% CI: 5.5, NE) for the overall population. Median OS was not reached for any analyzed populations. The 12 month OS rate was 72.9%

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(95% CI: 60.1, 82.2) in CRC, 83.3% (95% CI: 56.8, 94.3) in GC, 75.0% (95% CI: 50, 88.7) in other tumors and 74.6% (95% CI: 64.7, 82.1) in overall population. The following tables summarize the efficacy results:

	<b>Advanced CRC (n=65)</b>					
	<b>total (n=65)</b>	<b>≥2 prior therapies* (n=41)</b>	<b>1 prior therapy** (n=24)</b>	<b>Advanced GC (n=18)</b>	<b>Other solid tumors (n=20)</b>	<b>Overall population (n=103)</b>
<b>Best of overall response, per BIRC</b>						
CR	3 (4.6%)	0	3 (12.5%)	0	2 (10.0%)	5 (4.9%)
PR	25 (38.5%)	13 (31.7%)	12 (50.0%)	8 (44.4%)	6 (30.0%)	39 (37.4%)
SD	12 (18.5%)	11 (26.8%)	1 (4.2%)	7 (38.9%)	5 (25.0%)	24 (23.3%)
PD	21 (32.3%)	13 (31.7%)	8 (33.3%)	2 (11.1%)	5 (25.0%)	28 (27.2%)
NE	4 (6.2%)	4 (9.8%)	0	1 (5.6%)	2 (10.0%)	7 (6.8%)
<b>ORR</b>	43.1%	31.7%	62.5%	44.4%	40.0%	42.7%
<b>DCR</b>	61.5%	58.5%	66.7%	83.3%	65.0%	66.0%
<b>DoR≥12 mos.</b>	88.4%	74.6%	100.0%	100.0%	100.0%	92.2%
<b>mPFS, mos.</b>	7.2	4.9	NR	NR	NR	11.1
<b>PFS, % at</b>						
<b>12 mos.</b>	43.7%	32.1%	62.5%	58.0%	52.6%	48.5%
<b>OS, % at 12 mos.</b>	72.9%	64.7%	87.1%	83.3%	75.0%	74.6%

Median follow up was 11.5 months in overall population, and 6.5 months for the last subject.

\* CRC with ≥2 prior therapies include those patients who were previously treated with fluoropyrimidine, oxaliplatin, and irinotecan containing regimens.

\*\* CRC with 1 prior therapy include those pts who were previously treated with a fluoropyrimidine and oxaliplatin, or a fluoropyrimidine and irinotecan containing regimen.

Source: *Efficacy and safety of envafolimab (KN035) in advanced tumours with mismatch-repair deficiency, 2020 European Society for Medical Oncology (ESMO) Asia Virtual Congress*



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As illustrated in the table below, the efficacy results of envafolimab were comparable to that reported for pembrolizumab and nivolumab monotherapy in similar populations.

	Pembrolizumab			Nivolumab <sup>(3)(4)</sup>	Envafolimab		
	KEYNOTE-164 <sup>(1)</sup>		KEYNOTE-158 <sup>(2)</sup>	CHECKMATE-142	KN035-CN-006		
Study population	CRC-cohort A (3 drugs failed CRC)	CRC-cohort B (overall CRC)	non-CRC (prior≥1 line)	3 drugs failed CRC	3 drugs failed CRC	Overall CRC	Overall population (prior≥1 line)
	Local/central lab verified MSI-H/dMMR	Local/central lab verified MSI-H/dMMR	Local/central lab verified MSI-H/dMMR	Local/central lab verified MSI-H/dMMR	Central lab verified MSI-H	Central lab verified MSI-H	Site/central lab verified MSI-H/dMMR
Sample size	61	63	233	53	41	65	103
ORR, %: IRC	33% (27.9% <sup>*</sup> )	33% (32% <sup>*</sup> )	34.3%	28%	31.7%	43.1%	42.7%
mPFS, months	2.3	4.1	4.1	–	4.9	7.2	11.1
6-m PFS rate	(43% <sup>*</sup> )	(49% <sup>*</sup> )	–	–	48.8%	53.8%	57.7%
mOS (months)	31.4	not reached	23.5	–	not reached	not reached	not reached
6-m OS rate	(87% <sup>*</sup> )	(84% <sup>*</sup> )	–	–	80.5%	84.5%	82.4%
12-m OS rate	72%	76%	60.7%	73%	64.7%	72.9%	74.6%

\* KEYNOTE 164 earlier published data<sup>(5)(6)</sup> 3 drugs failed: failed Fluorouracil, and Oxaliplatin and Irinotecan; 2 drugs failed, failed Fluorouracil combined with oxaliplatin or irinotecan

*Notes:*

The above comparisons are not based on head-to-head clinical trials. The major limitation of the comparisons that are not based on head-to-head clinical trials is that it is not possible to determine if any differences noted between the efficacy measures of different drugs can solely be attributable to the drugs themselves. Instead, the differences may reflect differences in other aspects of the various clinical trials, such as populations, comparators and outcomes. As such, you are cautioned not to place undue reliance on the above cross-trial comparison results.

- (1) J Clin Oncol. 2020 Jan 1; 38(1): 11-19
- (2) J Clin Oncol. 2020; 38(1): 1-10
- (3) Overman MJ, et al. Lancet Oncol. 2017; 18(9): 1182-1191
- (4) Opdivo (nivolumab). Highlights of Prescribing Information. Reference ID: 4427750ite.
- (5) Annals of Oncology. 2017; 28(S5): 128-129
- (6) ASCO 2018 Annual Meeting. 3514

*Source: Efficacy and safety of envafolimab (KN035) in advanced tumours with mismatch-repair deficiency, 2020 European Society for Medical Oncology (ESMO) Asia Virtual Congress*

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*Safety.* All grade (G) and G3-4 treatment-related adverse events (TRAE) in overall population were 84.5% and 15.5% separately. No G5 TRAE occurred. The most common immune-related TEAEs were hypothyroidism (15.5%) and hyperthyroidism (11.7%). No infusion-related reaction, pneumonitis, or colitis was reported. The occurrence of local injection-site reaction was 8.7% and were all G1-2. The following table summarizes drug related TEAEs in the subjects:

Occurrence ≥ 10% any grade drug related TEAEs	Overall population (N=103)		
	Any grade	Grade 3-4	Grade 5
Drug related TEAE	87 (84.5%)	16 (15.5%)	0
Laboratory test	56 (54.4%)	3 (2.9%)	0
white blood cell count decreased	17 (16.5%)	0	0
Neutrophils count decreased	12 (11.7%)	1 (1.0%)	0
General disease and injection site reactions	29 (28.2%)	0	0
fatigue	17 (16.5%)	0	0
Cutaneous reactions	21 (20.4%)	2 (1.9%)	0
rash	16 (15.5%)	1 (1.0%)	0
Endocrine disorders	21 (20.4%)	0	0
hypothyroidism	16 (15.5%)	0	0
hyperthyroidism	12 (11.7%)	0	0
Blood and lymphatic system disorders	12 (11.7%)	5 (4.9%)	0
anaemia	12 (11.7%)	5 (4.9%)	0

*Source: Efficacy and safety of envafolimab (KN035) in advanced tumours with mismatch-repair deficiency, 2020 European Society for Medical Oncology (ESMO) Asia Virtual Congress*

*Conclusion.* According to the 2020 ESMO Asia Presentation, envafolimab demonstrated durable antitumor activity in patients with previously treated MSI-H/dMMR advanced cancer. Safety profile was similar to the marketed PD-(L)1 antibodies but without infusion related reactions and potentially lower rates in pneumonitis or colitis. The data support envafolimab as a new safe and effective treatment option with durable benefit for patients with heavily-previously-treated MSI-H/dMMR advanced cancer.

(2) Phase III Pivotal Clinical Trial to Treat BTC in Combination with Chemotherapy in China

We are conducting a randomized, open-label, parallel, Phase III clinical trial in China. The study plan is to randomize approximately 480 subjects with previously untreated unresectable locally advanced or metastatic BTCs. The primary objective was to compare OS in subjects treated with envafolimab in combination with gemcitabine plus oxaliplatin (GEMOX) chemotherapy versus GEMOX alone. The

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first subject in this study was randomized on April 23, 2018. As of July 18, 2022, 472 subjects had been randomized. This trial is ongoing and no unblinded safety or efficacy data is currently available.

(3) Phase II Pivotal Clinical Trial to Treat Selected Types of SC in the U.S.

A multi-center, open-label, randomized, non-comparative, parallel cohort, Phase II pivotal clinical trial of envafolimab or envafolimab combined with ipilimumab in subjects with locally advanced, unresectable or metastatic undifferentiated pleomorphic sarcoma (UPS)/myxofibrosarcoma (MFS) is being conducted in the U.S. and sponsored by TRACON.

The primary endpoint is the ORR. Subjects are assigned at random into one of the two cohorts: cohort A that will receive single agent envafolimab (300 mg every 3 weeks by subcutaneous injection) or cohort B that will receive envafolimab (300 mg every 3 weeks by subcutaneous injection) in combination with ipilimumab (1 mg/kg every 3 weeks intravenously for four doses). Eighty subjects are to be enrolled into each cohort for a total of 160 subjects. The trial was granted the IND approval by the FDA on August 14, 2020. On June 1, 2021, Tracon announced that the Independent Data Monitoring Committee (IDMC) recommended to proceed as planned following the review of safety data from more than 20 patients (more than 10 patients from each arm) enrolled.

(4) Phase II Clinical Trial to Treat Advanced Gastric or Gastroesophageal Junction (G/GEJ) Cancer in Combination with Chemotherapy

We have completed a single-arm, multi-center, Phase II clinical trial to evaluate the safety and tolerability of combining envafolimab with chemotherapy in adult subjects with previously-untreated unresectable locally advanced or metastatic G/GEJ adenocarcinoma cancer in China.

*Study purpose.* The primary objective was to evaluate the safety and tolerability of envafolimab in combination with standard chemotherapy fluorouracil plus oxaliplatin (FOLFOX) regimen. The secondary objectives were to evaluate the ORR, DOR, DCR, PFS and OS of envafolimab in combination with FOLFOX.

*Study design.* Eligible subjects received up to eight cycles (two weeks each) of envafolimab plus FOLFOX regimen followed by envafolimab and 5-FU/leucovorin maintenance treatment until progression, death, unacceptable toxicity or withdraw of informed consent, whichever comes first. Envafolimab was administered subcutaneously at 5 mg/kg on day 1 of each cycle. FOLFOX consisted of 85 mg/m<sup>2</sup> oxaliplatin intravenous infusion on day 1 of each cycle, up to 8 cycles, 400 mg/m<sup>2</sup> 5-FU and 400 mg/m<sup>2</sup> leucovorin intravenous infusion on day 1, 2400 mg/m<sup>2</sup> 5-FU administered with a 48-hour continuous infusion on day 1 and 2 of each cycle. Tumor was assessed every six weeks per RECIST version 1.1. Safety assessments

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included adverse events, ECOG performance status, physical examination, laboratory changes (hematology, blood chemistry, coagulation, thyroid function, urinalysis, and blood pregnancy test), vital signs changes (blood pressure, heart rate, respiratory rate, and temperature), 12-lead ECG, and echocardiography. The severity of AEs was graded using Common Terminology Criteria for Adverse Events version 5.0 (CTCAE v 5.0).

A total of 15 subjects were enrolled and received treatment with envafolimab and FOLFOX regimen. The median age was 56 years, including 11 male subjects; the ECOG performance status score was 1 in 80% (12 subjects) and 0 in the rest subjects. The majority had gastric cancer (80.0%). All 15 (100.0%) subjects had tumors of clinical stage IV at baseline. At the data cutoff of July 15, 2019, the minimum follow-up was 4.0 months.

*Efficacy.* The confirmed ORR as assessed by investigators was 60% (95% CI: 32.3% – 83.7%) and the unconfirmed ORR was 73.3% (95% CI: 44.9% – 92.2%). The median DOR was not reached (range: 3.98 – 6.93+ months) and 66.7% of responding were ongoing. The DCR was 100%. The median PFS was 6.8 months (95% CI: 4.4-NE), and the median OS was not reached with 3-month, and 6-month OS rates of 100% and 87.5%, respectively.

*Safety.* As of July 15, 2019, among all 15 treated subjects, the TEAE occurrence was 100% (all grades (G)) and 73.3% (G3-4). The most frequent G3-4 TEAE included neutrophil count decreased 46.7%, white blood cell count decreased 20.0%, anemia 20.0%, and platelet count decreased 20%. No G5 TEAE occurred.

*Conclusion.* Envafolimab plus FOLFOX as a first-line therapy for advanced G/GEJ cancer demonstrated a manageable safety profile with preliminary promising clinical anti-tumor efficacy.

### (5) Phase II Clinical Trial to Treat TMB-H Advanced Solid Tumors in China

We are conducting a single-arm, open-label, multi-center, Phase II clinical trial for the treatment of TMB-H advanced solid tumors in China. As of July 18, 2021, 59 subjects had been enrolled. This trial is ongoing and no safety or efficacy data is currently available.

### (6) Phase I Clinical Trials of Envafolimab

As of the Latest Practicable Date, we had completed all three Phase I clinical trials of envafolimab in China, the U.S. and Japan.

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The three Phase I clinical trials have exhibited a favorable safety profile in patients with advanced malignancies. Multiple dosing regimens (0.01 mg/kg to 10 mg/kg QW, 2.5 mg/kg to 5.0 mg/kg Q2W, and 300 mg Q4W) were tested across the Phase I studies, and no DLT or MTD was reached in any of the Phase I studies. The efficacy results were also analyzed based on pooled data from the three Phase I clinical trials. The pooled analyses showed that among the 269 subjects who were efficacy evaluable, the ORR (confirmation of response not required) was 12.27%. Responses were observed across multiple tumor types, as summarized in the table below:

**Table: ORR per investigator assessment by tumor types based on pooled analyses of efficacy evaluable subjects from three Phase I trials in China, the U.S., and Japan. (only tumor types with subjects  $\geq 9$  are displayed)**

	<b>Responders/ Subjects</b>	<b>ORR</b>	<b>95% CI</b>
Overall	33/269	12.27	(8.60%, 16.80%)
Tumor Histology			
Hepatocellular Carcinoma	3/41	7.32	(1.54%, 19.92%)
Lung Cancer, Non-Small Cell	4/35	11.43	(3.20%, 26.74%)
Biliary Tract Cancer	3/26	11.54	(2.45%, 30.15%)
Colon Cancer	2/24	8.33	(1.03%, 27.00%)
Esophageal Cancer	3/13	23.08	(5.04%, 53.81%)
Melanoma	0/12	0.00	(0.00%, 26.46%)
Neuroendocrine Tumor	2/12	16.67	(2.09%, 48.41%)
Rectal Cancer	0/12	0.00	(0.00%, 26.46%)
Renal Cell Carcinoma	5/10	50.00	(18.71%, 81.29%)
Soft Tissue Sarcoma	2/9	22.22	(2.81%, 60.01%)
Urothelial Carcinoma	2/9	22.22	(2.81%, 60.01%)

*Abbreviations:* ORR = objective response rate; CI = confidence interval.

*Notes:*

- (1) Proportion with CR or PR, confidence interval based on the Clopper and Pearson method.
- (2) Only tumor histology with  $N \geq 9$  is included.
- (3) Subjects completed baseline and at least one post baseline tumor assessment are considered efficacy evaluable.
- (4) Database snapshot date: CN001 (2019-09-02), JP001 (2020-03-31), US001 (2019-11-25).

*Source: Company data*

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### v. *Clinical Development Plan*

We collaborate with Alphasab Group on a broad development program targeting a number of strategically selected indications in China, the U.S., Japan and other countries, to support regulatory submissions for multiple indications both in China and other countries.

Under our Co-Development Agreements with Alphasab Group, we are responsible for the clinical development and commercialization of envafolimab. We led the clinical development for envafolimab in multiple countries and regions including China, the U.S. and Japan based on our commercialization strategy. Japan and the U.S. are members of the ICH. A multi-regional clinical trial conducted in ICH member countries is expected to lower operational costs in light of the consistency of general regulatory requirements. Moreover, the subjects in clinical trials conducted in Japan and China are of East Asian ethnicity, and therefore clinical trial data from one country could be leveraged to support clinical trials and accelerate the clinical development process in the other country.

In addition to the ongoing clinical trials that we are conducting, we plan to explore the clinical potential of envafolimab for the treatment of a variety of indications, including NSCLC, HCC, RCC, EC, TMB-H, CRC and UC. Furthermore, we plan to evaluate the potential synergy of envafolimab in combination with our other pipeline drug candidates, including 3D189 and 3D229.

The table below sets forth the details (including the basis) of our clinical development plan for envafolimab:

<u>Indication</u>	<u>Status</u>	<u>(Expected) first patient in date</u>	<u>Expected NDA submission date</u>	<u>Expected number of patients</u>	<u>Location and competent authority</u>
NSCLC (combination with chidamide) <sup>(1)</sup>	Phase II	Q4 2021	Q2 2024	66-69	China and NMPA
NSCLC (vs. standard of care) <sup>(2)</sup>	Phase III	Q2 2023	Q2 2027	400-500	China and NMPA
NSCLC, HCC, RCC (combination with lenvatinib) <sup>(3)</sup>	Phase Ib/II	Q4 2021	Q4 2026	113-170	China and NMPA
EC (monotherapy and combination with lenvatinib) <sup>(4)</sup>	Phase II	Q2 2022	Q4 2024	108	China and NMPA
TMB-H advanced solid tumors <sup>(5)</sup>	Phase II	Q3 2021	Q1 2024	160-200	China and NMPA

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<u>Indication</u>	<u>Status</u>	<u>(Expected) first patient in date</u>	<u>Expected NDA submission date</u>	<u>Expected number of patients</u>	<u>Location and competent authority</u>
UC (first line maintenance therapy; MRCT) <sup>(6)</sup>	Phase III	Q2 2023	Q4 2025	534	China and NMPA Europe and EMA Japan and PMDA
HCC, CRC, NSCLC (combination with BD0801) <sup>(7)</sup>	Phase II	Q4 2021	Q1 2025	86	China and NMPA
Microsatellite stable CRC (combination with cetuximab) <sup>(8)</sup>	Phase II	Q2 2023	Q2 2026	50	China and NMPA

*Abbreviations:* NSCLC = non-small cell lung cancer; HCC = hepatocellular carcinoma; RCC = renal cell carcinoma; EC = endometrial cancer; TMB-H = tumor mutational burden-high; UC = urothelial carcinoma; MRCT = multi-regional clinical trial; CRC = colorectal cancer; Q1 = first quarter; Q2 = second quarter; Q3 = third quarter; Q4 = fourth quarter.

*Note:*

- (1) NSCLC (combination with chidamide): We obtained the IND approval from NMPA in July 2021. We enrolled the first patient for a Phase II clinical trial in China in the fourth quarter of 2021. We expect a potential NDA submission in the second quarter of 2024. As of July 18, 2022, 22 patients were enrolled in this clinical trial.
- (2) NSCLC (vs. standard treatment): We had communications with CDE in January 2021, and are still in the process of communicating with CDE regarding the design of the phase III study. Based on the preliminary feedback, we expect that this study will likely enroll the first patient in the second quarter of 2023 with expected NDA submission in the second quarter of 2027. As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled.
- (3) NSCLC, HCC, RCC (combination with lenvatinib): We obtained the IND approval from NMPA in June 2021. We enrolled the first patient for a Phase Ib/II clinical trial in China in the fourth quarter of 2021 to explore the efficacy of envafolelimab in combination with lenvatinib across multiple tumor types. The results of this phase Ib/II study will be used to inform the “Go” or “No Go” decision on subsequent registrational phase II or III study/studies. We expect that subsequent pivotal study/studies will enroll the first patient in 2023 with expected NDA submission in the fourth quarter of 2026. As of July 18, 2022, 27 patients were enrolled in this clinical trial.
- (4) EC (monotherapy and combination with lenvatinib): We submitted the IND in June 2021 and received the IND approval in September 2021. We enrolled the first patient for this trial in the second quarter of 2022. We expect that the study will fully enroll in the fourth quarter of 2023 with a potential NDA submission in the fourth quarter of 2024. As of July 18, 2022, 12 patients were enrolled in this clinical trial.
- (5) TMB-H advanced solid tumors: We enrolled the first patient for this trial in August 2021. We expect that this trial to fully enroll in the first quarter of 2023 with a potential NDA submission in the first quarter of 2024. As of July 18, 2022, 59 patients were enrolled in this clinical trial.
- (6) UC (monotherapy vs. best supportive care, first line maintenance therapy): We had communications with CDE in March 2021, and we have completed pre-IND communication with CDE in July 2021. We expect to initiate pre-IND communications with PMDA and EMA in the fourth quarter of 2022. We expect to submit IND in the fourth quarter of 2022 with expected FPI

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in the second quarter of 2023. If the interim analysis on the primary endpoint is successful, the NDA submission is expected to occur in the fourth quarter of 2025. As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled.

- (7) HCC, CRC, NSCLC (combination with BD0801): We obtained the IND approval from NMPA in July 2021 and enrolled the first patient for this trial in November 2021. We expect that this study will fully enroll in the first quarter of 2023 with a potential NDA submission in the first quarter of 2026. As of July 18, 2022, 41 patients were enrolled in this clinical trial.
- (8) Microsatellite stable CRC (combination with cetuximab): We submitted IND to NMPA in June 2022 with expected FPI in the second quarter of 2023. As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled.

*vi. Licenses, Rights and Obligations*

We maintain the rights to develop envafolimab globally in oncology field. We obtained all the intellectual property rights relating to envafolimab from Alphamab Group pursuant to Co-Development Agreements between us and Alphamab Group. Please refer to the paragraphs headed “Our Collaboration Arrangements – Collaboration with Alphamab Group for Envafolimab” in this section.

*vii. Material Communications.*

The material communications with the relevant competent authorities on all ongoing and completed clinical trials in respect of the Core Product envafolimab are as follows:

- In November 2016, we received the IND approval for envafolimab from FDA for solid tumors;
- In December 2016, we received an umbrella IND approval for Phase I, II and III trials for envafolimab from NMPA;
- In May 2017, we received the IND approval for envafolimab from PMDA for solid tumors;
- In April 2018, we consulted with CDE and received feedback from CDE with respect to the commencement of a Phase III clinical trial of envafolimab for the treatment of advanced BTC in China, which was a “no objection” from CDE for the commencement of this trial, in the view of our PRC Legal Advisers;
- In April 2018, we consulted with CDE and received feedback from CDE with respect to the commencement of a pivotal Phase II clinical trial of envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors in China, which was a “no objection” from CDE for the commencement of this trial, in the view of our PRC Legal Advisers;



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- In September 2019, we had a meeting with FDA with respect to the development of envafolimab in combination with axitinib versus sunitinib as first-line treatment of patients with advanced RCC;
- In January 2020, we received orphan drug designation from FDA for envafolimab for the treatment of advanced BTC;
- In May 2020, our partner TRACON had a meeting with FDA with respect to the proposed strategy to initiate pivotal clinical trial of envafolimab in patients with advanced SC;
- In May 2020, we had communications with CDE with respect to a Phase II clinical trial of envafolimab in combination with chidamide for the treatment of NSCLC;
- In July 2020, we consulted the CDE with respect to the submission of BLA of envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors;
- In August 2020, our partner TRACON received the IND approval for envafolimab from FDA for selected types of advanced SC;
- In December 2020, we obtained the BLA acceptance from NMPA for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors;
- In December 2020, we had communications with CDE with respect to a Phase Ib/II clinical trial of envafolimab in combination with lenvatinib for the treatment of advanced solid tumors;
- In December 2020, we had communications with CDE with respect to a Phase II clinical trial of envafolimab for the treatment of TMB-H advanced solid tumors;
- In January 2021, the BLA for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors was publicly announced to be accepted for priority review by NMPA;
- In January 2021, we had communications with CDE with respect to a Phase II clinical trial of envafolimab for the treatment of EC;
- In January 2021, we had communications with CDE with respect to a Phase III clinical trial of envafolimab for the treatment of NSCLC;
- In March 2021, we had communications with CDE with respect to a Phase III clinical trial of envafolimab for the treatment of UC;

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- In June 2021, we received the IND approval for envafolimab from NMPA for a Phase Ib/II clinical trial in combination with lenvatinib for the treatment of advanced solid tumors;
- In July 2021, we received the IND approval for envafolimab from NMPA for a Phase II clinical trial in combination with chidamide for the treatment of NSCLC;
- In July 2021, we received the IND approval for envafolimab from FDA for a Phase II clinical trial for the treatment of advanced BTC;
- In July 2021, we received the IND approval for envafolimab from NMPA for a Phase II clinical trial in combination with BD0801 for injection with or without chemotherapy for the treatment of advanced solid tumors;
- In September 2021, we received the IND approval for envafolimab from NMPA for a Phase II clinical trial for the treatment of EC;
- In November 2021, we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors; and
- In February 2022, we conducted an interview with a senior officer of NMPA with the attendance of professional parties, which reconfirmed, amongst others, that based on the initial safety, efficacy and PK data across multiple dose levels from the Phase I Clinical Trials, that NMPA had no objection for us to commence each of the clinical trials for the treatment of previously treated MSI-H/dMMR advanced solid tumors, advanced BTC and G/GEJ cancer.

We had not received any relevant regulatory agency’s objections to our clinical development plans as of the Latest Practicable Date.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCT ENVAFOLIMAB FOR INDICATIONS OTHER THAN THE APPROVED INDICATION IN PREVIOUSLY TREATED MSI-H/DMMR ADVANCED SOLID TUMORS.**

## **2. Our Other Clinical-Stage Drug Candidates**

According to J Immunother Cancer. 2021 Jan;9(1):e001698. Critical Rev Oncology Hematol. 2021 Apr;160:103302, although the emergence of PD-1/PD-L1 inhibitors has brought new treatment for many cancer patients, tumor cells and tumor microenvironment can limit the effect of PD-1/PD-L1 inhibitors, and sizable numbers of cancer patients have limited response to PD-1/PD-L1 inhibitor as monotherapy. These limitations bring the needs to use PD-1/PD-L1 inhibitors in combination with other treatments. More patients benefit when PD-1/PD-L1 antibodies are used in combination with chemotherapy, targeted therapies, or other immune

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therapies. According to National Rev Drug Discov. 2021 Mar;20(3):168-169, Chinese Society of Clinical Oncology, PD-1/PD-L1 therapy is currently still a backbone therapy while combination therapy is becoming the mainstream for oncology treatment. Other drug candidates in our pipeline have encouraging clinical results on standalone basis and promising potential to synergize with envafoimab through varied complementary mechanism of actions.

*a. 3D189*

3D189, also known as galinpepimut-S (GPS), is a peptide cancer vaccine that targets the Wilms Tumor 1 (WT1) protein, which is present and over-expressed in an array of hematological malignancies and solid tumors. We own the exclusive rights to develop, manufacture and commercialize 3D189 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses through our exclusive license agreement with SELLAS Group. 3D189 has the potential to target over 20 types of cancers (including lung cancer and CRC) that over-express WT1. Due to its strong T-cell immune response, it is designed to prevent/delay relapses (by prolonging the progression-free interval) and eventually potentially prolong survival in these patients, which is evidenced by the encouraging preliminary results in Phase I and II clinical trials performed to date in acute myelocytic leukemia (AML) (after first- and second-line therapy), malignant pleural mesothelioma (MPM) (after first-line therapy), high-risk multiple myeloma (MM) (after upfront therapy including autotransplant), and relapsed ovarian cancer (OC) (after second-line therapy). We obtained the IND approval for 3D189 in China in March 2022. We plan to initiate a Phase I clinical trial in patients with hematological malignancies who have achieved objective response after receiving standard treatment in the second half of 2022. We plan to potentially join SELLAS Group sponsored registration-enabling, randomized, multi-center, pivotal Phase III clinical trial currently ongoing in the U.S. and Europe in patients with AML who have successfully achieved their second complete remission (CR2), subject to our license agreement with SELLAS Group entered into in December 2020. 3D189 (GPS) has been granted fast track and orphan drug designations by the FDA for the treatment of AML, MPM and MM as well as orphan medicinal product designations from the European Medicines Agency (EMA) in AML, MPM, and MM.

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The table below shows the indications for which 3D189 is currently being evaluated in clinical trials:

Indication <sup>(1)</sup>	Status				
	IND (Accepted)	Phase I	Phase II	Phase III	NDA/BLA (Filed)
<b>China</b>					
Hematological malignancies (AML, etc.)	●	●		●	
NSCLC, RCC, UC and other solid tumors	●	●	●		
<b>U.S. (SELLAS Group)</b>					
AML	●	●	●	●	
MPM	●	●	●		
MM	●	●	●		
OC (combination with PD-1 antibodies)	●	●			
Selected advanced cancers (combination with PD-1 antibodies)	●	●	●		

*Abbreviations:* AML = acute myelocytic leukemia; NSCLC = non-small cell lung cancer; RCC = renal cell carcinoma; UC = urothelial carcinoma; MPM = malignant pleural mesothelioma; MM = multiple myeloma; OC = ovarian cancer.

Symbols: ● = complete; ● = in progress (a clinical trial is deemed to have been initiated when the first study site is activated); ● = to be initiated

*Note:*

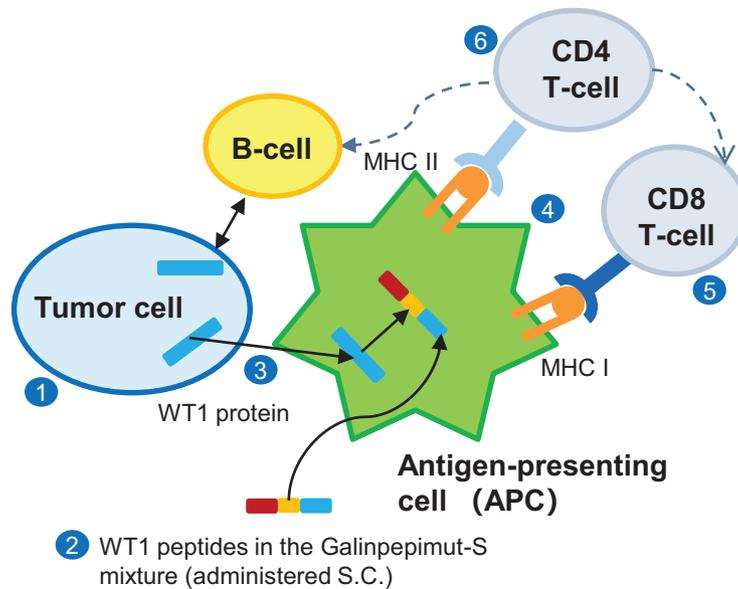
(1) Some indications may not require every phase of the clinical trials indicated on this chart to be completed prior to the filing of an NDA/BLA.

*i. Mechanism of Action*

3D189 targets malignancies characterized by an overexpression of the WT1 antigen. The WT1 antigen is one of the most widely expressed cancer antigens in multiple malignancies. It was the top ranked cancer antigen for immunotherapy by the U.S. National Cancer Institute (NCI) in 2009. The WT1 gene encodes for a zinc finger transcription factor that is normally expressed in mesodermal tissues during embryogenesis. The putative role in leukemia biology and the continued low level expression in patients who would otherwise be considered to be without evidence of disease by conventional criteria make WT1 a potential target for therapeutic intervention.

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The WT1 immunotherapy 3D189 is comprised of four peptide chains, two of which are modified chains that induce a strong immune response (CD4+/CD8+) against the WT1 antigen and access a broad range of HLA types. When administered to a patient, 3D189's induced immune response has the potential to recognize and destroy cancer cells and provide ongoing support and memory to the immune system so that it can continue to target and destroy recurring tumors and residual cancer cells. 3D189 has the potential to be a highly effective approach to prolonging survival by delaying or preventing relapse/recurrence in patients in complete remission or with low tumor burden. The diagram below shows the mechanism of action for 3D189:



*Abbreviations:* APC = antigen-presenting cells; MHC = major histocompatibility complex

*Source:* *Biochem J.* 2014 Jul 1;461(1):15-32., *Frost & Sullivan Report*

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*ii. Market Opportunities and Competition*

WT1 immunotherapy has the potential to target various cancers that over-express WT1. As of the Latest Practicable Date, there was no approved WT1 immunotherapy in the world. The following table sets out details of WT1 immunotherapy in clinical development worldwide as of the Latest Practicable Date:

<u>Drug Name</u>	<u>Company</u>	<u>Target</u>	<u>Indications</u>	<u>Status</u>	<u>Location</u>	<u>Date</u>
Galinpepimut-S/3D189	3DMed/Sellas Life Sciences Group	WT1	Acute myeloid leukemia; Multiple myeloma; Mesothelioma; CRC; Ovarian cancer; TNBC; SCLC	Phase III	U.S.	2018-12
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TLP0-001	Tella; Wakayama Medical University	WT1	Pancreatic cancer	Phase III	Japan	2017-05
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DSP-7888	Sumitomo Dainippon Pharma Oncology Inc	WT1	Glioblastoma; advanced solid tumor	Phase III	MRCT	2017-05
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INO-5401	Inovio Pharmaceuticals	WT1	Glioblastoma; Urothelial Carcinoma	Phase I/II	Spain; U.S.	2018-04

*Note:*

(1) Date denotes the date on which the relevant status was publicly disclosed.

*Source: Clinicaltrials.gov, FDA, Frost & Sullivan Report*

*iii. Competitive Advantages*

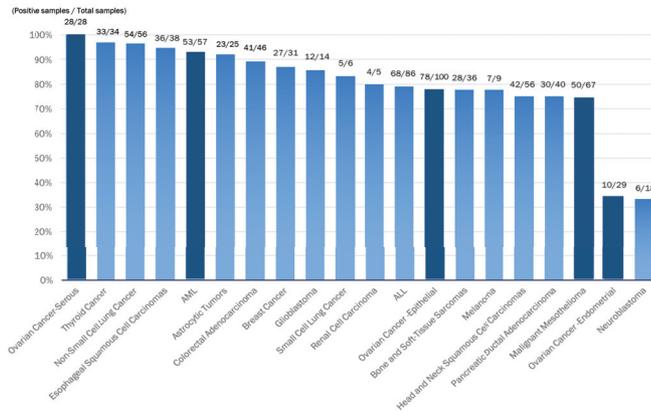
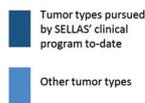
(1) Targeting WT1, an optimal target for immunotherapy, with a potential to treat various types of cancers and a wide coverage of patients

3D189 is an immunotherapy that targets WT1, which was a top ranked antigen for immunotherapy according to the NCI in 2009. As shown in the figure below, WT1 targeting therapies can potentially treat over 20 cancer types (including lung cancer and CRC), which creates a large potential market with a wide coverage of patients. Specifically, WT1 is broadly detectable in AML, where it is densely and almost universally expressed at 90% to 95% of cases, and it is also expressed in multiple solid tumors and cancer stem cells. Since it is highly expressed and present

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in cancer cells, it enables recognition and killing by specifically immunized T-cells, thus potentially preventing and delaying relapses in patients with hematological malignancies and solid tumors.

- Potential to treat 20 or more cancer types
- Expressed broadly in hematological malignancies and solid tumors



Source: Memorial Sloan Kettering Cancer Center data (based on review of literature and multiple studies)

### (2) Potential synergy with envafolimab

3D189 is an immunotherapy that is able to activate the antigen-presenting cells and elicit T-cell-dependent immune responses against WT1-expressing cancer cells. 3D189 monotherapy has previously shown to be well tolerated and has promising clinical activity in multiple studies, which demonstrated that 3D189 could elicit anti-tumor immune response in the setting of low tumor burden and enhance immune surveillance. Therapies blocking PD-1/PD-L1, such as envafolimab, an anti-PD-L1 single domain antibody, have shown the ability to reduce inhibitory immune signals, thus allowing cytotoxic T cells to infiltrate the tumor and cause tumor regression in an expanding group of human malignancies. The preliminary data from studies of 3D189 in combination with pembrolizumab and nivolumab have displayed encouraging activity in patients with certain WT1-positive advanced solid tumors. Combining 3D189 with envafolimab is hypothesized to increase the proportion of patients who develop an immune response against their cancer and prolong the duration of such a response by induction of memory T cells. In addition, as 3D189 allows for “off the shelf” subcutaneous injection use and requires a simple manufacturing process by lyophilized formulation, it creates potentially good synergy with our envafolimab that is also subcutaneously injectable.

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(3) Favorable safety profile with good patient compliance

3D189 is a peptide cancer vaccine consisting of 4 peptide chains, which can stimulate a strong immune response to various types of cancer. Pharmacology studies have reported that 3D189 elicits a strong immune response, yielding cytotoxic T-cells to cancer cells that present the WT1 antigen/peptide.

Based on the Phase I combination study of 3D189 with the anti-PD-1 nivolumab in the treatment of recurrent ovarian cancer patients, 3D189 exhibited highly tolerable safety profile with few significant systemic drug-attributed TEAEs, while its administration leads to mostly grade G1/G2 local skin and subcutaneous tissue inflammatory reactions that are transitory in nature. In addition, across the five completed studies with 3D189 monotherapy, the only Treatment Related Adverse Events (TRAEs) of any grade that occurred in more than 10% of the patients across all studies were injection site reaction in 18.2% of all patients (Grades 1 and 2 only) and fatigue in 14.9% of all patients (Grades 1 and 2 only). None of the Grade 3 or 4 TRAEs were observed in  $\geq 10\%$  of patients. Grade 3 and 4 TEAEs observed in 5% ~ 10% of patients were hematological (leukopenia, lymphopenia and neutropenia) and they occurred only in patients with hematologic cancers. No TEAE-related deaths occurred in any clinical studies thus far.

(4) Simultaneously boosting CD4+ and CD8+ T-cells using unique technology

3D189's mechanism of action relies on a unique heteroclitic technology to generate a strong anti-tumor immune response. 3D189 consists of four peptides designed for differentiated immunotherapy using the heteroclitic technology for the development of two of the four peptides. Utilizing such unique heteroclitic technology, heteroclitic peptides are engineered to have an artificially introduced single point amino acid sequence mutation, resulting in synthetic peptide analogs with improved immunogenicity by virtue of its higher binding affinity to human leukocyte antigen (HLA) on antigen-presenting cells, thereby breaking tolerance to the native sequence and stimulating a stronger T cell response than the native sequence. In order to broaden immunogenicity over a range of HLA subtypes, 3D189 contains four selected WT1 peptides, with one WT1 heteroclitic peptide to stimulate CD8 responses, two longer WT1 native peptides to stimulate CD4 responses and one longer heteroclitic peptide which could stimulate both CD4 and CD8 cells.

*iv. Summary of Clinical Trials*

Our partner SELLAS Group is conducting a Phase III pivotal clinical trial in patients in the U.S. and Europe with 3D189 (GPS) in patients with AML who have achieved second hematologic complete remission, with or without thrombocytopenia (CR2/CR2p).



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In addition, SELLAS Group has completed several Phase I and II clinical trials including in AML (after first- and second-line therapy), MPM (after first-line therapy), high-risk MM (after upfront therapy including autotransplant), and relapsed OC (after second-line therapy).

Subject to the SELLAS Agreement, we plan to potentially join SELLAS Group’s sponsored registration-enabling, randomized, multi-center, Phase III pivotal clinical trial in patients with AML who have successfully achieved their CR2. In addition, we received the IND approval for 3D189 for a Phase I clinical trial in patients with hematological malignancies in China in March 2022.

In January 2020, SELLAS Group commenced the Phase III clinical study of GPS in AML, also known as the REGAL study. The Phase III pivotal REGAL study is a 1:1 randomized, open-label study comparing GPS monotherapy in the maintenance setting to investigators’ choice of best available treatment in AML patients who have achieved hematologic complete remission, with or without thrombocytopenia (CR2/CR2p), after second-line antileukemic therapy and who are deemed ineligible for or unable to undergo allogeneic stem-cell transplantation. The study is expected to enroll approximately 116 patients across up to approximately 135 clinical sites primarily in the U.S. and Europe. The primary endpoint is OS from the time of study entry. The Phase II study in AML CR2 patients, which is the same indication as the Phase III REGAL study, showed a median OS of 21.0 months, at a median follow-up of 30.8 months, in patients receiving GPS compared to 5.4 months in contemporaneously treated patients with best standard therapy. Please refer to the paragraphs headed “– Our Core Product and Other Drug Candidates – 2. Our Other Clinical-Stage Drug Candidates – a. 3D189 – iv. Summary of Clinical Trials – (1) AML Phase III Clinical Trial” in this section.

The following summarizes the clinical trials completed and/or being conducted by our partner SELLAS Group with 3D189 (GPS):

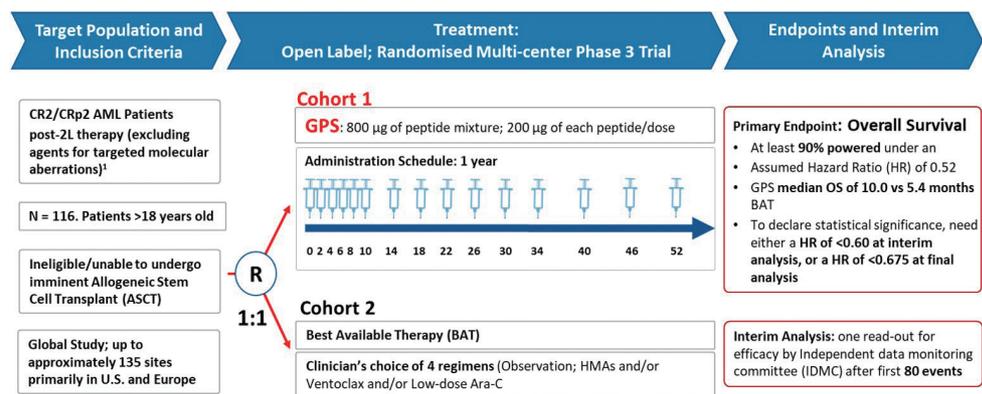
(1) AML Phase III Pivotal Clinical Trial

In January 2020, a Phase III pivotal registration-enabling study was commenced for GPS in AML patients in second complete remission, including those in complete remission with incomplete platelet recovery. This study, which is referred to as the REGAL study, is a 1:1 randomized, open-label study comparing GPS in the maintenance setting to investigators’ choice of best available treatment, in adult AML patients (age >18 years) who have achieved their second hematologic (morphological) complete remission, with or without thrombocytopenia (CR2/CRp2; with “p” designating platelets), after second-line antileukemic therapy and who are deemed ineligible for or unable to undergo allo-HSCT. The primary endpoint is OS and secondary endpoints include leukemia-free survival rates of achievement of minimal residual disease (MRD) negativity. We plan to potentially join this study by enrolling patients from China in 2022. This study is expected to

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be used as the basis for a BLA submission, subject to a statistically significant and clinically meaningful data outcome and agreement with the FDA and other health authorities including NMPA in China.

The key features and schema of this study are shown in the following graphic:



Notes: 1. Excluding agents that should be continued in the maintenance setting after achievement of CR2 with usage of 2L regimens containing such agents (e.g. FLT3 inhibitors); CRp2: CR2 with incomplete platelet recovery, i.e., platelet count of  $\geq 60 \times 10^9/L$  (as defined for this study); PB: peripheral blood; BM: bone marrow

Source: SELLAS's annual report on Form 10-k

### (2) AML Phase I/II Clinical Trials

In an initial pilot clinical trial in AML, a total of 10 adult patients of all ages with *de novo* AML were treated with upfront standard chemotherapy and were able to achieve their first complete remission, or CR1. Of the 9 evaluable patients, administration of GPS resulted in a median OS that was at least 35 months from the time of GPS administration. In this study, specifically for patients who were 60 years and older (n=5), median OS was at least 33 months from the time of GPS administration or approximately 43 months from the time of initial AML diagnosis. The mean time of follow-up was 30 months from the time of diagnosis at the time of this analysis for all patients. Of the eight patients tested for immunologic response, seven, or 87.5%, demonstrated a WT1-specific immune response.

In a subsequent Phase II clinical trial in AML, a total of 22 adult patients of all ages with *de novo* AML were treated with upfront standard chemotherapy and were able to achieve CR1. Most patients also received one to four cycles of “consolidation” chemotherapy per standard AML treatment guidelines. GPS was then administered within three months from the completion of the consolidation chemotherapy regimen in up to 12 total doses: six initial doses (priming immunization) followed by six additional “booster” immunizations over a total period of up to nine months to qualifying patients (*i.e.*, patients who were clinically stable and did not show disease recurrence after the first six injections). This Phase II clinical trial met its primary endpoint of an actual OS rate of at least 34%, measured three years into the clinical trial (*i.e.*, percentage of patients alive after

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three years of follow-up). An actual OS rate of 47.4% was demonstrated at three years post-GPS treatment, exceeding historical published data of OS of 20% to 25% by 2.4- to 1.9-fold (or 240% to 190%), respectively.

GPS administration was also shown to improve median OS in comparison to historical data in patients in CR1. Administration of GPS resulted in a median OS that was poised to exceed 67.6 months from the time of initial AML diagnosis in patients of all ages, which represents a substantial improvement compared to best standard therapy. Only five of the 22 patients underwent allo-HSCT and an ad hoc statistical analysis failed to show a significant effect of the transplant upon OS (either in median survival times or survival rates at specific landmark time-points). In this study, the patients' median age was 64 years old. The most frequent toxicities were mild to moderate local skin reactions and inflammation, as well as fatigue, which were self-limited and responded to local supportive measures and analgesics. None of the patients developed significant serious or high grade systemic adverse reactions (including anaphylaxis) attributable to GPS. GPS elicited WT1-specific immune responses in 88% of patients, including CD4 and CD8 T-cell responses. Further, the heteroclitic principle was confirmed, in that immune responses were seen against the native version of the two mutated WT1 peptides within the GPS mixture. The results showed a trend in improved clinical outcomes in patients who mounted an immune response with GPS compared to those patients who did not. Importantly, a preplanned subgroup analysis for the cohort of 13 patients within the clinical trial who were 60 years of age or older demonstrated a median OS of 35.3 months from time of initial diagnosis. Comparable historical populations have a median OS ranging from 9.5 to 15.8 months from initial diagnosis, which represents a 2.25 to 3.75-fold improvement in OS associated with GPS therapy in the CR1 maintenance setting as contrasted to these historical cohorts of broadly comparable patients.

An additional Phase II clinical trial of GPS was performed at the H. Lee Moffitt Cancer Center & Research Institute, or Moffitt. This Phase II trial included 10 AML patients who had received first-line therapy for their disease, who then experienced relapse and were subsequently treated with second-line chemotherapy and achieved a CR2. This group of patients had a more advanced disease in comparison to those treated in the Phase II clinical trial in CR1 patients discussed above, and typically demonstrated a historical OS of less than approximately 8 months, even with post-CR2 allo-HSCT. In the Moffitt trial, the efficacy of GPS (measured as median OS, from the time of achievement of CR2 until death from any cause) was compared with that of "watchful waiting" in a cohort of 15 contemporaneously treated (but not matched by randomization) broadly comparable patients treated by the same clinical team at Moffitt. Initial data, at a median follow-up of 19.3 months, showed that GPS administration resulted in a median OS of 16.3 months (495 days) compared to 5.4 months (165 days) from the time of achievement of CR2. This was a statistically significant difference ( $p=0.0175$ ). Two of 14 AML patients demonstrated relapse-free survival of more than one year. Both

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of these patients were in CR2 at time of GPS administration, with duration of their second remission exceeding duration of their CR1, strongly suggesting a potential benefit based on immune response mechanisms. Final data, at a median follow-up of 30.8 months, showed a median OS of 21.0 months in patients receiving GPS therapy compared to 5.4 months in the AML CR2 patients treated with best standard care (not randomized control). This is a statistically significant difference (p-value < 0.02). GPS was well-tolerated in this clinical trial.

### (3) MPM Clinical Trials

A randomized, double-blind, placebo-controlled Phase II clinical trial in MPM patients enrolled a total of 41 patients at Memorial Sloan Kettering Cancer Center (MSK) and MD Anderson Cancer Center (MDACC). Data from this Phase II clinical trial was presented in 2016. Based on an initial analysis of 40 patients who were eligible at the time with a median follow-up of 16.3 months, a median OS of 24.8 months was seen for GPS-treated MPM patients, compared to a median OS of 16.6 months for patients in the control arm. In a subsequent analysis for the entire cohort (n=41) in August 2016, with a median follow-up of 17.2 months, a median OS of 22.8 months was observed for GPS-treated MPM patients, compared to a median OS of 18.3 months for patients in the control arm (difference is not statistically significant). In the datasets from both of these analyses, GPS was shown to induce WT1-specific CD8 and CD4 T-cell activation. There were no clinically significant severe adverse events in this study.

### (4) MM Clinical Trials

SELLAS Group has reported comprehensive final data from a Phase I/II study for GPS in 19 patients with MM. All non-progression events were confirmed and remained ongoing as of the time of the latest presentation (median follow-up at 20 months for survivors). The data indicate promising clinical activity among MM patients with high-risk cytogenetics at initial diagnosis who also remain MRD(+) after successful frontline therapy (induction regimen followed by ASCT). This subgroup of MM patients, when serially assessed per IMWG criteria, typically relapse/progress within 12 to 14 months after ASCT, even when they receive maintenance therapy with IMiDs such as thalidomide or proteasome inhibitors such as bortezomib. Of note, 18 of the 19 patients received lenalidomide maintenance starting after the first three GPS administrations following ASCT; the remaining single patient received bortezomib under the same schedule. All patients had evidence of at least MRD after ASCT, while 15 of the 19 also had high-risk cytogenetics at diagnosis. Combined, these characteristics typically result in low PFS rates that do not exceed 12 to 14 months following ASCT, even while on maintenance therapy with IMiDs or proteasome inhibitors, which are the current standards of care. At June 2017, median PFS with GPS was 23.6 months, while median OS had not been reached. The results compare favorably with an unmatched cohort of broadly comparable MM patients with high-risk cytogenetics published by

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the Spanish PETHEMA group from the PETHEMA Network No. 2005-001110-41 trial. The GPS therapy demonstrated a 1.87-fold increase in median PFS, as well as a 1.34-fold increase in the PFS rate at 18 months compared to the aforementioned historical cohort, which included MM patients with high-risk cytogenetics and MRD(+) post-ASCT and on continuous intensive maintenance with thalidomide +/- bortezomib. The safety profile was devoid of grade 3/4/5 treatment-related adverse events. Immune response data showed that up to 91% of patients had successfully developed T-cell (CD8 or CD4) reactivity to any of the four peptides within the GPS mixture, while up to 64% of patients demonstrated immune response positivity (CD4/CD8) against more than one WT1 peptide (multivalent responses). Moreover, multifunctional cross-epitope T-cell reactivity was observed in 75% of patients to antigenic epitopes against which hosts were not specifically immunized, in a pattern akin to epitope spreading. Further, a distinctive link was shown between the evolution of immune responses and changes in clinical response status (achievement of CR/very good partial response clinical status per IMWG criteria) over time following treatment with GPS, with each patient being used as his or her own control for each longitudinal comparison. This association has not been previously described for a peptide vaccine in MM.

### (5) GPS Combination Therapy with PD1 blocker (nivolumab) for Ovarian Cancer

GPS was studied in combination with nivolumab, a PD-1 immune checkpoint inhibitor, in an open-label, non-randomized Phase I/pilot clinical trial, which was independently sponsored by MSK. The aim of the study was to evaluate the safety and efficacy of this combination in patients with WT1-expressing (WT1+) recurrent ovarian, fallopian tube or primary peritoneal cancer who were in second or greater clinical remission (after their successful first or subsequent "salvage" therapy). Eligible patients were devoid of macroscopic residual or recurrent disease, i.e., were free of locally or distantly metastatic deposits detectable by imaging modalities (CT, MRI and/or PET scan). This Phase I/pilot clinical trial enrolled 11 patients with recurrent ovarian cancer who were in second or greater clinical remission at MSK, of whom 10 were evaluable. Patients enrolled in the clinical trial received the combination therapy during the clinical trial's 14-week treatment period. Individuals who had not progressed by the end of this period also received a maintenance course of GPS. In this study, treatment was continued until disease progression or toxicity. Information on the primary endpoint of this clinical trial, which was the safety of repeated GPS administrations, for a total of six doses, in combination with seven infusions of nivolumab was presented at the American Society of Clinical Oncology, or ASCO, 2018 annual meeting. The secondary endpoint of the study was immune response, and the exploratory endpoints included landmark one-year PFS rate compared to historical controls and correlative analyses between clinical and immune responses. Exploratory efficacy interim data from this pilot trial showed that GPS, when combined with a PD-1 inhibitor, in this case nivolumab, demonstrated PFS of 64% at one year in an intent to treat the group of 11 evaluable patients with WT1+ ovarian cancer in second or greater remission. Among patients

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who received at least three doses of GPS in combination with nivolumab, PFS at one year was 70% (7/10). The historical rates with best standard treatment do not exceed 50% in this disease setting. The most common adverse events were Grade 1 or 2, including fatigue and injection site reactions. Dose limiting toxicity was observed in one patient, following the second dose of the combination. No additional adverse event burden was observed for the combination as compared to nivolumab monotherapy. The combination induced a high frequency of T- and B-cell immune responses.

Follow-up data now show that three of the 11 patients enrolled in the study have continued to show no signs of disease progression. The mean PFS for these three patients is 35.4 months from the initiation of salvage chemotherapy, or mean PFS of 30.1 months from the first administration of GPS plus nivolumab. Based on this follow-up information, the estimated two-year PFS rate for this study is now 27.3% for the intent-to-treat, or ITT, patients (n=11) and approximately 30% for patients who received greater than two doses of GPS and nivolumab (n=10), as compared to a historical 3% to 10% PFS rate for patients receiving only salvage chemotherapy. No new serious adverse events were noted during the longer follow-up period.

(6) GPS Combination Therapy with PD1 blocker (pembrolizumab)

This clinical study was initiated in December 2018. The tumor type currently being investigated is ovarian cancer (second or third line). In December 2020, it was announced that the first set of evaluable patients (n=8) in the study, diagnosed with 2nd or 3rd line WT1(+) relapsed or refractory metastatic ovarian cancer, demonstrated a disease control rate (the sum of overall response rate and rate of stable disease) of 87.5% with a median follow-up of 9.4 weeks. At the first assessment time-point of 6 weeks post-therapy initiation, 100% of the patients were free of disease progression. Using a validated immunohistochemistry (IHC) assay during the screening period, the rate of WT1 positivity in this ovarian cancer patient population was approximately 70%. Six of the eight evaluable patients are continuing to receive GPS plus pembrolizumab. Enrollment in this arm of the study is continuing with a target of a total of 20 patients.

(7) GPS Combination Therapy with PD1 blocker (nivolumab) for MPM

A single-center, open-label, single-arm, non-randomized investigator-sponsored Phase I trial of concomitant administration of GPS in combination with nivolumab was initiated in February 2020 at MSK in patients with MPM who have previously received treatment with pemetrexed-based chemotherapy and have measurable disease on imaging, either due to residual disease after prior treatment or recurrent disease. SELLAS Group is providing GPS and BMS is providing nivolumab for this study.

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The IST is planned to accrue a minimum of 10 patients. Its primary objective is to determine the tolerability of the GPS plus nivolumab combination in patients with previously treated MPM who have documented progression of disease on imaging at the time of study entry, while the secondary objective is to evaluate the immunogenicity of the above combination by assessing the WT1-specific cell-mediated immune response both in peripheral blood and at the tumor site.

In December 2020, it was announced that the first set of evaluable patients (n=3) had a median PFS of at least 10 weeks since therapy initiation. In primary refractory MPM patients, any prolongation of progression-free interval greater than 8 weeks would be considered clinically meaningful, considering the current lack of effective therapies. All patients had the epithelioid variant of MPM, a tumor which is universally expressing WT1. GPS was found to be appropriately immunogenic, leading to the emergence of antigen (WT1)-specific CD4+ T-memory cell responses at three months post-therapy initiation. Additional MPM patients are currently being enrolled.

### v. *Clinical Development Plan*

We plan to join the ongoing Phase III clinical trial in AML sponsored by SELLAS Group. In addition, we plan to conduct an open-label Phase I trial to evaluate the safety, immunogenicity and efficacy of 3D189 in patients with hematological malignancies in China. Following this Phase I trial, we plan to further explore the clinical potential of 3D189 in combination with envafolimab in selected solid tumors, such as NSCLC, RCC, UC and other solid tumors. Depending on initial data, additional tumor types and combination with additional treatments may be studied.

The table below sets forth the details of our clinical development plan in China for 3D189:

<u>Indication</u>	<u>Status</u>	<u>Expected first patient in date</u>	<u>Expected NDA submission date</u>	<u>Expected number of patients</u>	<u>Location and competent authority</u>
HM <sup>(1)</sup>	Phase I	2H 2022	-	15	China and NMPA
NSCLC <sup>(2)</sup>	Phase Ib/II	Q2 2023	-	20	China and NMPA
RCC <sup>(2)</sup>	Phase Ib/II	Q2 2023	-	20	China and NMPA
UC <sup>(2)</sup>	Phase Ib/II	Q2 2023	-	20	China and NMPA
Other solid tumors <sup>(2)</sup>	Phase Ib/II	Q2 2023	-	30	China and NMPA

*Abbreviations:* HM = hematological malignancies; NSCLC = non-small cell lung cancer; RCC = renal cell carcinoma; UC = urothelial carcinoma; 2H = second half; Q1 = first quarter.

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*Notes:*

- (1) This planned clinical trial is based on positive immune response and preliminary efficacy signal from phase I/II studies in AML and MM completed by SELLAS. As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled. First patient is expected to be enrolled in second half of 2022.
- (2) These planned clinical trials are based on over expression of WT1 in NSCLC, RCC, UC etc. and complementary mechanism of action between PD-L1 inhibition and WT1 vaccine. As of July 18, 2022, these clinical trials were still in preparation stage and no patient had been enrolled. First patient is expected to be enrolled in second quarter of 2023.

*vi. Licenses, Rights and Obligations*

We maintain the exclusive rights to develop, manufacture and commercialize 3D189 in China, Hong Kong, Macau and Taiwan region for all therapeutic and other diagnostic uses. We obtained all the intellectual property rights relating to 3D189 pursuant to an exclusive license agreement between us and SELLAS Group. Please refer to the paragraphs headed “Our Research and Development – Collaboration Agreements – Collaboration with SELLAS Group for 3D189 and 3D059” in this section.

*vii. Material Communications*

We obtained the IND approval for 3D189 in China in March 2022. We had not received any relevant regulatory agency’s objections to our clinical development plans as of the Latest Practicable Date.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET 3D189 SUCCESSFULLY.**

***b. 3D229***

3D229 (also known as batiraxcept, AVB-500), is a high-affinity, soluble Fc-fusion protein designed to bind GAS6 (Growth Arrest Specific 6), intercept the binding of GAS6 to its receptor AXL and block the activation of the GAS6-AXL signaling pathway. We own the exclusive rights to develop, manufacture and commercialize 3D229 in China, Hong Kong, Macau and Taiwan region through our collaboration and license agreement with Aravive. The FDA has permitted our partner Aravive to initiate a Phase III clinical trial to evaluate 3D229 in the U.S. in platinum resistant ovarian cancer (PROC), and Aravive started recruiting patients in the U.S. for this trial in April 2021. Results of a Phase I clinical trial of 3D229 conducted by Aravive in healthy human volunteers showed a favorable safety profile, with no reported serious or dose-limiting adverse events. Moreover, results of this trial showed a dose-related reduction of circulating free GAS6 in serum, which serves as a robust pharmacodynamics marker for 3D229 (batiraxcept, AVB-500). In preclinical studies, GAS6-AXL inhibition has shown activity both as a single agent and in combination with other of anticancer therapies including radiation therapy, immunotherapies, and drugs that affect DNA replication and



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repair. We submitted the IND for 3D229 for a Phase I clinical trial in healthy human volunteers in China and obtained the IND approval in China in May 2021. We completed this Phase I clinical trial in May 2022. We obtained the IND approval for a Phase Ib/II clinical trial in patients with NSCLC, RCC and UC in April 2022. Furthermore, we submitted the IND for 3D229 for a Phase III clinical trial in patients with PROC in China in April 2021 to participate in the multi-regional clinical trial (MRCT) and obtained the IND approval for this trial in July 2021, and we initiated this Phase III clinical trial in China in February 2022. Additional feedback from the U.S. FDA regarding standard of care treatment with bevacizumab will be obtained to determine China’s participation in the Phase III.

The table below shows the indications for which 3D229 is currently being evaluated by us or our partner Aravive or its collaborators in clinical trials:

Indication <sup>(1)</sup>	Status					
	IND	Phase I		Phase II	Phase III	NDA/BLA (Filed)
		Ia	Ib			
<b>China</b>						
Healthy human volunteers	●	●				
PROC (MRCT; combination with paclitaxel)	●				● <sup>(2)</sup>	
<b>U.S. (Aravive)</b>						
Healthy human volunteers	●	●				
PROC (combination with paclitaxel or pegylated liposomal doxorubicin)	●		●			
PROC (MRCT; pivotal study; combination with paclitaxel)	●				●	
ccRCC (combination with cabozantinib)	●		●	●		
PC (combination with gemcitabine and nab-paclitaxel)	●		●	●		
PROC (combination with durvalumab) <sup>(3)</sup>	●		●			
UC (combination with avelumab) <sup>(3)</sup>	●		●			
IgA Nephropathy	●			○ <sup>(4)</sup>		

*Abbreviations:* PROC = platinum-resistant ovarian cancer; MRCT = multi-regional clinical trial; ccRCC = clear cell renal cell carcinoma; PC = pancreatic cancer; UC = urothelial carcinoma.

Symbols: ● = complete; ● = in progress (a clinical trial is deemed to have been initiated when the first study site is activated); ● = to be initiated; ○ = terminated

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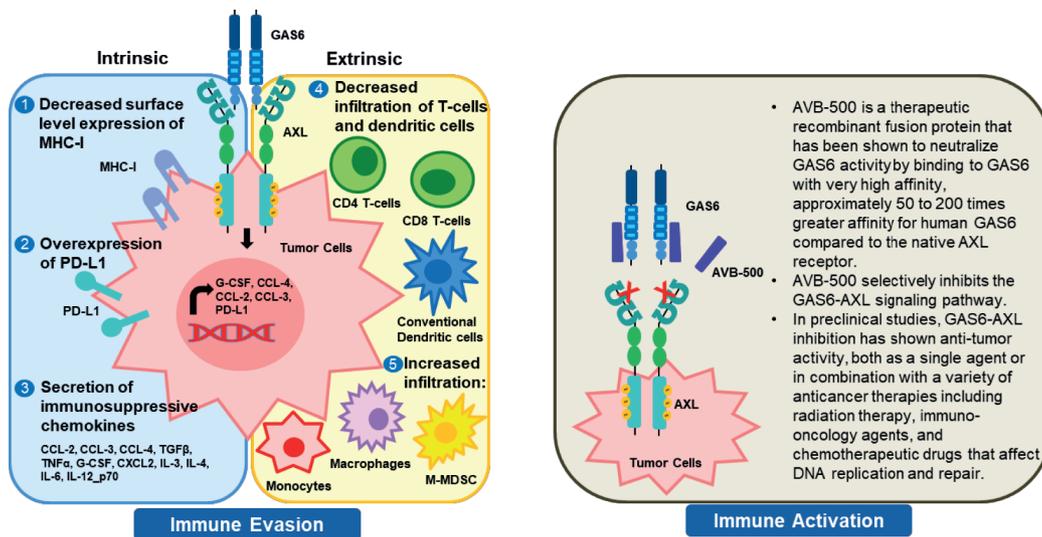
### Notes:

- (1) Some indications may not require every phase of the clinical trials indicated on this chart to be completed prior to the filing of an NDA/BLA.
- (2) As of July 3, 2022, four patients have been enrolled to this MRCT in China.
- (3) Investigator sponsored trials (IST).
- (4) Aravive decided to focus on oncology indications and terminated this study.

### i. Mechanism of Action

Activation of the receptor tyrosine kinase AXL by its sole ligand, GAS6, leads to increased cellular adhesion, invasion, migration, pro-tumoral immune response, anti-apoptosis, proliferation, and survival in several cancers. 3D229 is a high affinity GAS6 decoy receptor protein designed by combining an engineered soluble portion of AXL receptor with the Fc region of human IgG1.

AXL is a member of TAM family of tyrosine kinases that include Tyro3, AXL, and Mer (TAMs), and is activated by a single ligand, GAS6. Mer and Tyro3 can be activated by GAS6 and protein S. Upregulated in many cancers, AXL overexpression is linked to metastasis, poor survival, and drug resistance. Research has shown GAS6-AXL signaling to be a key molecular pathway that promotes tumor growth and metastases, as well as immune evasion and resistance to other anticancer agents. AXL and GAS6 expression also correlates with poor prognosis in cancer. Unusually strong binding affinity between GAS6 and AXL of about 30 pM makes development of antibody inhibitors to the pathway challenging. 3D229's affinity to GAS6 is about 200-fold stronger than wild-type AXL receptor and therefore can effectively inhibit the GAS6-AXL signaling pathway. The diagram below shows the mechanism of action for 3D229 (batiraxcept, AVB-500):



Source: *Cancers (Basel)*. 2020 Jul; 12(7): 1850., Frost & Sullivan Report

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ii. *Market Opportunities and Competition*

GAS6-AXL pathway drugs have the potential to impair multiple stages of tumor progression from both neoplastic and host cell axes. Compared to an AXL tyrosine kinase inhibitors, a GAS6 decoy receptor has the potential advantage to selectively inhibit the GAS6-AXL signaling pathway. As of the Latest Practicable Date, there were no approved AXL tyrosine kinase inhibitors that selectively inhibits AXL and a total of eleven GAS6-AXL pathway drugs in clinical development. The following tables sets out details of GAS6-AXL pathway drugs in clinical developments worldwide as of the Latest Practicable Date:

<u>Drug Name</u>	<u>Company</u>	<u>Target</u>	<u>Indications</u>	<u>Status</u>	<u>Location</u>	<u>Date</u>
AVB-S6-500/3D229	Aravive Biologics; Aravive Inc; 3DMed	GAS6/AXL	Fallopian tube cancer; Transitional cell carcinoma; Renal cell carcinoma; Ovarian cancer; Peritoneal carcinoma; Ovary epithelial carcinoma; Urothelial Carcinoma; Pancreatic Neoplasms	Phase III	U.S.; China	2018-08
BA-3011	Bioatla Inc; AstraZeneca PLC	AXL	NSCLC; Osteosarcoma; Melanoma; Synovial sarcoma; Leiomyosarcoma; Sarcoma; Pancreatic cancer; Ewing's sarcoma; Liposarcoma; Solid Tumor; Ovarian Neoplasms	Phase II	U.S.	2018-02
HK-001/ Butylidenephthalide	Everfront Biotech Co Ltd;	AXL	Glioma; Amyotrophic lateral sclerosis	Phase II	China Taiwan region	2017-07
ONO-7475	Ono Pharmaceutical	AXL	Leukemia; Myelodysplastic syndrome; Acute myeloid leukemia; Solid tumors	Phase II	U.S.	2017-06
Dubermatinib/ TP-0903	Sumitomo Dainippon Pharma Oncology Inc	AXL	Chronic lymphocytic leukemia; NSCLC; Melanoma; CRC; Ovarian cancer, AML, Solid Tumor	Phase II	U.S.	2016-04

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<u>Drug Name</u>	<u>Company</u>	<u>Target</u>	<u>Indications</u>	<u>Status</u>	<u>Location</u>	<u>Date</u>
Bemcentinib/ BGB324	Bergenbio; Bergenbio Asa; MSD; Rigel Pharmaceuticals Inc	AXL	Myelodysplastic syndrome; Melanoma; Breast cancer; NSCLC; Lung adenocarcinoma. Acute myeloid leukemia; Non-alcoholic fatty liver disease; Idiopathic pulmonary fibrosis; COVID-19; Pancreatic Neoplasms; Brain and Central Nervous System Tumors	Phase II	U.S.; France; Germany; Netherlands; Italy; Norway	2015-07
Enapatamab vedotin	Genmab	AXL	Ovarian Cancer; Cervical Cancer; Endometrial Cancer; Non Small Cell Lung Cancer; Thyroid Cancer; Melanoma; Sarcoma	Phase I/II	Belgium; Denmark; Netherlands; Spain; UK; U.S.	2016-12
BGB-149	Bergenbio	AXL	Ovarian Neoplasms	Phase I	South Korea; UK; Norway; Singapore	2021-05
PF-07265807	Pfizer Inc	AXL	Neoplasm Metastasis	Phase I	U.S.	2020-07
SLC-391/ XZB-0004	Signalchem Lifesciences Co; Xuanzhu Biotechnology	AXL	Solid Tumor	Phase I	Canada	2019-06
CCT301-38	Shanghai PerHum Therapeutics Co., Ltd.	AXL	Relapsed or Refractory AXL Positive Sarcomas	Phase I	China	2021-11

*Note:*

(1) Date denotes the date on which the relevant status was publicly disclosed.

Source: CDE, FDA, Annual Reports of Listed Pharmaceutical Companies, Frost & Sullivan Report

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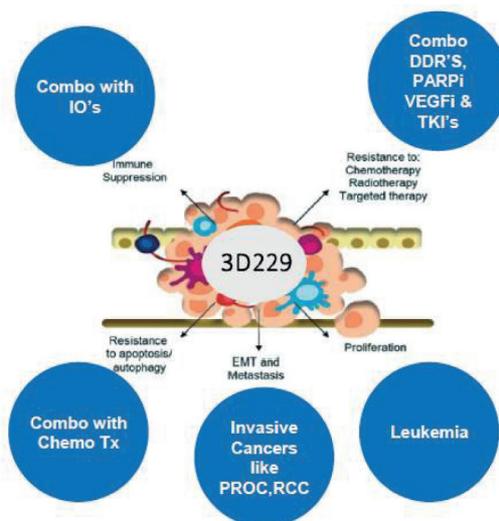
### iii. Competitive Advantages

- (1) Differentiated product in advanced clinical stage in the world with demonstrated promising effectiveness

3D229 is a differentiated GAS6-AXL signaling pathway inhibitor that selectively binds GAS6 to suppress AXL signaling while other products are tyrosine kinase inhibitors (TKIs) or monoclonal antibody. Please refer to the paragraphs headed “Our Core Product and Other Drug Candidates – 2. Our Other Clinical-Stage Drug Candidates – 3D229 – ii. Market Opportunities and Competition” in this section. Limited selectivity of TKIs likely leads to off-target toxicity and tumor cells often acquire resistance. In addition, monoclonal antibodies likely do not have a high enough affinity to compete effectively with and disrupt the high-affinity GAS6-AXL interaction. The approaches of such other products to target GAS6-AXL signaling pathway have drawbacks which limit their ability to effectively target this pathway.

- (2) Good synergy with other immunotherapies with potential in various indications

3D229 has the potential to treat indications such as leukemia and invasive cancers that are outside the treatment scope of PD-1/PD-L1 and may overcome resistance to PD-1/PD-L1 antibodies. It can therefore potentially achieve good synergy with PD-1/PD-L1 antibodies including our envafolimab. In addition, as illustrated in the diagram below, 3D229 has the potential to work in combination with chemotherapy, radiotherapy, and targeted therapies.



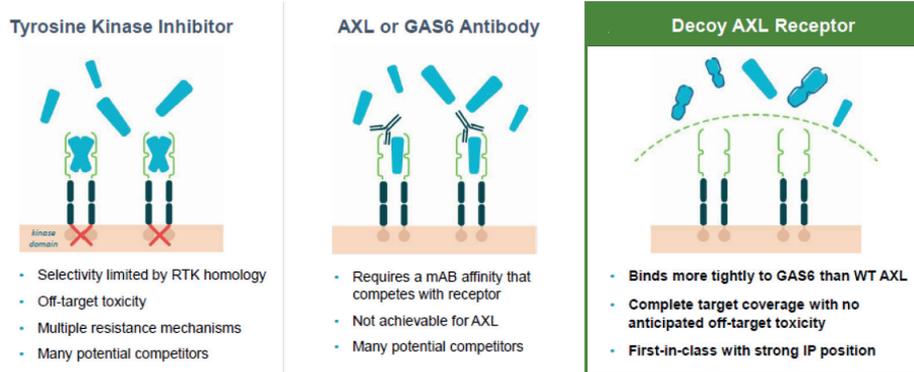
*Abbreviations:* IO = immune-oncology; DDR = DNA damage response; PARPi = polymerase inhibitor; VEGFi = vascular endothelial growth factor receptor inhibitor; TKI = tyrosine kinase inhibitor; PROC = platinum-resistant ovarian cancer; RCC = renal cell carcinoma.

*Source: Company data*

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(3) Promising efficacy due to its advantages in design and mechanism of action

As illustrated by the diagram below, compared to tyrosine kinase inhibitors and AXL or GAS6 antibodies, engineered decoy receptors are potentially the best approach for potently and selectively inhibiting the GAS6-AXL signaling pathway. A GAS decoy receptor can bind more tightly to GAS6 than wild-type AXL with no anticipated off-target toxicity. 3D229 is a high affinity decoy protein that suppresses GAS6 to undetectable levels in early clinical studies and has prolonged target engagement. The safety and tolerability profile of 3D229 in the Phase I clinical trial of 3D229 with healthy volunteers supports its good safety profile and potential for use as a combination and/or maintenance therapy. Please refer to the paragraphs headed “Our Core Product and Other Drug Candidates – 2. Our Other Clinical-Stage Drug Candidates – a. 3D229 – iv. Summary of Clinical Trials – (1) Phase I Clinical Trial in Healthy Volunteers in the U.S.” in this section.



Source: Company data

In addition, in the Phase Ib/II clinical trial of 3D229 in combination with pegylated liposomal doxorubicin (PLD) or paclitaxel (PAC) in patients with platinum-resistant recurrent ovarian cancer, as illustrated in the table below, 3D229 in combination with PAC showed ORR of 35% (95% CI of 16% to 58%) while historically, PAC monotherapy has demonstrated an ORR of approximately 10% to 15%. Please refer to the paragraphs headed “Our Core Product and Other Drug Candidates – 2. Our Other Clinical-Stage Drug Candidates – a. 3D229 – iv. Summary of Clinical Trials – (2) Phase Ib/II Clinical Trial for the Treatment of Patients with PROC” in this section. Historically, high sAXL was associated with poor prognosis. However, PAC in combination with 3D229 in this study demonstrated higher response rate with higher sAXL/GAS6 ratio in a post-hoc analysis and will be further explored in future studies. The Phase II portion of this trial was not conducted.

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**Table: Investigator-Assessed Best Response per RECIST V1.1**

	<b>PAC (N=23)</b>	<b>PLD (N=26)</b>
CR	2 (8.7%)	0
PR	6 (26%)	4 (15%)
ORR	<b>8 (35%)</b>	4 (15%)
SD	6 (26%)	12 (46%)
CBR	14 (61%)	16 (61.5%)
PD	9 (39%)	10 (38.5%)

*Abbreviations:* CR = complete response; PR = partial response; ORR = overall response rate; SD = stable disease; CBR = clinical benefit rate; PD = Pharmacodynamic.

*Source: Company data*

(4) Favorable clinical safety profile

Our partner Aravive has completed a single-blind, randomized, placebo-controlled, Phase I, single ascending-dose (SAD) and repeat-dose (RD), safety and tolerability study of intravenous 3D229 in healthy human volunteers in the U.S. Based on the safety, PK and PD profile of 3D229 in healthy volunteers Phase I clinical trial, 3D229 was well tolerated at all doses levels (1.0, 2.5, 5.0, 10 mg/kg) without clinically significant TEAEs. Please refer to the paragraphs headed “Our Core Product and Other Drug Candidates – 2. Our Other Clinical-Stage Drug Candidates – a. 3D229 – iv. Summary of Clinical Trials – (1) Phase I Clinical Trial in Healthy Volunteers in the U.S.” in this section.

*iv. Summary of Clinical Trials*

As of the Latest Practicable Date, our partner Aravive had evaluated the safety and efficacy profiles of 3D229 (batiraxcept, AVB-500) in several completed and ongoing clinical trials covering a wide variety of tumor types, including PROC, advanced clear cell renal cell carcinoma (ccRCC). Our partner Aravive is conducting a Phase III clinical trial with of 3D229 in combination with PAC versus PAC alone in patients with PROC in the U.S. and Europe. The first patient was enrolled in the U.S. in April 2021. Aravive initiated this Phase III pivotal clinical trial during the first quarter of 2021. The primary endpoint of the Phase III clinical trial is progression free survival. We submitted the IND for 3D229 in China in April 2021 to participate in the MRCT and obtained the IND approval for this trial in July 2021, and we initiated this Phase III clinical trial in China in February 2022.

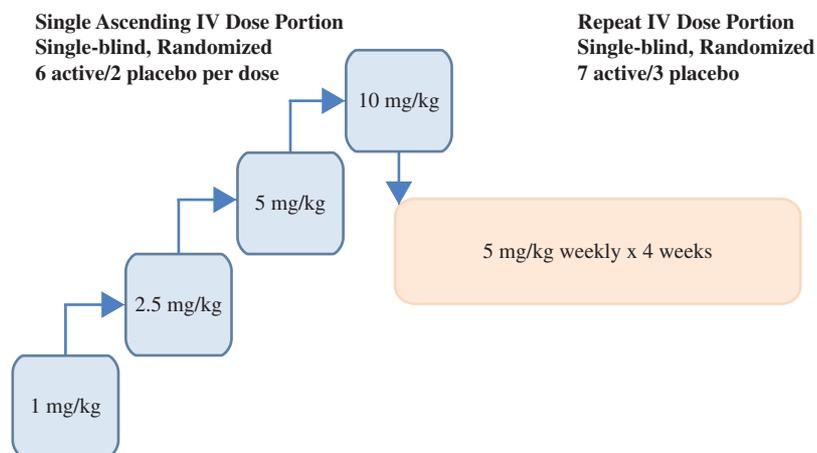
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The following summarizes the clinical trials completed and/or being conducted by our partner Aravive with 3D229 (batiraxcept, AVB-500):

(1) Phase I Clinical Trial in Healthy Volunteers in the U.S.

In 2018, a Phase I clinical trial with 3D229 (batiraxcept, AVB-500) was completed in 42 dosed normal healthy human volunteers. Subjects in the Phase I trial were given single ascending intravenous, doses and 4 weekly repeat intravenous doses of 3D229 (batiraxcept, AVB-500). The primary objective of the trial was to evaluate the safety and tolerability in healthy subjects of intravenously administered 3D229 (batiraxcept, AVB-500). Secondary objectives were to characterize the pharmacokinetics and pharmacodynamics of intravenously administered 3D229 (batiraxcept, AVB-500) over a range of dose levels and at a single dose level (5mg/kg) for a total of 4 weekly doses.

First Clinical Study in Healthy Volunteers Identified Well-Tolerated and Pharmacologically Active Doses  
*Data Presented at 2018 EORTC-NCI-AACR*



*Source: Aravive's annual report on Form 10-k*

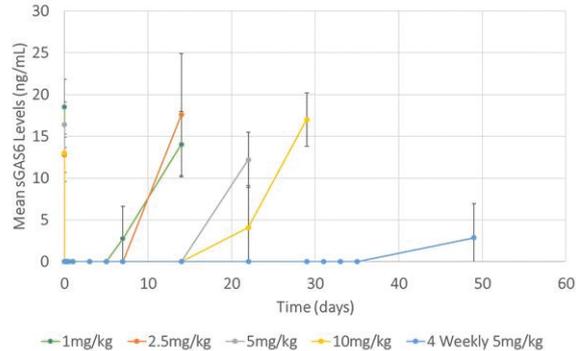
In this study all laboratory values outside the normal limits as defined in the NCI-CTCAE v4.03 after the first dose of study drug were recorded as adverse events (AEs) whether or not the Investigator deemed them clinically significant. There were no AEs classified as serious and no dose-related AEs. No anti-drug antibodies were noted. As anticipated from preclinical studies, a maximum tolerated dose was not reached and 3D229 (batiraxcept, AVB-500) was well-tolerated across all doses (1, 2.5, 5, 10mg/kg single doses and 4 weekly 5mg/kg doses). The clinical trial met the safety and tolerability endpoints for the trial and demonstrated clinical proof-of-mechanism for 3D229 (batiraxcept, AVB-500) at all doses in neutralizing GAS6, as all doses tested in human subjects suppressed serum GAS6 for at least one week. As shown in the figure below, serum GAS6 levels were suppressed until 22



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and 29 days following the 5 mg/kg and 10 mg/kg doses, respectively. Weekly administration of 5mg/kg resulted in suppression of sGAS6 in 4 out of 6 subjects for at least 3 weeks after the fourth dose.

Proof of Mechanism Demonstrated At All Doses  
Increased AVB-S6-500 Dose Increased Duration of Abrogation of Serum GAS6



Source: Aravive's annual report on Form 10-k

### (2) Phase Ib/II Clinical Trial for the Treatment of Patients with PROC

In December 2018, following a normal healthy volunteer trial that identified a dose of 10mg/kg 3D229 (batiraxcept, AVB-500) as sufficient to suppress serum GAS6 levels for a two-week period, Aravive began treating patients in a Phase Ib clinical trial combining 10mg/kg (administered every 2 weeks) 3D229 (batiraxcept, AVB-500) with standard-of-care therapies (specifically, PAC or PLD) in patients with PROC. The Phase Ib clinical trial was designed, in part, to confirm the dosing regimen predicated on the Phase 1 trial in healthy volunteers and to identify the dose to investigate in later stage trials. The primary objective of the Phase Ib clinical trial was to assess the safety and tolerability of 3D229 (batiraxcept, AVB-500) in combination with PAC or PLD, and secondary objectives were to assess pharmacokinetics and pharmacodynamics or PK/PD (serum GAS6 and soluble AXL (sAXL) levels), efficacy, and potential immunogenicity of 3D229 (batiraxcept, AVB-500). Exploratory objectives included efficacy endpoints in biomarker (GAS6, AXL) defined populations based on expression of those biomarkers in serum and/or tumor tissue. In September 2019, positive data from the initial 12 patients of the Phase Ib clinical trial in a late breaking oral presentation was presented at the European Society for Medical Oncology (ESMO) Congress in Barcelona and based upon the analysis of the data decided to study higher doses of the drug and expanded the Phase Ib trial to study 15 mg/kg and 20 mg/kg dose levels.

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On July 23, 2020, a press release was issued to present data from the Phase Ib clinical trial of 3D229 (batiraxcept, AVB-500) combined with standard of care therapies in patients with PROC, the selection of 15 mg/kg as the recommended dose and other results of the trial. The Phase1b clinical trial results are set forth below:

The safety of 3D229 (batiraxcept, AVB-500) has been studied in 84 subjects as of July 2020, including 31 healthy volunteers in a Phase Ia clinical trial and 53 patients with PROC in a Phase Ib clinical trial (40 in 10 mg/kg cohort, 6 in 15 mg/kg cohort, and 7 in 20 mg/kg cohort). The primary objective of the Phase Ib clinical trial was to assess safety of 3D229 (batiraxcept, AVB-500) in combination with PAC or PLD. Secondary endpoints included ORR, CA-125 response, clinical benefit rate, PFS, overall survival, PK profile, GAS6 serum levels, and anti-drug antibody titers.

*Safety Data:* Analysis of all safety data to date demonstrates that 3D229 (batiraxcept, AVB-500) has been generally well-tolerated with no dose-limiting toxicities or unexpected safety signals. There have been no 3D229 (batiraxcept, AVB-500)-related significant adverse events reported to date. There were two types of adverse events that were considered related to 3D229 (batiraxcept, AVB-500), as determined by an independent medical monitor: infusion reactions and fatigue. A premedication regimen was designed and implemented during the trial to manage potential infusion reactions.

*Pharmacokinetics:* Prior data analysis of 31 patients from the 10 mg/kg cohort showed that blood trough levels of 3D229 (batiraxcept, AVB-500) demonstrated statistically significant correlation with clinical activity, as patients who achieved minimal efficacious concentration or MEC >13.8 mg/L demonstrated a greater likelihood of response and prolonged PFS. Updated modeling using actual data from all enrolled patients demonstrated that the 20 mg/kg dose is not predicted to improve PFS relative to the 15 mg/kg dose so the dose of 15 mg/kg was selected as the recommended Phase II dose (RP2D) for 3D229 (batiraxcept, AVB-500).

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*Clinical Activity:* While the Phase Ib clinical trial was a safety trial and not powered to demonstrate efficacy, the investigator-assessed best response or RECIST V1.1 to 3D229 (batiraxcept, AVB-500) across all cohorts supports promising clinical activity, as summarized in the table below:

<b>Cohort</b>	<b>Patients Evaluable</b>	<b>Key Findings</b>
10 mg/kg cohort	37 out of 40 patients evaluable	21.6% ORR (8/37) in all evaluable patients, regardless of their MEC or use of PAC or PLD. 33% ORR (5/15) among those treated with 3D229 (batiraxcept, AVB-500) in combination with PAC, with 1 complete response or CR. 50% ORR (4/8), with 1 CR in PAC patients who achieved MEC (13.8mg/L) of 3D229 (batiraxcept, AVB-500). The PFS among those patients treated with 3D229 (batiraxcept, AVB-500) plus PAC who achieved MEC was 7.5 months versus 2.28 months in patients with blood trough levels below MEC (p=0.0062).
15 mg/kg cohort	5 out of 6 patients evaluable	5/5 efficacy evaluable patients in this cohort experienced clinical benefit, with 1 CR, 2 partial responses (PR), and 2 stable disease (SD)
20 mg/kg cohort	7 out of 7 patients evaluable	Of the 7 patients in this cohort, there was 1 PR (with CR of target lesion), 1 SD, and 5 with progressive disease (PD). A post-hoc analysis of tumor expression showed that 4 patients whose best response was PD did not express GAS6 (3) and/or had low amounts of AXL (2) on immunohistopathology of their tumors. While they were enrolled per protocol in the Phase Ib clinical trial, these patients do not appear to be representative of the eventual 3D229 (batiraxcept, AVB-500) target population, as they are mostly rare subtypes of PROC and such patients based on their clinical characteristics will not be eligible for the pivotal trial. The pivotal trial has been designed to only enroll patients with high grade serous ovarian cancer as that is the pathology associated with elevated AXL expression.

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Conclusion: 3D229 (batiraxcept, AVB-500) plus PAC appeared to perform better than 3D229 (batiraxcept, AVB-500) plus PLD. Across all cohorts, 3D229 (batiraxcept, AVB-500) plus PAC data show an ORR of 35% (8/23, including 2 CRs) compared to ORR of 15% (4/26) in 3D229 (batiraxcept, AVB-500) plus PLD. 3D229 (batiraxcept, AVB-500) performed well in patients with later lines of therapy and showed improved clinical benefit over published data showing response for patients who were on their third and fourth lines of therapy or who progressed in less than 3 months following their last platinum-containing regimen. 3D229 (batiraxcept, AVB-500) treatment alone demonstrated an ability to maintain tumor response. Three patients' responses were maintained for 3 to 6 months on 3D229 (batiraxcept, AVB-500) following PAC (2 patients) or PLD (1 patient). One was treated at 15 mg/kg had a CR, and 2 patients treated at 10 mg/kg had partial responses (PR). For the 2 patients on maintenance 3D229 (batiraxcept, AVB-500) alone, tumors progressed after missed scheduled 3D229 (batiraxcept, AVB-500) administration.

### (3) Phase III Clinical Trial for the Treatment of Patients with PROC

On November 19, 2020, Aravive announced that it had received guidance from the FDA on a registrational Phase III trial design for 3D229 (batiraxcept, AVB-500) in PROC. The FDA feedback received was that this trial, if successful, could support full approval of 3D229 (batiraxcept, AVB-500) for the treatment of PROC. No further preclinical or clinical pharmacology studies are required at this time. The global, randomized, double-blind, placebo-controlled adaptive trial is designed to evaluate efficacy and tolerability of 3D229 (batiraxcept, AVB-500) at a dose of 15 mg/kg in combination with PAC. The Phase III trial was initiated by Aravive in the first quarter of 2021. The pivotal Phase III trial is expected to enroll approximately 350 patients with high-grade serous ovarian cancer who have received one to four prior lines of therapy. This global trial is planned to be conducted at approximately 165 sites in the U.S., China and Europe. The primary endpoint for the trial is PFS, and secondary endpoints include overall survival, objective response rate based on RECIST 1.1, safety and tolerability, duration of response, quality of life, clinical benefit rate, and pharmacokinetic and pharmacodynamic profile. Exploratory biomarkers include serum GAS6, serum sAXL and 3D229 (batiraxcept, AVB-500) drug levels.

In April 2021, Aravive dosed the first patient in its registrational Phase 3 trial of 3D229 (batiraxcept, AVB-500). Aravive projected BLA submission in the second half of 2023 if the ongoing MRCT Phase III is successful.

### (4) Phase Ib/II Clinical Trial for the Treatment of Patients with ccRCC

This is an open-label Phase 1b/2 study (NCT04300140) of 3D229 (batiraxcept, AVB-500) designed to evaluate the safety and efficacy of 3D229 (batiraxcept, AVB-500) in combination with cabozantinib, 3D229 (batiraxcept, AVB-500) in

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combination with cabozantinib and nivolumab, and 3D229 (batiraxcept, AVB-500) monotherapy in subjects with advanced or metastatic clear cell renal cell carcinoma (ccRCC). The trial has a Phase Ib safety portion and a Phase II randomized, controlled portion.

The Phase Ib portion investigates the safety and tolerability of escalating doses (15 mg/kg and 20mg/kg Q2W) of 3D229 (batiraxcept, AVB-500) in combination with cabozantinib (60mg QD) in 26 patients with advanced ccRCC that have progressed after front-line treatment. The primary endpoints for the Phase Ib portion of the clinical trial are safety, PK and PD measurements with secondary endpoints including preliminary activity measures.

As of April 30, 2022, the Phase 1b study completed enrollment with 26 patients (16 patients treated with 15 mg/kg and 10 patients treated with 20 mg/kg 3D229 (batiraxcept, AVB-500) Q2W in combination with cabozantinib 60 mg QD). 3D229 (batiraxcept, AVB-500) 15 mg/kg in combination with cabozantinib 60 mg has a manageable safety profile in previously treated ccRCC. No dose-limiting toxicities have been observed. A similar safety profile was observed across the 15 mg/kg and 20 mg/kg dose cohorts. 3D229 (batiraxcept, AVB-500) given every two weeks suppressed serum GAS6 to below the level of quantitation in 25/26 patients (one patient did not have an assessment), showing a clear PK/PD relationship. 23 out of 26 patients had 3D229 (batiraxcept, AVB-500) trough levels above the minimally efficacious concentration of 13.8 mg/L by Cycle 2. The confirmed and unconfirmed response rate in the total population was 46%, with a 50% confirmed response rate in the 15mg/kg (RP2D) 3D229 (batiraxcept, AVB-500) group. The proportion of patients in the total population who were progression-free at seven months was 71%. The proportion of patients in the total population who had a duration of response of at least seven months was 75%. A baseline biomarker enriched the confirmed response rate in the RP2D (15mg/kg) biomarker high population to 67%, increased the proportion of patients progression-free at seven months to 91%, and increased the proportion of patients who had a duration of response of at least seven months to 80%. 58% (15/26) of the total population achieved a better response on the 3D229 (batiraxcept, AVB-500) trial than they did with their therapy prior to study entry, which was only 23%. This combination's safety and clinical activity with PK/PD data support an RP2D of 15 mg/kg.

The Phase II portion of the clinical trial includes three parts: part A (n=25): 3D229 (batiraxcept, AVB-500) 15 mg/kg Q2W in combination with cabozantinib 60 mg QD for ccRCC subjects who have progressed on or after at least one line of therapy; part B (n=20): 3D229 (batiraxcept, AVB-500) 15 mg/kg Q2W with cabozantinib 40 mg QD and nivolumab (240 mg Q2W or 480 mg Q4W, at the investigator's choice) for first-line treatment of advanced or metastatic ccRCC subjects; and part C (n=10): 3D229 (batiraxcept, AVB-500) 15 mg/kg Q2W monotherapy for subjects with advanced/metastatic ccRCC ineligible for curative intent therapies. The primary objective for each arm is objective response rate by

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RECIST v1.1. Secondary objectives include safety, duration of response, clinical benefit rate, progression-free survival by RECIST v1.1, and overall survival. On January 31, 2022, the first patient in the Phase 2 portion was dosed.

(5) Phase Ib/II Clinical Trial for the Treatment of Patients with Pancreatic Cancer

On May 6, 2021, Aravive announced its plans to initiate a Phase 1b/2 clinical trial to investigate 3D229 (batiraxcept, AVB-500) as a first-line treatment in pancreatic cancer.

Aravive plans to expand development of 3D229 (batiraxcept, AVB-500) in a Phase 1b/2 trial as a first-line treatment for pancreatic cancer. The expected design of the trial will evaluate 3D229 (batiraxcept, AVB-500) in combination with gemcitabine and nab-paclitaxel (Abraxane®) in patients with advanced metastatic pancreatic cancer eligible to receive gemcitabine and nab-paclitaxel (Abraxane®) combination therapy. The Phase 1b portion of the clinical trial will assess safety, tolerability, and clinical activity of 3D229 (batiraxcept, AVB-500) in combination with gemcitabine and nab-paclitaxel (Abraxane®). The randomized, controlled Phase 2 portion of the clinical trial will evaluate 3D229 (batiraxcept, AVB-500) in combination with gemcitabine and nab-paclitaxel (Abraxane®) versus gemcitabine and nab-paclitaxel (Abraxane®) alone. The first patient in (FPI) for the Phase 1b portion of the clinical trial was on August 9, 2021.

v. *Clinical Development Plan*

We completed the Phase I clinical trial in May 2022, and we have expanded the Phase III pivotal trial to China. The results of the Phase III together with Phase I studies in China and the U.S. will be used to support a potential BLA in China. In addition, we plan to conduct Phase Ib/II studies to assess 3D229 in combination with envafolimab in NSCLC, RCC, UC and OC. The inclusion of OC will be initiated if the ongoing Phase III study is successful. If supported by the data from the Phase Ib/II study, we will conduct Phase III studies in these tumor types. Specifically, in the second-line treatment of OC, we plan to evaluate 3D229 in combination with envafolimab versus PAC/PLD if the first PROC Phase III trial is positive, and the Phase II data is supportive. If successful, this will potentially establish a chemotherapy free regimen. In the first-line treatment, we plan to evaluate 3D229 (+/-envafolimab) plus pac/carbo versus pac/carbo if the data from the Phase II study is supportive. For NSCLC, 3D229 will be evaluated in combination with envafolimab in second-line or later subjects who have failed first-line PD-1/PD-L1 treatment and patients who are KRAS mutation positive and have failed chemotherapy. If supported by data, Phase III studies in these NSCLC patient populations will be conducted. If supported by data, we plan to conduct registrational studies of 3D229 for the treatment of RCC and UC, and potentially other tumor types.

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The table below sets forth the details of our clinical development plan in China for 3D229:

Indication	Status	(Expected) first patient in date	Expected NDA submission date	Expected number of patients	Location and competent authority
Healthy Volunteers <sup>(1)</sup>	Phase I	Q3 2021 (trial completed)	-	24	China and NMPA
NSCLC <sup>(2)</sup>	Phase Ib/II	Q4 2022	-	60	China and NMPA
RCC <sup>(2)</sup>	Phase Ib/II	Q4 2022	-	60	China and NMPA
UC <sup>(2)</sup>	Phase Ib/II	Q4 2022	-	50	China and NMPA
2L PROC (Aravive sponsored) <sup>(3)</sup>	Phase III	Q2 2022	2024	350	China and NMPA U.S. and FDA Europe and EMA
1L OC <sup>(4)</sup>	Phase III	2H 2023	2026	300-500	China and NMPA
2L OC <sup>(4)</sup>	Phase III	2H 2023	2026	300-500	China and NMPA
NSCLC <sup>(5)</sup>	Phase III	2H 2023	2026	300-500	China and NMPA

*Abbreviations:* NSCLC = non-small cell lung cancer; RCC = renal cell carcinoma; UC = urothelial carcinoma; PROC = platinum-resistant ovarian cancer; OC = ovarian cancer; 1L = first-line; 2L = second-line; Q1 = first quarter; Q3 = third quarter; 2H = second half.

*Notes:*

- (1) This trial is conducted in healthy volunteers to enable comparison of PK between US and Chinese subjects. The US phase I was completed in healthy volunteers as well. This was made possible due to the favorable safety profile of 3D229. The study was completed in May 2022. The study showed similar PK and safety profiles between Chinese and U.S. subjects.
- (2) The reason for choosing NSCLC, RCC and UC were based on pre-clinical and clinical evidence suggesting additivity and synergy between AXL inhibition and PD-(L)1 inhibition as well as role of AXL signaling in immune checkpoint inhibitor (ICI) resistance. We obtained the IND approval for these Phase Ib/II clinical trials in April 2022. As of July 18, 2022, these clinical trials were still in preparation stage and no patient had been enrolled. First patient is expected to be enrolled in the fourth quarter of 2022.
- (3) As of July 18, 2022, four patients had been enrolled in this clinical trial in China.
- (4) The initiation of Phase III clinical trials in 1L OC and 2L OC will depend on the positive results from the ongoing Aravive sponsored MRCT Phase III clinical trial.
- (5) The initiation of Phase III in NSCLC will depend on the results of the Phase Ib/II clinical trial of NSCLC.

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*vi. Licenses, Rights and Obligations*

We maintain the exclusive rights to develop, manufacture and commercialize products that contain 3D229 as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in China, Hong Kong, Macau and Taiwan region, pursuant to a collaboration and license agreement between us and Aravive. Please refer to the paragraph headed “Our Research and Development – Collaboration Agreements – Collaboration with Aravive for 3D229” in this section.

*vii. Material Communications*

We submitted the IND for 3D229 for a Phase I clinical trial in healthy volunteers in China and obtained the IND approval in China in May 2021. We obtained the IND approval for a Phase Ib/II clinical trial in patients with NSCLC, RCC and UC in April 2022. In addition, we submitted the IND for 3D229 for a Phase III clinical trial in patients with PROC in China in April 2021 to participate in the MRCT and obtained the IND approval for this trial in July 2021. We have not received any relevant regulatory agency’s objections to our clinical development plans as of the Latest Practicable Date.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET 3D229 SUCCESSFULLY.**

*c. 3D011*

3D011 is an in-house discovered tyrosine kinase inhibitor (TKI) prodrug for the treatment of advanced solid tumors. 3D011 is formed by linking ABT-869 (linifanib), an orally available multi-targeted anti-angiogenesis TKI investigational drug, with a linker (12 carbon chain fatty acid) and a specific 5-peptide (Asp-Glu4). A number of non-clinical studies have been completed for 3D011, including *in vivo* and *in vitro* PD, PK/TK studies, and safety pharmacology studies to support its clinical trials in patients with advanced cancer. Based on such non-clinical data, and the existing clinical data of ABT-869 (linifanib), it is expected that 3D011 can achieve similar or better efficacy than ABT-869 (linifanib) in human trials while reducing its toxicity, which may provide a more effective choice versus available VEGFR multi-TKIs. We received the IND approval from the NMPA in January 2021. We initiated an open-label, single-arm Phase I dose escalation and dose expansion clinical trial in patients with advanced malignant solid tumors in February 2022 and plan to enroll the first patient for this trial in the third quarter of 2022.



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The table below shows the indications for which we are currently evaluating 3D011 in clinical trials in China:

Indication <sup>(1)</sup>	Status				
	IND	Phase I	Phase II	Phase III	NDA/BLA (Filed)
<b>China</b>					
Locally advanced, unresectable solid tumors	●	◐			

Symbols: ● = complete; ◐ = in progress (a clinical trial is deemed to have been initiated when the first study site is activated); ◑ = to be initiated

Note:

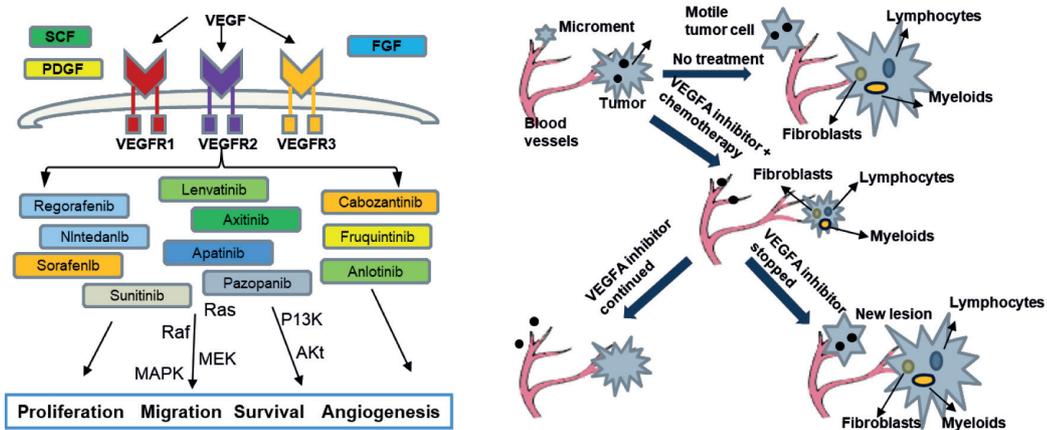
- (1) Some indications may not require every phase of the clinical trials indicated on this chart to be completed prior to the filing of an NDA/BLA.

*i. Mechanism of Action*

Excessive abnormal angiogenesis is one of the hallmarks of solid tumors. Tumor angiogenesis plays a key role in the occurrence, development and metastasis of malignant solid tumors. Anti-angiogenesis is an important development direction of tumor therapy, and the signaling pathway of vascular endothelial growth factor and its receptor (VEGF/VEGFR) is key to tumor angiogenesis. Besides, PDGFRs and C-KIT pathways also play an important role in tumor angiogenesis. Today, anti-angiogenesis agents represent standard-of-care therapies for multiple types of cancers. As of the Latest Practicable Date, 11 VEGFR targeted anti-angiogenesis TKIs have been approved for cancer treatment by the FDA or the NMPA. The benefits of these anti-angiogenesis agents have proved to be modest, as they provide moderate improvement of overall survival in some indications and delay disease progression without prolonging overall survival in other cancers. Importantly, recent studies demonstrated that anti-angiogenesis therapy not only prunes blood vessel which is essential to cancer growth and metastasis, but also reprograms the tumor immune microenvironment. Anti-angiogenesis induces tumor vessel normalization and improves blood perfusion. Alleviated hypoxia decreases PD-L1 expression on tumor cell while blocked VEGF signal downregulates immune checkpoint expression (e.g. PD-1) on CTL. In the meanwhile, activated immune response-derived inflammatory factors such as interferon- $\gamma$  (IFN- $\gamma$ ) promotes vessel normalization and regression. Interaction between vessel normalization and immune microenvironment reprogramming could be regulated by anti-angiogenesis agents (bevacizumab or VEGFR-TKI such as axitinib, sorafenib, sunitinib, and vatalanib) and ICI (especially anti-PD-1/PD-L1 mAb). The combination of immunotherapy and anti-angiogenesis agent has

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shown more potent anti-tumor effects in multiple tumor types and is now the hotspot in clinical studies.



Source: *Angiogenesis*. 2010; 13(1): 1-14., *Int J Biochem Cell Biol*. 1996 Apr;28(4):373-85., *Oncotarget*. 2017 Feb 28; 8(9): 16052-16074., *Drug Des Devel Ther*. 2016; 10: 2443-2459., *Molecular Cancer* volume 21, Article number: 31 (2022), Frost & Sullivan Report

As illustrated in the diagram above, the mechanism of action of multi-targeted small molecule drugs targeting VEGFRs is mainly inhibition of tumor growth by inhibiting tumor angiogenesis. Patients who received anti-angiogenesis therapies are those with advanced-stage disease. They have highly vascularized tumors in the primary organ and/or metastatic sites. In addition, they likely harbor undetected micrometastatic lesions (Micromet). If left untreated, the large tumors will continue to grow and some micromets will develop into new lesions. There are many different cell types in the lesions, which include fibroblasts, lymphocytes, and myeloid cells. Fibroblasts and some myeloid cells may promote tumor growth. When late-stage tumors are treated with VEGFA pathway inhibitors in combination with chemotherapy, vascular pruning occurs. The anti-angiogenesis function of VEGFA pathway antagonists could also prevent micromets from growing into new lesions. VEGFA pathway antagonism has also been shown to increase transendothelial migration of lymphocytes and myeloid cells. After treatment with multiple cycles of VEGFA inhibitor plus chemotherapy, continuation of VEGFR pathway inhibition would exert the antiangiogenesis effect, preventing the regrowth of tumor vasculature and the development of new lesions from micromets. Discontinuation of VEGFA antagonist has been shown to result in the restoration of dense tumor vasculature and the resumption of tumor growth, and may also enable micromets to form new lesions. The exposure of the drug in the body will affect the degree of inhibition of tumor blood vessels.

3D011's parent drug, ABT-869 (linifanib), is an orally available, multi-targeted anti-angiogenesis drug, which has a good inhibitory effect on angiogenesis-related kinases such as VEGFRs, PDGFRs, CSF1R, c-KIT and FLT1/3. 3D011 is formed by linking ABT-869 (linifanib) with a linker (12-carbon chain fatty acid) and a specific

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5-peptide (Asp-Glu4). Pre-clinical data has shown that 3D011 is stable *in vitro*, and exert pharmacological activity *in vivo*, potentially by degrading linker and specific 5-peptide via cathepsin and hydrolase systems to release the parent drug ABT-869 (linifanib). In addition, specific 5-peptide have certain tumor targeting properties, which can facilitate preferential distribution of 3D011 to tumor tissues where it is metabolized locally to produce the parent drug ABT-869 (linifanib) to exert its anti-tumor effect.

*ii. Market Opportunities and Competition*

TKI drugs targeting angiogenesis have the potential to impair multiple stages of tumor progression and reprogram the tumor immune microenvironment. In 2020, the global sales of VEGF/VEGFR targeting TKI reached US\$16.0 billion, according to Frost & Sullivan. As of the Latest Practicable Date, 3D011 is the only angiogenesis targeting TKI prodrug in clinical development in China.

*iii. Competitive Advantage*

(1) Strong demonstration of our *de novo* in-house discovery capabilities

With its unique pro-drug design, 3D011 demonstrates our *de novo* in-house discovery capabilities, from early discovery to clinical stage. The discovery process of 3D011 was initiated in 2016. After comprehensively investigating dozens of drugs that have failed in Phase III clinical trials, we selected an orally available, highly effective drug as the starting compound for systematic development and optimization. After rounds of structure design and optimization, synthesis, optimization of detection assay, our discovery team fully considered and verified the effects of different combinations on the activity and toxicity of the compound, and finally obtained a candidate molecule with well-balanced profiles. In September 2017, our discovery team made a major breakthrough in salt type, which not only greatly improved the water solubility, but also broke through the dilemma of synthesis and purification. And then we managed to obtain gram-level compounds and carry key experiments. We received the IND approval from the NMPA in January 2021.

(2) Potential synergy with PD-L1 inhibitor

3D011 has the potential to be used in combination with our envafolimab for the treatment of solid tumors. There are intricate relationships between angiogenesis and immunity in tumors. Vascular endothelium plays a barrier function and has an important role in activation of immunity by increasing the expression of endothelial cell adhesion molecules that directly interact with macrophages, NK cells, granulocytes, B and T-cells for antigen recognition, rolling, adhesion and extravasation during immune responses. In tumors, vascular endothelial often have abnormal expression of adhesion molecules, including CD34, intracellular cell adhesion molecule-1 (ICAM-1) and vascular cell adhesion molecule-1 (VCAM-1).

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Downregulation of these adhesion molecules is in part mediated by angiogenic factors, including VEGF. VEGF also inhibits the maturation of dendritic cells, which suppresses immune activation. Anti-angiogenic treatment with sorafenib, sunitinib or bevacizumab increased PD-L1 expression. PD-L1 is considered to be a target of HIF1- $\alpha$  and the elevation in its expression may be a consequence of anti-angiogenic treatment-induced hypoxia. But other studies have shown that anti-angiogenic treatment could elevate the expression of PD-L1 independently of hypoxia or HIF1- $\alpha$ . In addition, VEGF could increase PD-1 expression on T-cells and mediate "exhaustion" of CD8+ T-cells in tumors.

Preclinical and clinical studies have shown that PD-1/L1 blockade plus anti-angiogenic treatment with axitinib or bevacizumab or lenvatinib reduced Tregs, increased CD8+ T-cells and inhibited the growth of various solid tumors, and demonstrate PFS and/or OS benefit in hepatocellular carcinoma, advanced renal cell carcinoma, and NSCLC cancer patients.

(3) Improved efficacy compared to ABT-869 (linifanib) in preclinical models

The results of preclinical PD studies have shown that applying 3D011 in xenograft tumor-bearing mice model can effectively inhibit the growth of xenotransplanted tumors such as liver cancer, prostate cancer, lung cancer and breast cancer, and the inhibition rate is dose-dependent. Compared with its parent drug ABT-869 (linifanib), 3D011 has better anti-tumor activity at the same molar dose. ABT-869 (linifanib) has shown anti-tumor effect in clinical studies in solid tumors such as hepatocellular carcinoma, renal cell carcinoma, NSCLC, colorectal cancer and breast cancer. Therefore, 3D011 is expected to have better anti-tumor activity in advanced solid tumors.

(4) Better safety and tolerability compared to ABT-869 (linifanib) in preclinical models

The preclinical studies of 3D011 have shown that, compared to its parent drug ABT-869 (linifanib), the its kinase inhibitory activity and cell proliferation inhibitory activity of 3D011 is successfully blocked. In the toxicological research of mice, when administered in equimolar doses (considering the molecular weight of 3D011 is 1,204 and molecular weight of ABT-869 (linifanib) is 375, 3D011 30 mg/kg intravenous infusion once daily (QD) is equivalent to ABT-869 (linifanib) 10 mg/kg oral administration QD), 3D011 had better safety than ABT-869 (linifanib). Based on the findings of preclinical studies, 3D011 is expected to have better safety and tolerability than ABT-869 (linifanib) in clinical studies.

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iv. *Summary of Clinical Trials*

We initiated an open-label, single-arm Phase I dose escalation and dose expansion clinical trial in patients with advanced malignant solid tumors in February 2022 and plan to enroll the first patient for this trial in the third quarter of 2022. No clinical data was available as of the Latest Practicable Date.

v. *Clinical Development Plan*

We plan to enroll the first patient for a Phase I clinical study of the safety, tolerability, PK and preliminary efficacy of 3D011 monotherapy in human subjects with advanced malignant solid tumors. The trial is designed as an open, single-arm, multi-center Phase I clinical trial, including a dose escalation stage and a dose expansion stage.

The main target population of the dose escalation stage are adult subjects with advanced malignant solid tumors who have no standard treatment or failed standard treatment. It aims to evaluate the safety, tolerability and PK characteristics of 3D011 monotherapy in subjects with advanced malignant solid tumors, as well as preliminary anti-tumor properties to determine RP2D.

The main target population of the dose expansion stage are human subjects with advanced hepatocellular carcinoma and advanced renal cell carcinoma who have failed or refused first-line treatment in the past, and human subjects with metastatic castration-resistant prostate who have failed chemotherapy and/or endocrine therapy. It aims to evaluate the preliminary efficacy, safety, PK and PD characteristics of 3D011 monotherapy of advanced hepatocellular carcinoma, advanced renal cell carcinoma and metastatic castration-resistant prostate cancer in human subjects with RP2D dosing regimen.

We plan to enroll a total of up to 93 patients for this trial, and expect to enroll the first patient in the third quarter of 2022. Following this Phase I trial, we plan to further explore the clinical potential of 3D011 monotherapy or in combination with envafolimab for the treatment of advanced malignant solid tumors.

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The table below sets forth the details of our clinical development plan for 3D011:

<u>Indication</u>	<u>Status</u>	<u>Expected first patient in date</u>	<u>Expected NDA submission date</u>	<u>Expected number of patients</u>	<u>Location and competent authority</u>
Advanced malignant solid tumors <sup>(1)</sup>	Phase I	Q3 2022	-	93	China and NMPA

*Abbreviations:* Q1 = first quarter.

*Notes:*

- (1) The design of this trial is based on the mechanism of action of 3D011 which is a pro-drug of a VEGFR inhibitor, the tumor types chosen are known to be sensitive to VEGFR inhibitors or express enzyme that can convert pro-drug to its active form in the tumor tissue. The site for this clinical trial was activated in first quarter of 2022. Patient enrollment was temporarily delayed due to the control measures taken by the Shanghai government in response to the COVID-19 Recurrences.

### *vi. Licenses, Rights and Obligations*

We internally discovered and developed 3D011, and maintain the global rights to develop and commercialize this drug candidate.

### *vii. Material Communications*

We received the IND approval from the NMPA in January 2021. We had not received any relevant regulatory agency’s objections to our clinical development plans as of the Latest Practicable Date.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET 3D011 SUCCESSFULLY.**

### *d. 3D185*

3D185, also known as HH185, is a dual FGFR1-3 and CSF-1R inhibitor with high selectivity for the treatment of advanced solid tumors. We own the exclusive rights to develop and commercialize 3D185 globally in the oncology and pulmonary fibrosis treatment through our patent license agreements with Haihe Biopharma and Shanghai Institute of Materia Medica, Chinese Academy of Sciences. Preclinical experiments have observed that 3D185 has an inhibitory effect on tumor cells with FGFR genetic alterations, and its toxicity characteristics are consistent with its expected effect as a selective FGFR inhibitor and are reversible. These results support the clinical study of 3D185 in patients with advanced solid tumors. The IND approval was obtained from the NMPA in January 2018. We received the IND

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approval from the FDA in September 2019. We initiated a Phase I clinical trial in patients with locally advanced or metastatic solid tumors in China and the U.S. The FPI in China was December 2018 and the FPI in the U.S. was February 2020. We completed the Phase I clinical trial in August 2021. Clinical investigation of alternative formulation for 3D185 is ongoing.

The table below shows the indications for which we are currently evaluating 3D185 in clinical trials:

Indication <sup>(1)</sup>	Status				
	IND (Accepted)	Phase I	Phase II	Phase III	NDA/BLA (Filed)
China and the U.S.					
locally advanced or metastatic solid tumors	●	●			

Symbols: ● = complete

Note:

- (1) Some indications may not require every phase of the clinical trials indicated on this chart to be completed prior to the filing of an NDA/BLA.

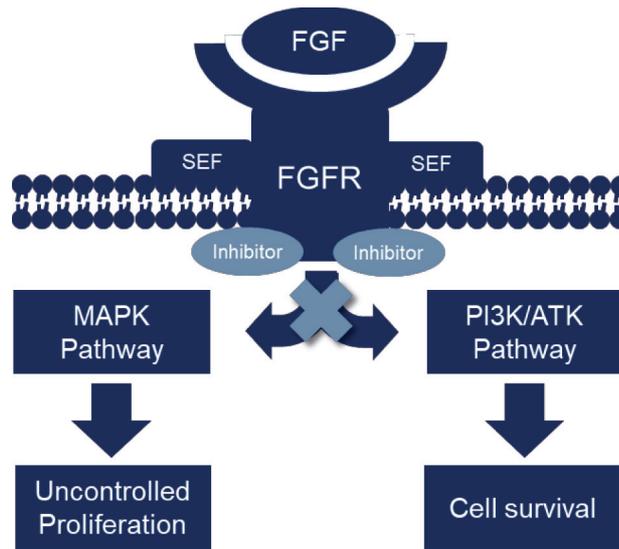
*i. Mechanism of Action*

3D185 is an orally-administered small molecule adenosine triphosphate (ATP) competitive inhibitor of FGFR, which can selectively inhibit the kinase activity of FGFR1, FGFR2, and FGFR3. 3D185 also inhibits CSF1R.

The oxidative metabolism of 3D185 is mainly catalyzed by the cytochrome P-450 enzyme (CYP) 3A4, and CYP2C8, CYP2D6 and CYP3A5 are also involved to a lesser degree. 3D185 basically has (1) no inhibitory effect on CYP1A2 and CYP3A4; (2) a weak inhibitory effect on CYP2B6, CYP2C9, CYP2C19, CYP2D6 and CYP3A4; and (3) a moderate inhibitory effect on CYP2C8. It has no induction effect on CYP1A2, CYP2B6 and CYP3A4 enzymes. In conclusion, 3D185 has a relatively low potential for drug-drug PK interaction.

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3D185, which simultaneously targets FGFR and CSF-1R, is expected to inhibit both tumor cells and remodel the tumor microenvironment to synergistically antagonize tumors and delay the development of resistance to FGFR inhibitors alone. Moreover, 3D185 could inhibit the survival and M2-like polarization of macrophages, reversing the immunosuppressive effect of macrophages on CD8+ T cells. The diagram below shows the mechanism of action for 3D185:



Source: *Oncotarget*. 2017 Feb 28; 8(9): 16052-16074., Frost & Sullivan Report

### ii. Market Opportunities and Competition

FGFR inhibitors can inhibit tumor cells and remodel the tumor microenvironment to synergistically antagonize tumors. In 2020, the global sales of pan-FGFR inhibitors reached US\$84.1 million, according to Frost & Sullivan.



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As of the Latest Practicable Date, there were a total of three approved pan-FGFR inhibitors in the global market, all of which were in the U.S and one of them was also approved in China. As of the same date, there were one and nine pan-FGFR inhibitor candidates in Phase III and Phase I/II clinical trials worldwide, respectively. As of the same date, there were ten pan-FGFR inhibitor candidates registered with the NMPA, of which there were three in Phase III clinical trials and seven in Phase I/II clinical trial. The following table sets out details of the FDA approved pan-FGFR inhibitors in the U.S. as of the Latest Practicable Date:

Drug Name	Company	Target	Indications	Marketed Location	Date of FDA/NMPA Approval	Price	Annual Cost (thousand)	Patent Expiration Date	2020 Revenue
Pemigatinib	Incyte Corp; Innovent Biologics, Inc.	FGFR1, FGFR2, FGFR3	cholangiocarcinoma	U.S. China	2020-04 2022-04	13.5mg: US\$1,351.6	\$321.7	2035-01	\$26 million
Erdaftinib	Fisher Clinical Services; Janssen Research & Development LLC; Johnson & Johnson Ltd	FGFR1, FGFR2, FGFR3, FGFR4	urothelial carcinoma	U.S.	2019-04	3mg: US\$291.1 4mg: US\$388.1 5mg: US\$485.2	\$277.1-311.8	2031-04	N/A
Infigratinib	QED Therapeutics, Inc.	FGFR1, FGFR2, FGFR3	cholangiocarcinoma	U.S.	2021-05	125mg: \$534.7	\$146.0	2030-12	N/A

Source: FDA, Annual Reports of Listed Pharmaceutical Companies, Frost & Sullivan Report

### iii. Competitive Advantages

3D185 has the potential to be used in combination with our envafolimab for the treatment of solid tumors. A preclinical study of combination potential of erdafitinib, a fibroblast growth factor receptor (FGFR) inhibitor under clinical development, with PD-1 blockade in an autochthonous FGFR2K660N/p53mut lung cancer mouse model showed that the erdafitinib and anti-PD-1 combination induced significant tumor regression and improved survival. A decreased fraction of tumor-associated macrophages also occurred but only in combination-treated tumors. Treatment with erdafitinib decreased T-cell receptor (TCR) clonality, reflecting a broadening of the TCR repertoire induced by tumor cell death, whereas combination with anti-PD-1 led to increased TCR clonality, suggesting a more focused antitumor T-cell response.

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iv. *Summary of Clinical Trials*

(1) Phase I Clinical Trial in China and the U.S.

An open-label, global multi-center, dose-escalation Phase I study of safety, tolerability, preliminary PK profile, and preliminary efficacy of 3D185 monotherapy in subjects with advanced solid tumors was completed in China and the U.S. in August 2021. As of December 31, 2020, in the Phase I clinical trial (dose escalation phase), the 25 mg, 50 mg, 100 mg, 150 mg, 200 mg and 250 mg dosing cohorts have been completed, and no DLT event was reported.

*Study purpose.* The primary objective is to assess the safety and tolerability of 3D185 monotherapy in subjects with advanced solid tumors and explore the maximum tolerated dose (MTD) and the recommended dose for subsequent studies (RP2D) of 3D185 monotherapy in subject with advanced solid tumors. The primary endpoint of this trial is the safety and tolerability of 3D185. The secondary endpoint of this trial is the PK, PD and efficacy of 3D185.

*Study design.* The starting dose in this dose-escalation study is 25 mg, and the preset 7 dose-escalation cohorts are 25 mg, 50 mg, 100 mg, 150 mg, 200 mg, 250 mg and 300 mg, respectively. This study adopts a combination of accelerated titration and 3+3 for dose escalation. All subjects in each cohort will receive a single oral dose of 3D185, followed by a 7-day washout period (i.e. single-dose PK study period). Then, subjects will receive consecutive daily doses (28 days/cycle) until disease progression, death, unacceptable toxicity, or withdraw of informed consent, whichever comes first. The dose limiting toxicity (DLT) evaluation period includes the single-dose PK study period and the first treatment cycle (within 35 days after the first dose).

*Safety.* As of December 31, 2020, a total of 15 subjects with advanced malignant solid tumors were enrolled in one of 6 dose cohorts (25 – 250 mg) in this study and received 3D185 tablets monotherapy. Among them, there were 1 subject in each of the 25 mg and 50 mg dose cohorts, 3 subjects in each of the 100 mg, 150 mg, and 200 mg dose cohorts, and 4 subjects in the 250 mg dose cohort. The median treatment days was 37 days (range: 1-256 days). The proportion of subjects who received treatment  $\geq 3$  months and 6 months was 13.3% (n=2) and 6.7% (n=1), respectively. The median follow-up time was 2.1 months (range: 0.3-8.5 months). With respect to the primary endpoint, based on the final clinical study report, 3D185 has shown favorable safety and tolerability. No DLT occurred in six dose cohorts (25 to 250 mg) and the TEAE occurrence rate was similar among all dose cohorts. In addition, we completed the studies of secondary endpoint of PK, PD and efficacy in accordance with the protocol.

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v. *Clinical Development Plan*

Following the completion of the Phase I clinical trial, we plan to further explore the clinical potential of 3D185 for the treatment of cholangiocarcinoma, UC and other tumors with FGFR genetic alterations.

The table below sets forth the details of our clinical development plan for 3D185:

<u>Indication</u>	<u>Status</u>	<u>Expected first patient in date</u>	<u>Expected NDA submission date</u>	<u>Expected number of patients</u>	<u>Location and competent authority</u>
Previously treated locally advanced or metastatic cholangiocarcinoma with FGFR2 gene alterations <sup>(1)</sup>	Phase II	1H 2024	1H 2026	50-100	U.S. and FDA China and NMPA
Previously treated advanced UC with FGFR alterations <sup>(1)</sup>	Phase II	2H 2024	2H 2026	50-100	US and FDA China and NMPA

*Abbreviations:* UC = urothelial cancer; 1H = first half; 2H = second half.

*Notes:*

(1) Each of these planned clinical trials was based on marketed FGFR inhibitors that have shown activity in these two tumor types with FGFR alterations. As of July 18, 2022, the proposed studies were still on track and these clinical trials are expected to enroll the first patient in 2024.

vi. *Licenses, Rights and Obligations*

We maintain the exclusive rights to develop, manufacture and commercialize 3D185 for oncology and pulmonary fibrosis treatment globally. We obtained all the intellectual property rights relating to 3D185 pursuant to patent license agreements with Haihe Biopharma and Shanghai Institute of Materia Medica, Chinese Academy of Sciences. Please refer to the paragraph headed “Our Research and Development – Collaboration Agreements – Collaboration with Haihe Biopharma for 3D185” in this section.

vii. *Material Communications*

The IND approval was obtained from the NMPA in January 2018. We received the IND approval from the FDA in September 2019. We submitted a protocol to FDA on September 6, 2021 for a Phase II clinical trial for 3D185 as monotherapy in subjects with previously treated locally advanced or metastatic cholangiocarcinoma with FGFR2 gene

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alterations, but withdrew our submission we decided to establish a RP2D first before we start the Phase II clinical trial. As of the Latest Practicable Date, we were still testing the new formulation in the ongoing Phase I clinical trial, primarily in the dose escalation phase. We had not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET 3D185 SUCCESSFULLY.**

*e. 3D1001*

3D1001, also known as RMX1001, is a differentiated COX-2 inhibitor with foreign Phase IIb clinical data. We own the exclusive rights to develop, manufacture and commercialize 3D1001 in China in the pain indication field through our license agreement with Haihe Biopharma Group. According to available data, 3D1001 is a safe and effective non-opioid analgesic with efficacy, rapid onset, long-lasting pain relief and acceptable safety profile. The IND approval for 3D1001 was obtained from the NMPA in February 2019. We plan to develop 3D1001 for the treatment of post-surgical dental pain and potentially other pain indications, including cancer pain management. We are in the preparation stage for the Phase I/II clinical trial for 3D1001 oral solution in China.

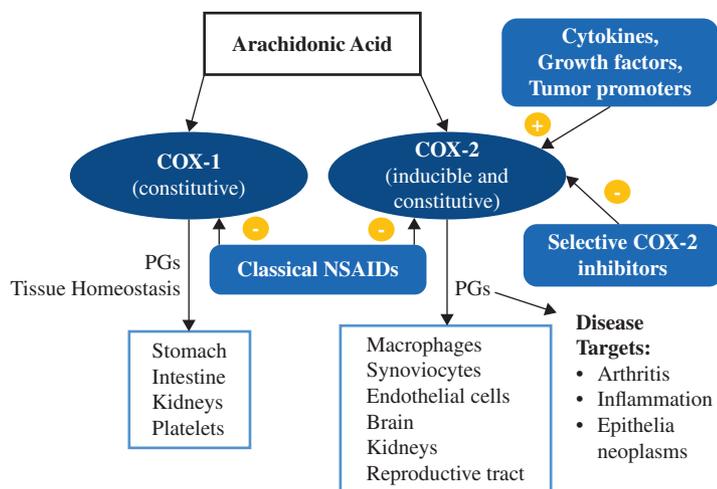
*i. Mechanism of Action*

Cyclooxygenases-2 (COX-2) is an enzyme responsible for the production of prostaglandins, which contribute to inflammation. The role of COX-2 as a target for inflammation and pain has been validated by the clinical effectiveness of selective COX-2 inhibitors. COX-2 inhibitors are a type of nonsteroidal anti-inflammatory drug (NSAID) that selectively targets COX-2, which is responsible for inflammation and pain. Selectivity for COX-2 reduces the risk of peptic ulceration and is the main feature of celecoxib, rofecoxib, and other members of this drug class.

Despite the wide use of NSAIDs over the last century, their mechanism of action was not fully understood until the COX enzyme was identified in 1971. COX-1 and COX-2 are both isoenzymes. Since isoenzymes are genetically independent proteins, the genes in humans for the two enzymes are located on different chromosomes and show different properties. COX-1 is expressed constitutively in many tissues and PGs produced by COX-1 mediate the "housekeeping" functions such as cytoprotection of gastric mucosa, regulation of renal blood flow and platelet aggregation. In contrast, COX-2 is not detected in most normal tissues, but its expression is rapidly induced by stimuli such as proinflammatory cytokines (IL-1b, TNF $\alpha$ ), lipopolysaccharides, mitogens and oncogenes (phorbol esters), growth factors (fibroblast growth factor, FGF; platelet-derived growth factor, PDGF; epidermal growth factor, EGF), hormones (luteinizing hormone, LH) and disorders of water-electrolyte hemostasis, resulting in increased synthesis of PGs in

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inflamed and neoplastic tissues. Thus, the inducible isozyme has been implicated in pathological processes such as inflammation, pain and cancer pathogenesis. The diagram below shows the mechanism of action for 3D1001:



Source: *Best Pract Res Clin Gastroenterol.* 2001 Oct;15(5):801-20., National Library of Medicine, *Front. Pharmacol.*, 07 September 2018, Frost & Sullivan Report

### ii. Market Opportunities and Competition

COX-2 inhibitors selectively target COX-2, an enzyme responsible for inflammation and pain. Selectivity for COX-2 reduces the risk of peptic ulceration and is the main feature of celecoxib, rofecoxib, and other members of this drug class. In 2020, the China cancer pain drug market reached US\$6.8 billion, according to Frost & Sullivan.

As of the Latest Practicable Date, there were a total of seven COX-2 inhibitors were approved for pain management in China. The following table sets out details of approved COX-2 inhibitors for pain management in China as of the Latest Practicable Date:

<u>Drug Name</u>	<u>Company</u>	<u>Immune Checkpoint</u>	<u>Indications</u>	<u>Date of NMPA Approval</u>
Imrecoxib	Hengrui Pharmaceutical	COX-2	Osteoarthritis	2011
Etoricoxib	Merck Sharp & Dohme (Australia) Pty Ltd	COX-2	Osteoarthritis; gouty arthritis; dysmenorrhea	2002
Parecoxib Sodium	Pfizer Europe Ma Eeig	COX-2	Postoperation pain	2002

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<u>Drug Name</u>	<u>Company</u>	<u>Immune Checkpoint</u>	<u>Indications</u>	<u>Date of NMPA Approval</u>
Celecoxib	Astellas Pharma Inc.; Dr Reddy's Laboratories; Gdsearle & Co; G.D. Searle Llc; Pfizer; Targeted Therapy Technologies Llc	COX-2	Osteoarthritis; acute pain; rheumatoid arthritis; ankylosing spondylitis	1998
Dexketoprofen Trometamol	Berlin-Chemie AG.Germany; Guangdong Trustever Pharmaceuticals; Shixing Pharmaceuticals; Menarini International Operations Luxembourg Sa	COX-2; COX-1	Migraine; pain	1998
Meloxicam	Baudax Bio Inc; Bidachem Spa; Boehringer Ingelheim Gmbh; CSPC Pharmaceutical Group Limited; Hengrui Pharmaceutical; Shenyang Pharmaceutical University	COX-2	Rheumatoid arthritis; ankylosing spondylitis	1995
Ketorolac Tromethamine	Allergan Inc; Allergan Plc	COX-2; COX-1	Acute pain; allergic conjunctivitis	1989

Source: FDA, Annual Reports of Listed Pharmaceutical Companies, Frost & Sullivan Report

iii. *Competitive Advantages*

Compared to other marketed COX-2 inhibitors in China, 3D1001 potentially has the competitive advantages of rapid onset and duration of pain relief owing to the rapid absorption and long half-life associated with the oral solution formulation of 3D1001.

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iv. *Summary of Clinical Trials*

The following summarizes the clinical trials completed and/or being conducted with 3D1001:

(1) Phase II Clinical Trial in Patients with Postoperative Dental Pain

A single-dose, double-blind, parallel-group, placebo- and positive-controlled, comparative efficacy study of 3D1001 oral solution in subjects with postoperative dental pain has been completed in the U.S.

*Study purpose.* The objectives of the trial are to assess the analgesic efficacy of a single dose of 360 mg 3D1001 compared to ibuprofen 400 mg and placebo in subjects with moderate or severe pain in a post-oral surgery model, to characterize the dose response for 3D1001 in subjects with moderate or severe pain in a post-oral surgery model, and to evaluate the safety and tolerability of single doses of 3D1001.

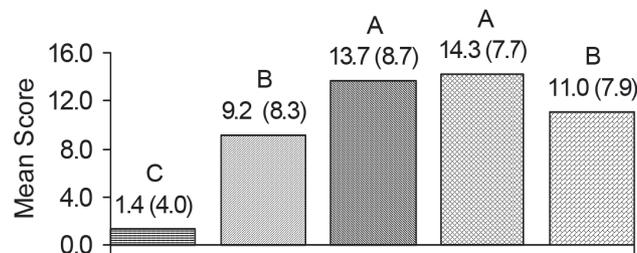
*Study Design.* This was a randomized, double-blind, double-dummy (3D1001 in solution; ibuprofen tablets), positive- and placebo-controlled, parallel group study in healthy volunteers undergoing multiple tooth extraction. Subjects who were over 18 years-of-age, in good health, and with a predose pain intensity score (100 mm visual analogue scale (VAS)) over 50 mm and a predose pain intensity score (categorical scale) of 2 (moderate) or 3 (severe) within six hours of oral surgery, were included in the study. Subjects were randomized to receive one of five treatments: solution of 3D1001, at 60, 180, or 360 mg; Ibuprofen (Motrin IB™) 400 mg (two 200 mg tablets); or placebo (to match ibuprofen and 3D1001).

Of the 352 subjects randomized to treatment, 351 subjects completed the study. The majority of subjects were between 18 and 44 years-of-age, with a mean age of approximately 23 years. Seventy-four percent of the subjects (262 subjects) were men and the majority of subjects were white. Sixty-eight percent of the subjects had four molars extracted during the dental surgery. The overall mean pain intensity (on a 0-100 VAS) at baseline (post-surgery/premedication) was 65.4; this score was similar across all treatment groups.

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*Efficacy.* The primary measure for efficacy evaluation was total pain relief through 6 hours (TOTPAR(6)). Secondary measures included pain relief, TOTPAR (8, 12, and 24 hours), pain intensity difference, pain relief intensity difference, summed pain relief intensity difference scores (6, 8, 12, and 24 hours), and summed pain intensity difference (6, 8, 12, and 24 hours). Time to perceptible PR, meaningful PR, onset of analgesia, and time to rescue medication were also analyzed. Subjects completed questionnaires indicating level of satisfaction with study medication.

Subjects treated with 60, 180, and 360 mg of 3D1001 had a significantly higher mean TOTPAR(6) score (improvement) (Categorical Scale, Range 0-4) compared with subjects who received placebo. Subjects treated with 180 and 360 mg 3D1001 had a significantly higher TOTPAR(6) score compared with subjects who were treated with 400 mg ibuprofen. A clear dose response was observed for both primary and secondary endpoints, with 360 mg 3D1001 showing the greatest improvements. The figure below shows the mean TOTPAR(6) score:



Treatments with the same letter code are not significantly different from each other. Comparisons are made at 5% level of significance. Type I error is protected with Fisher's protected LSD.

■ Placebo ■ SC-75416 60 mg ■ SC-75416 180 mg ■ SC-75416 360 mg ■ Ibuprofen 400 mg

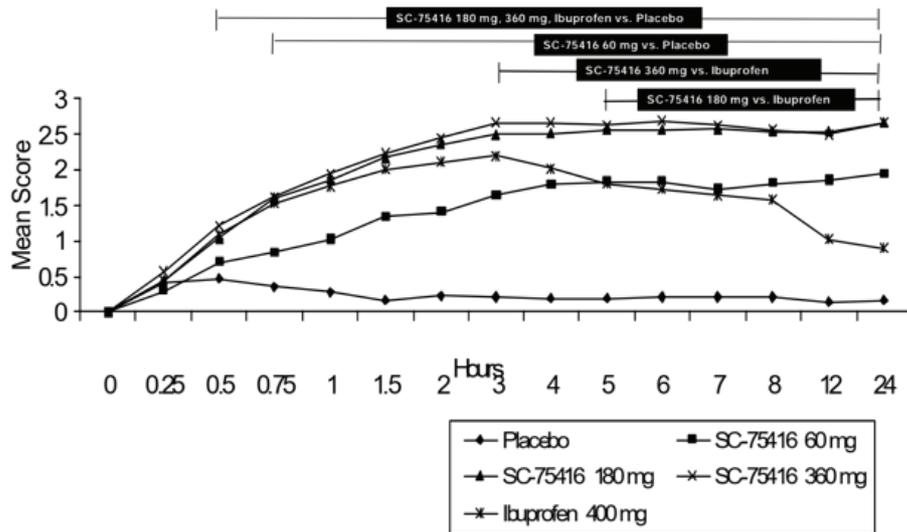
Note: SC-75416 represents 3D1001

Source: Company data



**BUSINESS**

Subjects treated with 60, 180, or 360 mg 3D1001 consistently showed significant improvement in secondary endpoints compared with placebo. Subjects who received 180 mg 3D1001 had significantly greater pain relief from hour 5 through 24 compared with subjects who received 400 mg ibuprofen; subjects treated with 360 mg 3D1001 had significantly greater pain relief from hour 3 through 24 compared with subjects treated with ibuprofen. The following figure shows the mean pain relief (0-24 hours):



*Notes:*

- (1) Positive values signify improvement.
- (2) |-----| identifies the range of assessment times for which there were significant differences between the active treatment as compared to Placebo and Ibuprofen.
- (3) SC-75416 represents 3D1001

*Source: Company data*

Subjects treated with 360 mg 3D1001 had significantly greater improvement in all secondary endpoints compared to subjects treated with 400 mg ibuprofen. The median time to onset of analgesia was significantly shorter for subjects treated with 360 mg 3D1001 (20 minutes) compared with subjects treated with ibuprofen (28 minutes). The median time to rescue medication was approximately 8.5 hours for ibuprofen subjects compared with >24 hours for 360 mg 3D1001-treated subjects. The subject’s global evaluation of study medication on a scale of 1 through 5 (1 = poor, 5 = excellent) resulted in a mean rating of 2.9 for ibuprofen- treated subjects compared with a 3.8 rating for 360 mg 3D1001 treated subjects. In general, efficacy increased with increasing dose of 3D1001.

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*Safety.* 3D1001 was well tolerated. Subjects treated with placebo had the highest incidence of AEs (48%) compared with subjects treated with 60 mg (33%), 180 mg (28%), or 360 mg 3D1001 (32%), or ibuprofen (25%). The most frequently reported AEs during the study were those typically associated with oral surgery, such as dry socket, nausea, vomiting, headache, and dizziness. These events were generally reported in a greater number of placebo- treated subjects. Throat irritation occurred in 4% of subjects treated with 180 mg 3D1001 and 3% of subjects treated with 360 mg 3D1001; throat irritation was not reported by placebo- or ibuprofen-treated subjects. There did not appear to be any relationship between dose of 3D1001 and the incidence of any AE.

There were no withdrawals due to AEs and one ibuprofen-treated subject had four unrelated serious adverse events (SAEs). There were no clinically meaningful changes in laboratory parameters or vital signs.

*Conclusion.* In subjects with acute pain following oral surgery: (1) a single oral dose of 60, 180, or 360 mg 3D1001 provided significantly (p <0.001) greater analgesic efficacy compared with placebo; (2) a single dose of 360 mg 3D1001 provided significantly greater (p <0.001) analgesic efficacy compared with 400 mg ibuprofen; (3) results confirmed the predictive performance of the PK/PD model; (4) 3D1001 systemic exposure indicates dose proportional extent but highly variable rate of absorption of this oral solution formulation; and (5) 3D1001 was safe and well tolerated; no dose-related safety findings were evident.

(2) Phase I Clinical Trials

Three Phase I clinical studies have been completed for 3D1001 oral solution, which has collectively demonstrated desirably a favorable PK and safety profile of 3D1001 oral solution, as summarized in the table below:

<b>Trial</b>	<b>Design</b>	<b>Sample size</b>	<b>Dose Levels</b>	<b>Key findings</b>
COXD-7577-001 (U.S) (oral solution)	Randomized, Double-Blind, Single Dose Escalating, Safety, tolerability and Pharmacokinetic Study of 3D1001 in Healthy Volunteers	63	0.01, 0.1, 0.5, 2.5, 7.5, 15, 30, and 60 mg	Single doses from 0.01 to 60 mg were well tolerated; PK dose proportionality between 0.1 and 60 mg was observed with half-life ranged approximately from 30-40 hours; 30 and 60 mg dose levels had the potential to selectively inhibit COX-2 while appeared to have no effect on renal safety parameters

**BUSINESS**

<b>Trial</b>	<b>Design</b>	<b>Sample size</b>	<b>Dose Levels</b>	<b>Key findings</b>
A6151001 (U.S) (oral solution)	Randomized, double-blind, placebo-controlled dose escalation study in healthy volunteers	40	1, 10, 20, 40, 60 mg or placebo	Steady state PK are linear from doses of 1 to 60 mg. systemic exposure is dose proportional. $t_{1/2}$ ranged from 29.0 to 37.8h, T <sub>max</sub> was 1.8 to 3.0h. Study drug was safe and well-tolerated at doses up to 60 mg/day for 10 days.
A6151010 (U.S) (oral solution)	Randomized, Double-Blind, Placebo-Controlled, Single- and Multiple-Dose Study to Investigate Safety, Tolerability and PK of 3D1001 in Healthy Adults	54	single dose, 60, 120, 180 240, 300, 360 mg or placebo Multiple-dose 60, 120, 180 mg, QD, 10d or placebo	Systemic exposure is dose proportional single and multiple-dose at doses up to 360 mg and 180 mg, respectively. Safe and well-tolerated at all dose levels in the single dose setting. Safe and tolerated in multiple dose setting with the exception of one case with significantly elevated ALT and one case with elevated blood pressure, both of which returned to acceptable level after stopping the study drug. Single- and multiple-dose had similar $t_{1/2}$ (single dose: 30.6-36.9; multiple dose: 29.5-35.8 hours) and T <sub>max</sub> (< 2h).

v. *Clinical Development Plan*

We are preparing for a potential phase I/II clinical trial in China to evaluate the PK, safety and efficacy of 3D1001 in Chinese subjects. If successful, a Phase III clinical trial in this post-surgical dental pain and additional clinical studies in other pain indications will be conducted.

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The table below sets forth the details of our clinical development plan for 3D1001 in China:

Indication	Status	Expected first patient in date	Expected NDA submission date	Expected number of patients	Location and competent authority
healthy and post surgical dental pain subjects <sup>(1)</sup>	Phase I/II	1H 2023	-	216	China and NMPA
post-surgical dental pain <sup>(2)</sup>	Phase III	2H 2024	2H 2025	330	China and NMPA

*Abbreviations:* 1H = first half; 2H = second half.

*Notes:*

- (1) The Phase I portion of the clinical trial is intended to study PK in Chinese healthy volunteers while the phase II portion of the clinical trial will evaluate efficacy and safety of 3D1001 at multiple dose levels versus control in Chinese subjects with post-surgical dental pain. As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled. First patient is expected to be enrolled in the first half of 2023.
- (2) The Phase III clinical trial is based on promising efficacy demonstrated with 3D1001 oral solution in post-surgical dental pain population in a Phase II clinical trial in US patients, which will be further informed by the Phase I/II study to be conducted in China. As of July 18, 2022, the proposed study was still on track and first patient is expected to be enrolled in second half of 2024.

*vi. Licenses, Rights and Obligations*

We maintain the exclusive rights to develop, manufacture and commercialize 3D1001 in China in the pain indication field. We obtained all the intellectual property rights relating to 3D1001 pursuant to a license agreement between us and Haihe Biopharma Group. Please refer to the paragraph headed “Our Research and Development – Collaboration Agreements – Collaboration with Haihe Biopharma Group for 3D1001 and 3D1002” in this section.

*vii. Material Communications*

The IND approval for 3D1001 was obtained from the NMPA in February 2019. We had not received any relevant regulatory agency’s objections to our clinical development plans as of the Latest Practicable Date.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET 3D1001 SUCCESSFULLY.**

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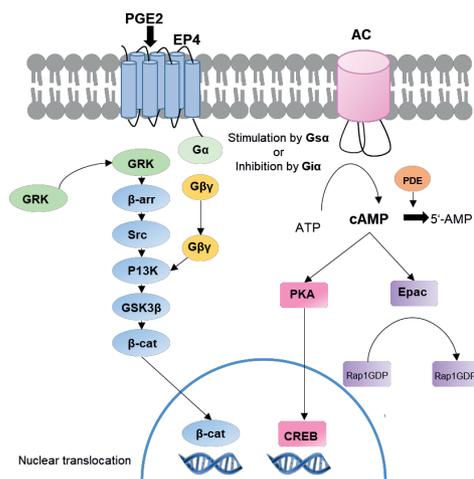
*f. 3D1002*

3D1002, also known as RMX1002, is an EP4 receptor antagonist. We own the exclusive rights to develop, manufacture and commercialize 3D1002 in China through our license agreement with Haihe Biopharma Group. Its Phase II clinical data in the U.S. has demonstrated an acceptable safety profile and analgesic effect in subjects with osteoarthritis pain. It is expected to become a new pain medication other than COX-2 inhibitor. IND approval for 3D1002 was obtained from the NMPA in July 2018.

*i. Mechanism of Action*

Prostaglandin E2 (PGE2) is an important pro-inflammatory pain mediator. It is also essential for the homeostasis of many vital organs, including the maintenance of mucosal integrity of the gastrointestinal tract, regulation of bicarbonate secretion in the intestines, modulation of renal sodium and water excretion, and prevention of ischemic cardiomyopathy after acute ischemic events. The physiological activities of PGE2 are mediated by 4 G-protein-coupled receptors identified as E prostanoid receptors 1–4 (EP1–EP4). EP4 has been shown to be the main receptor that mediates pain and inflammatory signaling in animal studies, whereas many of the other activities of PGE2 on physiological homeostasis are mediated by EP1, EP2, and EP3. Data has suggested that an agent that selectively antagonizes the EP4 receptor has the potential to provide an attractive risk/benefit profile in the treatment of painful, inflammatory conditions, such as osteoarthritis and cancer pain.

EP4 is classified as a relaxant type of prostaglandin receptor based on its ability, upon activation, to relax the contraction of certain smooth muscle preparations and smooth muscle-containing tissues that have been pre-contracted by stimulation. EP4 also interacts with Prostaglandin E receptor 4-associated protein (EPRAP) to inhibit a cell's ability to activate nuclear factor kappa B, a transcription factor that controls genes coding for cytokines and other elements that regulate inflammation, cell growth, and cell survival. The diagram below shows the mechanism of action for 3D1002:



Source: *Pharmacol Ther.* 2013 Jun; 138(3): 485-502., *Frost & Sullivan Report*

## BUSINESS

### ii. Market Opportunities and Competition

EP4 receptor antagonists demonstrate its rapid onset and long-lasting analgesic effect against osteoarthritis, rheumatoid arthritis and other inflammatory pains based on pre-clinical studies. In 2020, the China cancer pain drug market reached US\$6.8 billion, according to Frost & Sullivan.

As of the Latest Practicable Date, there were no approved EP4 receptor antagonists in the global market. As of the Latest Practicable Date, there were one EP4 receptor antagonists candidates registered with the NMPA and was in Phase I clinical trial. The following table sets out details of EP4 receptor antagonists in clinical development worldwide as of the Latest Practicable Date.

Drug Name	Clinical Phase	Company	Active Indications	Targets	Drug type	Therapeutic Strategy	Location	First Posted Date
3D1002/ RMX1002/ Grapiprant	Phase II	3DMed	Solid Tumor, Osteoarthritis; Pain	PTGER4	Chemical drugs	Combination therapy	China	22-Dec-21
CR-6086	Phase II	Rottapharm	Rheumatoid Arthritis, DMARD-naive and Early Disease Patients	PTGER4	Chemical drugs	Combination therapy	Czechia	23-May-17
YY001	Phase I	Yuyao Biotech; MingMed Biotech	Solid Tumor	PTGER4	Chemical drugs	Monotherapy	China	27-Jun-22
INV-1120	Phase I	Ionova	Solid Tumor	PTGER4	Chemical drugs	Monotherapy/ Combination therapy	China	30-Jul-21
KF-0210	Phase I	Keythera pharm	Advanced CRC, NSCLC, Esophageal squamous cell carcinoma, gastric cancer, bladder cancer, etc.	PTGER4	Chemical drugs	Monotherapy	China	25-Jun-21
AN0025	Phase I	Adlai Nortye	Esophageal cancer	PTGER4	Chemical drugs	Combination therapy	China	25-Jun-21

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<u>Drug Name</u>	<u>Clinical Phase</u>	<u>Company</u>	<u>Active Indications</u>	<u>Targets</u>	<u>Drug type</u>	<u>Therapeutic Strategy</u>	<u>Location</u>	<u>First Posted Date</u>
TPST-1495	Phase I	Tempest Therapeutics	Solid Tumor; Colorectal Cancer; Non Small Cell Lung Cancer; Squamous Cell Carcinoma of Head and Neck; Urothelial Carcinoma; Endometrial Cancer; Gastroesophageal Junction Adenocarcinoma; Gastric Adenocarcinoma	PTGER4; PTGER2	Chemical drugs	Combination therapy	US	14-Apr-20
ONO-4578/ BMS-986310	Phase I	BMS; Ono Pharmaceutical	Tumor; Solid tumor	PTGER4	Chemical drugs	Combination therapy	Japan	16-May-17
E-7046/AN0025	Phase I	Adlai Nortye Biopharma Co Ltd; Eisai Co Ltd;	Triple-negative Breast Cancer; NSCLC, Squamous or Non-Squamous; Urothelial Carcinoma of the Bladder; Microsatellite Stable (MSS) Colorectal Cancer (CRC); Cervical Cancer	PTGER4	Chemical drugs	Combination therapy	US; United Kingdom; Poland	15-May-17

*Note:*

(1) Date denotes the date on which the relevant status was publicly disclosed.

*Source: Annual Reports of Listed Pharmaceutical Companies, NMPA, CDE, FDA, ClinicalTrials.gov, Frost & Sullivan Report*

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### iii. *Summary of Clinical Trials*

The following summarizes the clinical trials completed and/or being conducted with 3D1002:

(1) Phase II Clinical Trial in Patients with Osteoarthritis (OA) Pain for a Period of Two Weeks

*Study design.* This was a two-week, randomized, double blind, placebo- and positive-controlled, parallel-group, multi-center study of 3D1002 in patients with osteoarthritis (OA) pain. 201 subjects were enrolled and treated over four dose levels, including 3D1002 50 mg BID, 3D1002 250 mg BID, placebo and rofecoxib.

*Efficacy.* This was a 2-week, randomized, double-blind, placebo- and positive-controlled, parallel-group, multi-center study of subjects with osteoarthritis pain. It was originally designed to compare 50 and 250 mg BID 3D1002 with placebo and rofecoxib 25 mg QD. However, the rofecoxib group was terminated on October 1, 2004 because rofecoxib was withdrawn from the U.S. market.

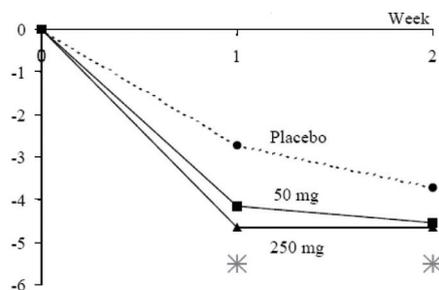
Compared with subjects who received placebo, the reduction of pain in subjects treated with 3D1002 (50 and 250 mg BID) was statistically and clinically significant. The primary parameter of efficacy endpoint was the change in the WOMAC (Western Ontario and McMaster Universities Arthritis Index) pain. Therefore, the proof-of-principle of this mechanism was completed. In the primary analysis of WOMAC's average improvement from baseline to week 2, the differences between 50 and 250 mg BID 3D1002 treatment groups and placebo were -0.83 and -0.92, respectively (The larger the number after the minus sign, the better the difference relative to placebo.). Both treatment groups were statistically significant at the level of 0.10 (one sided).

At week 1, the average response for 3D1002 (least squares mean) was greater than placebo response: as of week two, placebo response further improved, narrowing the difference between placebo and 3D1002. At week one, the mean differences between 50 and 250 mg BID treatment groups and placebo was -1.4 and -1.9, respectively, and the difference at week 2 was -0.8 and -0.9 respectively.



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The figure below showed the change from baseline in the least squares mean of WOMAC:



Source: Company data

In the primary analysis of WOMAC (full analysis set, mixed-effect model, week 2), the changes from baseline in the placebo group at week 1 and week 2 were -2.7 and -3.7, respectively, which may lead to efficacy underestimation (the difference between week 2 and placebo). Notably, despite of considerable placebo responses, the difference was still statistically significant.

Safety. The incidence of AEs was similar among all treatment groups, except for gastrointestinal events. The most frequently reported AEs during treatment were gastrointestinal events and headaches. Gastrointestinal events include abdominal pain, discomfort, bloating, and diarrhea (including loose stools). The most frequently reported treatment-related AEs were gastrointestinal events and headaches.

Conclusion. 3D1002 at the 50 mg BID dose and 250 mg BID dose demonstrated statistically significant and clinically meaningful reductions in OA pain over placebo as measured by WOMAC at Weeks 1 and 2, thus establishing proof of mechanism. 3D1002 at doses of 50 mg BID and 250 mg BID was generally well tolerated during this study.

### (2) Phase II Clinical Trial in Patients with Osteoarthritis (OA) Pain for a Period of Four Weeks

Study design. This was a four-week, randomized, double blind, placebo- and positive-controlled, parallel-group, multi-center study of 3D1002 in patients with osteoarthritis pain. 739 subjects were enrolled and treated over seven dose levels, including 3D1002 5 mg QD, 3D1002 5 mg BID, 3D1002 25 mg QD, 3D1002 25 mg BID, 3D1002 75 mg BID, naproxen 500 mg BID and placebo.

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*Efficacy.* The pairwise comparison between 3D1002 and placebo showed that in the following 3D1002 administration group, the change from the baseline to week 4 in WOMAC pain subscale was statistically different from the placebo group: 3D1002 5 mg BID administration group (difference=-1.31, p=0.0116), 3D1002 25 mg QD administration group (difference=-1.36, p=0.0095), 3D1002 25 mg BID administration group (difference=-1.47, p=0.0048) and 3D1002 75 mg BID administration group (difference=-1.81, p=0.0005). The p-value for comparison between naproxen and placebo group was 0.0007 (difference=-1.77), which verified the sensitivity of analysis in this study. The analysis result of ITT (intention-to-treat) population by using LOCF (carrying the last observation forward) method and the analysis result of per-protocol (PP) by using mixed-effects models for repeated-measures confirmed a definite dose-response relationship and demonstrated that the conclusions from primary analysis were robust.

*Safety.* The percentage of subjects who had AEs was similar among all treatment groups. The percentage of 3D1002 treatment group was between 44.2%-55.6%, naproxen group was 47.6%, and placebo group was 41.5%. In the 3D1002 treatment group, the proportion of subjects who reported AEs after 75 mg BID administration was the lowest, and the incidence of AEs was the highest after 25 mg BID administration. Generally speaking, half of all reported AEs were considered treatment-related. In the 3D1002 treatment group, the proportion of patients who had treatment-related AEs was between 22.4% to 31.5%, 23.8% in the naproxen group and 16.0% in the placebo group. Overall, of all 3D1002 administration groups and placebo group, the most frequently reported AEs was headache.

*Conclusion.* 3D1002 was efficacious for the treatment of OA pain. Doses over 20 mg per day achieved the target efficacy. 3D1002 was acceptably tolerated in this study.

### (3) Phase I Clinical Trials

Five Phase I clinical trials have been completed to assess the safety, tolerability, and pharmacokinetics with 3D1002. The table below summarizes the information of each trial:

<u>Trial</u>	<u>Design</u>	<u>Subjects</u>	<u>Dose Level</u>
RMX1002-1101 (China)	A randomized, double-blind, placebo-controlled, single-dose escalation Phase I clinical study to assess the safety, tolerability and PK characteristics of 3D1002 in healthy Chinese adult subjects	40	25 mg, 100 mg, 300 mg and 600 mg or placebo

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<b>Trial</b>	<b>Design</b>	<b>Subjects</b>	<b>Dose Level</b>
A5231003	A randomized, double-blind, placebo-controlled dose escalation study	78 (1 subject was lost to follow up)	1, 3, 10, 30, 100, 300, 600, 1000, 1500 and 2000 mg 3D1002 OPC or placebo
A5231004	A randomized and crossover study to assess the effects of food	12	375 mg tablet (3x125 mg tablet) in the fed and fasted states
A5231009	A randomized, placebo-controlled, sequential parallel group, multiple dose escalation study to assess the safety, tolerability and PK characteristics of 3D1002 tablets in healthy adult subjects and elderly subjects with mild renal impairment	36 (healthy subjects) 21 (elderly subjects)	50, 150 and 300 mg BID or placebo 250 mg BID or placebo
A5231018	A multi-center, randomized, placebo- and positive-controlled study to assess the effect of 3D1002 on the incidence of gastroduodenal endoscopic ulcers in healthy subjects	358	75 mg BID, naproxen 500 mg BID or placebo

3D1002 was well tolerated in single dose ranging from 1 mg to 1000 mg in healthy subjects, as well as in multiple dose for 14 days at doses up to 300 mg BID in healthy adult subjects and at 250 mg BID in elderly subjects with mild renal impairment. Systemic exposure increased in an approximate dose-proportional manner after single and multiple dose. Compared to the fasted condition, a standard high-fat meal decreased the absorption rate of 3D1002 tablets as indicated by a 36% decrease in C<sub>max</sub> and an approximately 3-hour delay in T<sub>max</sub>. The systemic exposure (as measured by AUC) of 3D1002 was not affected by food. There was no significant difference between 3D1002 and placebo in the incidence of gastroduodenal ulcer. There was a significantly lower incidence of ulcers in the 3D1002 group compared to naproxen in the elderly cohort. 3D1002 was well tolerated in healthy Chinese subjects in a single dose of 25 mg to 600 mg.

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iv. *Clinical Development Plan*

We plan to conduct a randomized Phase II clinical trial to evaluate the efficacy, safety and PK of 3D1002 in patients with cancer pain. If the data is supportive, a Phase III clinical trial in this setting will be conducted and other pain indications such as osteoarthritis may be studied.

The table below sets forth the details of our clinical development plan for 3D1002:

<u>Indication</u>	<u>Status</u>	<u>Expected first patient in date</u>	<u>Expected NDA submission date</u>	<u>Expected number of patients</u>	<u>Location and competent authority</u>
cancer pain <sup>(1)</sup>	Phase II	Q4 2022	2H 2025	130-177	China and NMPA

*Abbreviations:* Q3 = third quarter; 1H = first half.

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*Notes:*

- (1) The Phase II clinical trial in cancer pain is based on a potentially improved safety profile for 3D1002 attributable to its novel mechanism of action versus other nonsteroidal anti-inflammatory drugs (NSAIDs). As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled. First patient is expected to be enrolled in the fourth quarter of 2022.

v. *Licenses, Rights and Obligations*

We maintain the exclusive rights to develop, manufacture and commercialize 3D1002 in China in the pain indication field. We obtained all the intellectual property rights relating to 3D1002 pursuant to a license agreement between us and Haihe Biopharma Group. Please refer to the paragraph headed “Our Research and Development – Collaboration Agreements – Collaboration with Haihe Biopharma Group for 3D1001 and 3D1002” in this section.

vi. *Material Communications*

The IND approval was obtained from the NMPA in July 2018. We had not received any relevant regulatory agency’s objections to our clinical development plans as of the Latest Practicable Date.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET 3D1002 SUCCESSFULLY.**

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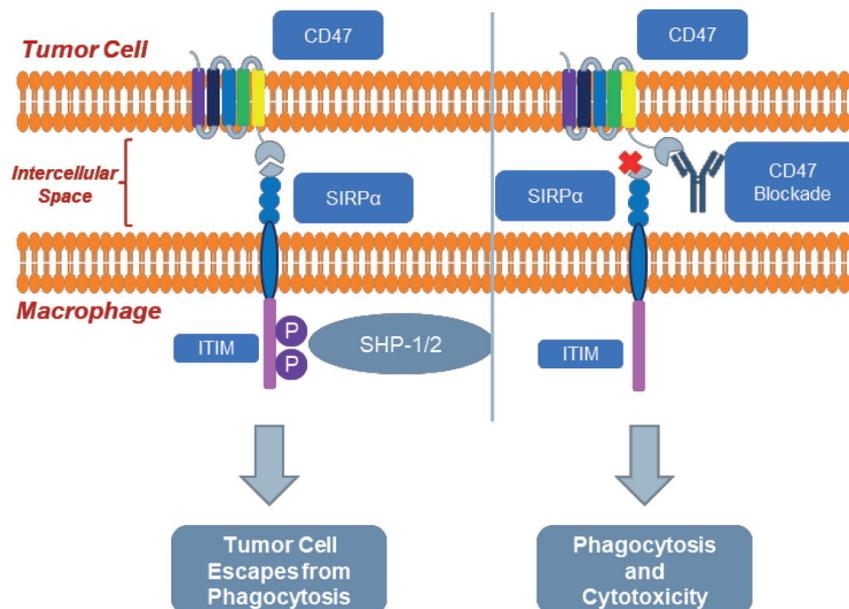
### g. 3D197

3D197, also known as IMC-002, is our next-generation fully human anti-CD47 IgG4 monoclonal antibody and designed to block the CD47–SIRP $\alpha$  interaction in order to promote the phagocytosis of cancer cells by macrophages. We own the exclusive rights to develop, manufacture and commercialize 3D197 in China, Hong Kong, Macau and Taiwan region in respect of oncology indications through our exclusive license agreement with ImmuneOncia. According to its pre-clinical results, it binds to human CD47 with an optimal affinity that maximizes efficacy. 3D197 did not cause hemagglutination in vitro nor induced anemia in pre-clinical toxicology studies. It is expected to treat hematological malignancies and solid tumors. We obtained the IND approval for 3D197 for the treatment of advanced malignant tumors in China in January 2022.

#### i. Mechanism of Action

CD47 is a transmembrane protein expressed on tumor cells that transmits “don’t-eat-me” signal to its receptor, signal regulatory protein  $\alpha$  (SIRP $\alpha$ ), on phagocytes, such as macrophages and dendritic cells. Binding of CD47 to SIRP $\alpha$  induces phosphorylation of the immunoreceptor tyrosine based inhibitory motifs (ITIM) in cytoplasmic domain of SIRP $\alpha$  that recruits Src homology phosphatases 1 and 2 (SHP-1 and SHP-2) and inhibits phagocytic uptake. This inhibitory mechanism is exploited by solid and hematologic malignancies that over-express CD47. Studies showed that blockade of CD47/SIRP $\alpha$  enables cancer cell phagocytosis by macrophages and promoted antitumor activities in various animal models. CD47 blockade also induces anti-tumor T cell responses through cross-presentation of tumor antigens by dendritic cells after engulfing tumor cells. In addition, targeting CD47/SIRP $\alpha$  synergistically enhances anti-tumor responses in combination with other treatments including chemotherapy or immune-modulatory agents, such as anti-PD-1 or PD-L1 antibodies.

3D197 is a fully human anti-CD47 IgG4 monoclonal antibody that blocks the CD47–SIRP $\alpha$  interaction. 3D197 blocks the “don’t eat me signal,” thereby enhances tumor phagocytosis by macrophage. The diagram below shows the mechanism of action for 3D197:



Source: *Front. Immunol.*, 28 January 2020, *Curr Opin Immunol.* 2012 Apr; 24(2): 225-232., *Journal of Hematology & Oncology* volume 13, Article number: 96 (2020), *Frost & Sullivan Report*

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*ii. Market Opportunities and Competition*

As of the Latest Practicable Date, there has not been any approved CD47 antibody globally. The following table sets forth the details of CD47 mono-antibodies in clinical development in China as of the Latest Practicable Date:

<u>Drug Name</u>	<u>Phase</u>	<u>Company</u>	<u>Indications</u>	<u>Target</u>	<u>Drug Type</u>	<u>Therapeutic strategy</u>	<u>Location</u>	<u>First Posted Date</u>
IBI188	III	Innovent Biologics	Myelodysplastic syndrome, Acute myeloid leukemia, Advanced malignant tumor	CD47	Whole human monoclonal antibody	Monotherapy/ Combination therapy	US; China	2018/11/22
TJ011133 (TJC-4)	II	I-Mab Biopharma	Myelodysplastic syndrome, Recurrent or refractory acute myeloid leukemia, CD20+ lymphoma, advanced solid tumor	CD47	Whole human monoclonal antibody	Monotherapy/ Combination therapy	US; China	2019/12/19
AK117	II	Akesobio	Myelodysplastic syndrome, Lymphoma, Solid tumor, Acute myelogenous leukemia	CD47	Monoclonal antibody	Monotherapy	China	2020/12/29
IMM01	II	ImmuneOnco Biopharm	Myelodysplastic syndrome, Acute myeloid leukemia	CD47	Monoclonal antibody	Monotherapy/ Combination therapy	China	2021/10/26
ZL-1201	I	Zai Lab (Shanghai)	Solid tumor, hematological malignancies	CD47	Monoclonal antibody	Monotherapy	US; China	2020/5/9
MIL95	I	Beijing Mabworks; Beijing Huafang Tianshi; Shanghai Lingyue Bio-tech	Lymphoma, Advanced malignant solid tumors	CD47	Humanized monoclonal antibody	Monotherapy	China	2020/11/27
Kintuzumab	I	Jinsai Pharmaceutical Co., Ltd	Hematological malignant tumor, Advanced malignant solid tumors and lymphomas	CD47	Monoclonal antibody	Monotherapy	China	2021/01/12
TQB2928	I	Chia Tai Tianqing	Advanced Solid Tumor	CD47	Monoclonal antibody	Monotherapy	China	2022/1/4

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<u>Drug Name</u>	<u>Phase</u>	<u>Company</u>	<u>Indications</u>	<u>Target</u>	<u>Drug Type</u>	<u>Therapeutic strategy</u>	<u>Location</u>	<u>First Posted Date</u>
BAT7104	I	Bio-thera	Advanced malignant tumor	CD47	Monoclonal antibody	Monotherapy	China	2022/2/22
IMC-002	I	3DMed	Locally advanced or metastatic solid tumors and relapsed or refractory hematological tumors	CD47	Monoclonal antibody	Monotherapy	China	2022/3/9
F527	I	Shandong Xinshidai	Relapsed or refractory lymphoma	CD47	Humanized monoclonal antibody	Monotherapy	China	2022/4/14

*Note:*

(1) Date denotes the date on which the relevant status was publicly disclosed.

*Source: CDE, Clinicaltrials.gov, Annual Reports of Listed Pharmaceutical Companies, Frost & Sullivan Report*

*iii. Clinical Development Plan*

We plan to conduct a phase I study in China to optimize the dose of single agent 3D197 in Chinese patients. We will subsequently conduct phase Ib/II study to evaluate the combination of 3D197 with envafolimab, azacitidine, rituximab, and other standard agents in solid tumors and hematological malignancies. Phase III study design will be informed by the results of the phase I/II studies.

The table below sets forth the details of our clinical development plan for 3D197:

<u>Indication</u>	<u>Status</u>	<u>Expected first patient in date</u>	<u>Expected NDA submission date</u>	<u>Expected number of patients</u>	<u>Location and competent authority</u>
Advanced tumors <sup>(1)</sup>	Phase I (single agent)	2H 2022	-	escalation phase: 42 expansion phase: 40	China and NMPA
Selected tumor types <sup>(2)</sup>	Phase Ib/II (combination)	2H 2023	-	170	China and NMPA

*Abbreviation: 2H = second half.*

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*Notes:*

- (1) The Phase I clinical trial is based on the design of the ongoing phase I study in the US and South Korea and based on the need to establish a recommended phase II dose (RP2D) in Chinese patients. As of July 18, 2022, this clinical trial was still in preparation stage and no patient had been enrolled. First patient is expected to be enrolled in second half of 2022.
- (2) The Phase Ib/II combination clinical trial is based on the published studies showing initial promising efficacy when CD47 antibody is combined with azacitidine or rituximab, and complementary mechanism of action between PD-(L)1 inhibition and CD47 blockade. As of July 18, 2022, the proposed studies were still on track and this clinical trial is expected to enroll the first patient in second half of 2023.

*iv. Licenses, Rights and Obligations*

We maintain the exclusive rights to develop, manufacture and commercialize 3D197 in China, Hong Kong, Macau and Taiwan region in respect of oncology indications pursuant to our exclusive license agreement with ImmuneOncia. Please refer to the paragraph headed “Our Research and Development – Collaboration Agreements – Collaboration with ImmuneOncia for 3D197” in this section.

*v. Material Communications*

We obtained the IND approval for 3D197 in China in January 2022. We had not received any relevant regulatory agency’s objections to our clinical development plans as of the Latest Practicable Date.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET 3D197 SUCCESSFULLY.**

### **3. Our Pre-Clinical Stage Drug Candidates**

In addition to our clinical-stage drug candidates, we are also evaluating a number of pre-clinical stage drug candidates in our rich pipeline. As of the Latest Practicable Date, our pre-clinical stage drug candidates included the following:

- 3D057, also known as YBL-013, our bispecific antibody drug which targets CD3 receptor of T-cells and PD-L1 of tumor cells, which is licensed from Y-Biologics. Please refer to the paragraphs headed “Our Research and Development – Collaboration Agreements – Collaboration with Y-Biologics for 3D057” in this section.



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- 3D059, also known as heptavalent galinpepimut-S (GPS+), our next-generation immunotherapeutic which targets the WT1 protein in hematological malignancies and solid tumors, which is licensed from SELLAS Group. Please refer to the paragraphs headed “Our Research and Development – Collaboration Agreements – Collaboration with SELLAS Group for 3D189 and 3D059” in this section.
- 3D060, our in-house discovered monoclonal antibody which targets Semaphorin 4D (Sema4D) of tumor cells.
- 3D062, our in-house discovered small molecule for patients with KRAS mutation.

**Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET 3D059, 3D057, 3D060 and 3D062 SUCCESSFULLY.**

### OUR RESEARCH AND DEVELOPMENT

#### Our Platforms

Our R&D platform has strong molecule screening and design capabilities that increase the possibility of success of moving molecules from pre-clinical studies to market, enable innovative therapeutic approaches and support rich pipeline assets built around key pathways and targets. Our R&D centers in Shanghai and Beijing include large and small molecule platforms, complete cell line screening platforms, high-throughput compound screening platforms and comprehensive animal models. Our R&D centers also support a drug activity screening platform, a platform for the study of cellular functions of drugs, a drug biochemical study platform, and a biomolecule detection platform, which can perform common molecular and cellular biology experimental studies such as cell activity detection, ELISA, real-time PCR, western blot, molecular cloning, biochemical enzymology and flow cytometry. Meanwhile, we have hundreds of commercial tumor cell lines from ATCC, ECACC, JCRB and RIKEN, the four largest cell banks in the world. The source of cell tumors covers prevalent tumor types such as lung cancer, liver cancer, colon cancer, gastric cancer, esophageal cancer and breast cancer in the American, European and Asian populations, which can provide broader, more effective and convenient drug candidate screening in early pre-clinical research and development, and these samples also demonstrate notable advantages in the development of tumor biomarkers.

#### Drug Discovery and Pre-Clinical Research

We believe that R&D is key to maintaining competitiveness in our industry. We have built a platform to enable our R&D in the areas of chronic cancer treatment. Leveraging our proprietary R&D platform, we are able to conduct pre-clinical R&D activities including drug activity screening, studies of cellular functions of drugs, drug biochemical studies and biomolecule detection. We are also fully capable to perform common molecular and cellular biology experimental studies, such as cell activity detection, ELISA, real-time PCR, western

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blot, molecular cloning, biochemical enzymology and flow cytometry. Our drug discovery and translational research function is led by Dr. Yihui Lin, our Head of Translational Medicine Center, who holds a Ph.D. from the Center for Excellence in Molecular Cell Science of Chinese Academy of Sciences. As of the Latest Practicable Date, our R&D team had a total of 151 employees, 82 of which have a master's degree or higher, including 17 with doctor's degrees.

During the drug discovery stage, we explore new R&D opportunities, conduct feasibility research and provide evaluation opinion for the opportunities. We also design and prepare new types of chemical compounds, conduct systematic research regarding the manufacturing process and quality management of the new drugs, and develop technology platforms to support, manage and supervise the related technologies. During pre-clinical research stage, we coordinate and accomplish pre-clinical R&D activities in relation to pharmacology, efficacy, toxicology and safety. We conduct extensive early-stage investigation on various drug candidates. We also assist in the registration process of the new drugs by collecting and preparing the required information and materials.

With our pre-clinical research capability, we can find products worldwide that best fit existing pipelines and strategies, and we can efficiently complete target determination, compound design, screening optimization and IND application. We have the experience and ability to independently complete the entire drug development process from drug discovery to pre-clinical research to clinical development and to NDA/BLA application.

### **Clinical Development**

We employ a clinical-demand-oriented and market-driven approach to our clinical research and development efforts. Our clinical development team is composed of scientists and physicians with years of experience in drug development. Our clinical development team carefully customizes clinical development plan for each of our candidate drugs by taking into consideration of unmet medical needs, scientific rationale, and probability of technical and regulatory success, competition, commercial assessment, expert feedback, timeline and cost. We apply state of art clinical trial designs based on our deep understanding of the disease, available evidence, regulatory requirements, feasibility and statistical methods to achieve efficient clinical development of our assets. We demonstrate our clinical capabilities by, for instance, only taking four years to bring a new molecular entity from IND to BLA. Our clinical development team consists of five functions in charge of all aspects of clinical development including clinical research, clinical operation, data management and biostatistics, pharmacovigilance, and drug supply. Our clinical development team is led by Dr. Dongfang Liu, who holds a Ph.D degree from Massachusetts Institute of Technology, a master's degree in pharmaceutical sciences from the University of Toledo, and a bachelor's degree in clinical medicine from Peking University School of Medicine (formerly Beijing Medical University). Dr. Liu is a recognized leader in the field of oncology clinical research and development with a proven track record in developing oncology drugs.

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During the clinical development stage, we manage clinical trials and carry out a comprehensive suite of clinical development activities in-house, including clinical trial design, implementation, and the collection and analysis of trial data. We supplement our internal efforts with CROs when necessary to help with operation aspects of selected studies. As of the Latest Practicable Date, we had obtained 16 IND approvals and implemented 12 Phase II/III clinical studies. Our experienced and capable leadership team has led us to differentiate from competitors in both clinical development strategy and execution of the studies as evidenced by being the first to complete the pivotal study in MSI-H/dMMR cancer despite stiff competition from several companies.

### COLLABORATION AGREEMENTS

#### Collaboration with Alphamab Group for Envafolimab

##### *1. Collaboration Agreements and Supplements*

In February 2016, we entered into a co-development agreement, as amended, with Alphamab Group for envafolimab (collectively with the subsequent amendments and supplemental agreements thereto, the “**Co-Development Agreements**”). Alphamab Group is a biopharmaceutical company in China, an Independent Third Party of our Group. We became acquainted with Alphamab Group when our founder, CEO and Chairman, Dr. Gong, was introduced to its founder, Dr. Xu Ting in a bio-pharmaceutical development opportunity summit forum in April 2009. Salient terms of the Co-Development Agreements are summarized below:

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- Allocation of Responsibility**
- Under the Co-Development Agreements, we are responsible for, among other things, designing, conducting and monitoring clinical trials, reviewing registration filings, and conducting commercialization of envafolimab globally at our own cost, while Alphamab Group is responsible for, among other things, completing CMC studies and pre-clinical studies and manufacturing envafolimab samples for clinical trials at its own cost. During the clinical stage, Alphamab Group is obligated to supply envafolimab drug samples for free. After envafolimab enters into the commercialization stage, Alphamab Group will supply envafolimab to us on a cost-plus basis. The “cost-plus basis” for the supply of envafolimab by Alphamab Group equals to the production costs times by a certain markup. The markup in the range of 25% to 35% is to cover the depreciation and fixed maintenance cost incurred with Alphamab Group’s manufacturing facilities. The commercial rationale for sharing 49% of the profit before tax to Alphamab Group on top of the “cost-plus” payments to Alphamab Group for the supply of envafolimab is that the “cost-plus basis” merely covers both the variable and fixed costs of producing envafolimab whereas the 49% represents the profit sharing of the collaboration between the two parties after deducting relevant costs and expenses.

We are also entitled to obtain the new drug certificate and would have exclusive commercialization rights for envafolimab worldwide. Alphamab Group is entitled to apply for and obtain the GMP certificate to manufacture envafolimab, and is obligated to manufacture and supply envafolimab to us.

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### Payment

- Under the Co-Development Agreements, we have the following payment obligations to Alphamab Group: (i) Alphamab Group was eligible to receive an upfront payment of RMB10 million, which we have paid in April 2016; and (ii) upon the approval and commercialization of envafolimab, we would be entitled to 51% while Alphamab Group would be entitled to 49% of the profit before tax generated from the sales of envafolimab in China. We are the marketing authorization holder of envafolimab and we will record 100% of revenue generated from the sales of envafolimab upon commercialization.

### Intellectual Property (IP) Arrangements

- Under the Co-Development Agreements, we agreed to co-own with Alphamab Group relevant patents and patent applications in relation to envafolimab (the “**Co-Owned Patents**”). Our ownership interests to the Co-Owned Patents include oncology treatment and may be used for envafolimab or drugs using envafolimab as a component, excluding bispecific antibodies, multi-functional antibodies, fusion proteins and other derivative antibodies. According to the Co-Development Agreements, upon approval of the marketing authorization for envafolimab, we would have 51% while Alphamab Group would be entitled to 49% of the ownership interests to the Co-Owned Patents.
- According to the Co-Development Agreements, we are exclusively entitled to use the Co-Owned Patents in the field of oncology or tumor therapy, such as to manufacture, use, offer for sale, sell and import envafolimab. Without our prior consent, Alphamab Group shall not mortgage or pledge the Co-Owned Patents, or change the patentee, applicant or other matters related to the Co-Owned Patents.

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- As further clarified and elaborated in the letter supplemental to the Co-Development Agreements, namely the Alphamab Confirmation Letter (as defined below), amongst others, although both parties will continue to hold co-ownership of the Co-Owned Patents, (i) we will continue to have an exclusive right of use in the field of oncology or tumor therapy which is relevant to the oncology indications of envafolimab, namely the current scope of indications of our Core Product; and (ii) we will continue to be free to independently use the residual rights in the Co-Owned Patents in the future development and commercialization of envafolimab. For more details, please refer to the following sub-paragraph headed “2. Alphamab Confirmation Letter – c. IP Confirmation”.

### **Remedies and Unilateral Right to Transfer the Co- Owned Patents**

- Any breach of the foregoing rights and obligations will constitute a breach of the Co-Development Agreements. According to the Co-Development Agreements, a breach of the agreements includes, among other things, (i) Alphamab Group’s interference of our exclusive rights to independently use the Co-Owned Patents in the field of oncology and tumor therapy, (ii) Alphamab Group’s mortgaging or pledging the Co-Owned Patents without our prior consent, or (iii) Alphamab Group’s ceasing the supply of envafolimab products during our commercialization stage.
- According to the Co-Development Agreements, if one party (the breaching party) causes losses to the other party (the non-breaching party) due to its breach of the agreement and fails to indemnify promptly, the non-breaching party shall have a unilateral right to transfer the patents related to envafolimab, and the proceeds from transfer or license shall be first used to compensate the losses of the non-breaching party.

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### **Term and Termination**

- The Co-Development Agreements can be terminated in the following situations: (i) if a contracting party breaches the agreements, (ii) if the obligations under the Co-Development Agreements cannot be performed due to force majeure, or (iii) if a party fails to perform its obligations related to the intellectual property rights. Based on the fact that the parties have amicably reached consents on all matters and there have not been any disputes between the parties historically, it is unlikely that either party will breach the Co-Development Agreements.
- The Co-Development Agreements are silent on the duration of the collaboration and which party will own the residual rights in the Co-Owned Patents upon the expiry of the Co-Development Agreements. In the absence of such clause, we and Alphamab Group, as co-owners of the Co-Owned Patents, would retain the residual rights in the Co-Owned Patents under PRC law, in the view of our legal advisers as to the intellectual property law.

### **Dispute Resolution and Joint Steering Committee (JSC)**

- In the event of disagreement over any terms of the agreements, including in respect of the amount of profit before tax to be shared between the parties, the parties should first resolve such disagreement through friendly negotiation. If the disagreement cannot be resolved through negotiation, such disagreement should be resolved by arbitration.
- A joint steering committee (JSC) was established to address matters relating to the development and commercialization of envafolimab. In December 2021, as a mutual agreement, the JSC arrangement was cancelled as part of the arrangement supplemental to the Co-Development Agreements, namely the Alphamab Confirmation Letter (as defined below). For details and reasons on the cancellation, please refer to the following sub-paragraph headed “2. Alphamab Confirmation Letter – b. JSC Cancellation”.

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### 2. *Alphamab Confirmation Letter*

In December 2021, as a supplemental agreement to the Co-Developments, Alphamab Group (through Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (“**Jiangsu Alphamab**”)) issued a confirmation letter to us (the “**Alphamab Confirmation Letter**”) which mainly concerns (i) cancellation of the JSC (the “**JSC Cancellation**”) and (ii) the confirmation of our exclusive right to use the Co-Owned Patents in the field of oncology and tumor therapy without interference from Alphamab Group (the “**IP Confirmation**”). For the avoidance of doubt, as a mutual agreement, we are not subject to any obligations (payment or otherwise) pursuant to the Alphamab Confirmation Letter or otherwise in relation to the cancellation of the JSC Cancellation and the IP Confirmation.

#### *a. Confirmation with Respect to Our Control*

According to the Alphamab Confirmation Letter, Alphamab Group confirms and acknowledges that, among other things: (a) during the term of cooperation, we have been undertaking and effectively controlling the global clinical R&D and commercialization of envafolimab in the field of oncology or tumor therapy; (b) we, as the MAH holder, have been solely responsible for the safety, efficacy and quality control of envafolimab throughout the entire process of R&D, manufacture, operation and utilization; (c) Alphamab Group respects and relies on the judgement and advice of us and there has been no inconsistency, conflict or dispute between Alphamab Group and us in terms of the performance and implementation of the Co-Development Agreements since the beginning of the cooperation; and (d) since the beginning of the cooperation, Alphamab Group has never attempted to alter or restrict our ability to effectively control envafolimab in the field of oncology or tumor therapy, and it will not attempt to do so in the future.

#### *b. JSC Cancellation*

Given that (i) we have obtained the BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors in November 2021 and we already initiated the commercialization in December 2021, (ii) our expertise has been validated during the development and commercialization of MSI-H/dMMR, which has been also utilized in other indications since the beginning of co-development with Alphamab Group, and (iii) we will undertake the further development of envafolimab and all costs, both parties considered that regular meeting and discussion of the JSC mechanism was no longer necessary and may be onerously burdensome. Hence, the parties cancelled the JSC so that we can make decisions more swiftly and efficiently in relation to envafolimab without having to confer with the JSC.

Furthermore, although the JSC arrangement entailed a voting mechanism, both parties, in actual practice, acted unanimously since the beginning of the cooperation, with Alphamab Group consistently deferring to us for decisions over envafolimab. Given there has never been any inconsistency, conflict or dispute between both parties and none is expected in the future which reasonably mitigates Alphamab Group’s concerns over the



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development and commercialization of envafolimab, it is reasonably agreed by both parties that the JSC Cancellation will not bring in any material adverse effect over the Co-Development over envafolimab as well as Alphamab Group's interests.

As such, considering (i) previous and existing close and mutual beneficial cooperative business relationship which is critical to us as well as Alphamab Group (for example, under a memorandum of understanding entered into between us and Alphamab in October 2020, we also assist and facilitate Alphamab Group's development of non-oncology indications of envafolimab outside the scope of the Co-Development Agreements by way of a specific arrangement under our subsidiary, 3DMed Sichuan. For details, please refer to the following sub-paragraphs headed "4. A Specific Arrangement in relation to 3DMed Sichuan") and (ii) the reliance upon our expertise and further development of envafolimab (including but not limited to indication expansion), both parties agreed to the JSC Cancellation to further reinforce mutual cooperation and to further enhance our effective control over envafolimab in line with original agreement and actual practice.

*c. IP Confirmation*

According to the Alphamab Confirmation Letter, with respect to the Co-Owned Patents Alphamab Group confirms and acknowledges the following:

- (a) Alphamab Group reaffirms and restates that we have the exclusive right to use the Co-Owned Patents in the field of oncology or tumor therapy, such as to manufacture, use, offer for sale, sell and import envafolimab, and Alphamab Group further commits not to interfere with our independent exercise of such rights.
- (b) Alphamab Group reaffirms and restates that, during the cooperation under the relevant Co-Development Agreements, Alphamab Group is obligated to strictly fulfil its obligations in relation to the maintenance of the Co-Owned Patents thereunder and will maintain full communication and coordination with us in this regard. If Alphamab Group fails to fulfil or fails to timely fulfil such obligations, we, as the co-owner of the Co-Owned Patents, have the right to, in our own discretion, carry out relevant maintenance work from time to time, including without limitation the payment of annual fees and other relevant government formalities and safeguarding the Co-Owned Patents in the case of third-party infringement.
- (c) Alphamab Group further commits that, in consideration of the long-term cooperation between Alphamab Group and us in relation to envafolimab under the relevant Co-Development Agreements and that there is no specific term of contract, in case of termination or expiration of relevant Co-Development Agreements (if any), we and Alphamab Group will continue to co-own the Co-Owned Patents that will remain valid upon such termination or expiration,

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and we, as the co-owner of the Co-Owned Patents, will continue to be entitled to the independently exclusive use of such remaining patents in the field of oncology or tumor therapy, and will continue to be entitled to be responsible for the continued research and development and commercialization of other indications of envafolimab in the field of oncology or tumor therapy.

As advised by our legal adviser as to intellectual property law, the Alphamab Confirmation Letter is a helpful supplement to the Co-Development Agreements by clarifying several issues with respect to the Co-Owned Patents upon any expiration or termination of the Co-Development Agreements: (i) both parties will continue to hold co-ownership of the Co-Owned Patents and we will continue to have an exclusive right of use in the field of oncology or tumor therapy; and (ii) we will continue to be free to independently use the residual rights in the Co-Owned Patents in the future development and commercialization of envafolimab.

### ***3. Effective Control over Core Product under the Co-Development Agreements and the Alphamab Confirmation Letter***

Based on the foregoing, we exercised and will continue to maintain effective control over the Core Product in various aspects. In addition, as discussed above, the Alphamab Confirmation Letter (including in particular, the JSC Cancellation) also confirms and acknowledges our control over the Core Product.

#### *a. Intellectual Property Rights in relation to the Core Product*

According to the Co-Development Agreements, we are exclusively entitled to use the Co-Owned Patents in the field of oncology or tumor therapy which covers the scope of indications of the Core Product and certain other indications under clinical stage.

According to the Co-Development Agreements and the Fifth Supplement thereto, commencing from the divisional application of PCT/CN/2016/092679 and PCT/CN/2016/092680 in 2016, we and Alphamab Group have been jointly responsible for the prosecution and maintenance of the Co-Owned Patents.

The PCT patent application (PCT/CN/2016/092680) was jointly filed by us and Alphamab Group in 2016 and has been granted to 3DMed Beijing and Alphamab Group as CN107849130B (the "**130B Patent**"). Our legal adviser as to intellectual property law is of the view that we are entitled to maintain and enforce the patent under PRC in the field of oncology or tumor therapy and the use of patent under the arrangement of co-ownership of the patent does not adversely affect our development and commercialization of current scope of oncology indications of envafolimab in China and abroad, including but not limited to our Core Product and several indications which are currently under clinical stage since there is a clear distinction of our Group and Alphamab Group.

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- i. Our exclusive right to the Co-Owned Patents in the field of oncology and tumor therapy is specified in and protected under both the Co-Development Agreements and the Alphamab Confirmation Letter.

The Co-Development Agreements explicitly provide us the exclusive right to use the Co-Owned Patents in the field of oncology or tumor therapy and as a result, Alphamab Group is not entitled to and has not interfered with our independent exercise of such rights. Alphamab Group further confirms and commits not to interfere with our independent exercise of these rights in the Alphamab Confirmation Letter.

According to our legal adviser as to intellectual property law, the IP Confirmation, which is supplemental to the Co-Development Agreements, reaffirms and restates the provisions under the Co-Development Agreements with respect to: (i) our exclusive right to use the Co-Owned Patents in the field of oncology and tumor therapy, (ii) our right to maintain the Co-Owned Patents, and (iii) our exclusive right of use in the field of oncology and tumor therapy after the expiration or termination of the Co-Development Agreements. Therefore, if Alphamab Group were to breach the Alphamab Confirmation Letter, e.g., by interfering with our exclusive rights or independent exercise of such rights, the breach would itself constitute both a breach of the Alphamab Confirmation Letter and a breach of the Co-Development Agreements. According to the breach of contract provisions of the Co-Development Agreements, in the worst case scenario, were Alphamab Group to commit a breach, we would be entitled to claim for monetary compensation for any losses we incurred and right to request for continued performance of the Co-Development Agreements. If Alphamab Group failed to compensate us for any losses incurred due to its breach of the Co-Development Agreements, we would be further entitled to exercise the unilateral right to transfer the Co-Owned Patents.

If we and Alphamab Group fail to reach an agreement on transferring the Co-Owned Patents, we may file a lawsuit with the competent PRC court to enforce our unilateral transfer right. According to our legal adviser as to intellectual property law, the court is likely to rule in favor of us since it would be relatively simple for us to produce supporting evidence if Alphamab Group interferes with our exclusive rights or independent exercise of such rights. With a judgment in our favor, we could apply to the China National Intellectual Property Administration (CNIPA) to transfer the Co-Owned Patents, according to the Rules for the Implementation of the PRC Patent Law (2010) and the Guidelines for Patent Examination (2010).

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- ii. The technologies we owned through the Co-Owned Patents are sufficient for us to develop the Core Product.

According to our legal advisers as to intellectual property law, as of the Latest Practicable Date, in relation to the Core Product, the Co-Owned Patents with Alphamab Group covered ten granted patents and ten filed patent applications, and we in-licensed four granted patents and two filed patent applications from Alphamab Group (the "**In-Licensed Patents**"); in total, we co-own or in-license 26 granted patents and patent applications in China and other jurisdictions.

According to our legal adviser as to intellectual property law, the technologies covered by the Co-Owned Patents are sufficient to independently develop the Core Product, a PD-L1 binding protein for preventing and/or treating cancer.

Specifically, in mainland China, the registered Co-Owned Patent of the 130B Patent, granted as of December 31, 2019 and expiring in 2036, is itself sufficient to cover the technologies for independently developing the Core Product.

The 130B Patent has been granted with 22 claims in total, including, among others, coverage of (i) the active pharmaceutical ingredients, (ii) the raw materials for production, (iii) the production method, and (iv) the use in the treatment of cancer indications of the Core Product. According to our legal adviser as to intellectual property law, the technologies under the above listed four areas of the 130B Patent are sufficient for us to independently develop the Core Product.

The Joint Sponsors concur with the views of ours and our legal adviser as to intellectual property law set forth in the preceding paragraphs i and ii.

- iii. The in-licensed IP rights serve to mitigate infringement risks.

Given the fact that certain claims of the In-Licensed Patents overlap with those of the Co-Owned Patents, we obtained an exclusive license for the In-Licensed Patents from Alphamab Group, which is intended to mitigate any potential infringement risks against these patents. In patent practice, it is not uncommon to obtain a license, or take transfer, of a target patent for the mere purpose of avoiding any infringement risks against the patent. According to our legal adviser as to intellectual property law, Alphamab Group as the patentee is legally responsible for the prosecution, maintenance and enforcement of the In-Licensed Patents.

Pursuant to the Fifth Supplement to the Co-Development Agreements in December 2018, Alphamab Group agrees to grant us a global, free-of-charge, exclusive license, with the right to sublicense, to freely manufacture, research, use, sell, offer to sell, and import envafolimab in oncology field, based on patent

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PCT/CN2016/092679 and patents obtained therefrom in various countries. Salient terms of the in-licensing arrangement with Alphamab Group are summarized below:

<b>Payments</b>	No payment obligations
<b>Intellectual Property (IP) Arrangements</b>	The intellectual property rights of the In-License Patents (including residual rights upon expiration/termination) always vest in Alphamab Group as the patentee.
<b>Term and Termination</b>	<p>The in-licensing arrangement shall remain effective from execution until termination or expiration of the Co-Development Agreements. The Co-Development Agreements can be terminated in the following situations: (i) if a contracting party breaches the agreements, (ii) if the obligations under the Co-Development Agreements cannot be performed due to force majeure, or (iii) if a party fails to perform its obligations related to the intellectual property rights.</p> <p>In the worst case scenario that the Co-Development Agreements are terminated, we might lose the protection afforded by the In-Licensed Patents and potentially be subject to claims of infringement of the In-Licensed Patents for its manufacture, research, use, sale, offer to sell, and importation of envafolimab in the oncology field.</p>

- iv. The co-ownership of the Co-Owned Patents and our exclusive right of use survive the termination or expiration of the Co-Development Agreements.

The Alphamab Confirmation Letter particularly specifies that, upon expiration or termination of the Co-Development Agreements: (i) both parties will continue to co-own the Co-Owned Patents and we will continue to have an exclusive right of use in the field of oncology and tumor therapy; and (ii) we will continue to be free to independently use the residual Patent Rights in the future development and commercialization of the Core Product.

Furthermore, the Alphamab Confirmation Letter also clearly states that it shall prevail in the case of any inconsistencies between the Alphamab Confirmation Letter and the Co-Development Agreements.

Based upon the above, the termination or expiration of the Co-Development Agreements will not jeopardize the abovementioned unilateral commitments made by Alphamab Group under the IP Confirmation. In other words, our co-ownership of

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the Co-Owned Patents and our exclusive right in the field of oncology and tumor therapy which covers, amongst others, the scope of indications of the Core Product, will survive the termination or expiration of the Co-Development Agreements.

*b. R&D and Clinical Trial*

We have control over envafolimab’s R&D in China and abroad such that we are the responsible party to bring the Core Product from pre-clinical stage to clinical trials and from clinical trial into commercialization. As advised by our PRC Legal Advisers, with respect to research and development, we are responsible for the clinical stage R&D activities in relation to envafolimab under the Co-Development Agreements. Specifically, under the Co-Development Agreements, we are responsible for reviewing new drug application documents and tracking registration progress in China and abroad, designing clinical trial strategy based on precision tumor treatment, implementing and managing clinical trials, managing the collection, reporting and summary of clinical data in China and abroad, arranging clinical and medical specialists to manage the clinical trials, and completing the Phase I clinical development plan and succeeding plans. Furthermore, we received the Umbrella IND Approval in December 2016, completed the China Phase I Clinical Trial and succeeding plans in April 2020 and completed the Pivotal Phase II Clinical Trial in July 2020, all of which occurred after first entering into the Co-Development Agreements in February 2016. To sum up, under the agreed arrangement, we are responsible for the whole clinical stage of R&D activities of envafolimab, while Alphamab Group is mainly responsible for the pre-clinical stage of R&D activities of envafolimab.

Envafolimab was in pre-clinical stage when the Co-Development Agreements were first entered into between us and Alphamab Group in February 2016. Since then, we have independently completed and been independently conducting a number of clinical trials in relation to envafolimab and achieved a number of major R&D milestones on our own and at our own cost, which amounted to approximately RMB614.9 million as of May 31, 2022, and we have significantly increased our R&D team to 151 members as of the Latest Practicable Date.

*c. Commercialization and Economic Interests*

We have control over envafolimab’s commercialization in China and abroad, from contractual, regulatory and accounting perspectives whereas in order to better promote commercialization of envafolimab, our Group may voluntarily choose to cooperate with other partners and leverage its established sales network in China.

In relation to commercialization, we are primarily responsible for envafolimab’s worldwide marketing and sales, under the Co-Development Agreements. In addition, under the memorandum with respect to envafolimab’s MAH entered into among 3DMed Beijing, Jiangsu Alphamab and Simcere Group dated in October 2020, the parties further agreed that 3DMed Sichuan is the sole MAH with respect to envafolimab and bears sole

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responsibility for the marketing and sales of envafolimab in China. According to our PRC Legal Advisers, pursuant to the Drug Administration Law of the PRC (2019 Revision) (中華人民共和國藥品管理法(2019修訂)), a MAH shall be liable for non-clinical study, clinical trial, manufacturing and business operation, post-market launch study, monitoring, reporting and handling of adverse reactions of the drugs, and the legal representative and the key person-in-charge of a MAH shall be fully responsible for the drug quality. Further, 3DMed Beijing retains 100% voting rights at shareholders’ meetings and 100% operational management rights over 3DMed Sichuan, and is entitled to 100% economic interests of and 100% nomination right of the director(s), supervisor(s) and senior management of 3DMed Sichuan. Based on the discussion with our management and the facts and circumstances set out by us, our Reporting Accountants concurred with us that, from an accounting perspective, 3DMed Sichuan is a wholly owned subsidiary of our Group, and the sales of envafolimab in China will be recognized on gross basis in our Group’s consolidation statement of profit or loss and other comprehensive income.

Furthermore, in order to better promote commercialization of envafolimab and leverage Simcere Group’s established sales network in China, we entered into the 3D Alphamab Simcere Agreement with Simcere Group in March 2020 whereby Simcere Group is responsible for preparing a promotion plan and promoting envafolimab in China in accordance with industry standards. Simcere Group is acting as a contract sales organization (CSO) which provides a series of services and solutions related to pharmaceutical marketing and sales activities under contract, and this type of CSO engagement is relatively common in the pharmaceutical industry, according to Frost & Sullivan. The above arrangement with Simcere Group applies to commercialization only in PRC, and we retain authority over envafolimab’s worldwide marketing and sales and may choose partner(s) or self-promote envafolimab outside China. For more details, please refer to the paragraphs headed “– Collaboration with Alphamab Group and Simcere Group for Envafolimab” in this section.

### *d. CMC and Manufacturing*

As discussed above, as an allocation of responsibility, we have control and are responsible for the primary aspects of clinical-stage development and commercialization of envafolimab, and is the sole responsible party for the manufacturing and product quality as the MAH for envafolimab, whereas the Alphamab Group is involved to act as a contract manufacturing organization (CMO) by providing drug manufacturing services on a contractual basis including, amongst others, performing CMC research for envafolimab, producing samples for clinical trials and manufacturing envafolimab. We believe that the above arrangement is also in the interests of ours and our Shareholders as a whole since the CMC functions and manufacturing facilities need substantial resources and cost and we elect to focus on the R&D and other functions and aspects of the responsibilities at the moment.

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*e. Accounting for Our Core Product’s Sales*

According to the Co-Development Agreements, we obtained exclusive rights to conduct clinical trials and commercialize envafolimab worldwide. Furthermore, under the memorandum of understanding dated October 2020, we and Alphamab Group further agreed that 3DMed Sichuan is the sole MAH with respect to envafolimab and bears sole responsibility for the marketing and sales of envafolimab in China. 3DMed Sichuan in this case acts as a principal in the sales of envafolimab, because it: (i) is the only authorized legal entity to engage in the sales of envafolimab under the Drug Administration Law of the PRC (2019 Revision) (中華人民共和國藥品管理法(2019修訂)) and (ii) controls the goods before goods are transferred to customers. Therefore, according to IFRS15.B35B, 3DMed Sichuan will recognise revenue in gross amount of consideration received for the sales of envafolimab. The profit-share payments represent the consideration to Alphamab Group for the acquisition of the exclusive rights, which is contingent upon the occurrence of successful commercialization of envafolimab. The profit-share payments will be recognised at the time when 3DMed Sichuan is obligated to pay and recorded as expenses.

As disclosed in note 1(g) to the Accountants’ Report set out in Appendix I to this document, 3DMed Sichuan is regarded as a wholly owned subsidiary of our Group because (i) 3DMed Beijing retains 100% voting rights at shareholders’ meetings over 3DMed Sichuan; (ii) 3DMed Beijing is entitled to 100% economic interests of 3DMed Sichuan; (iii) 3DMed Beijing is entitled to 100% nomination right of the director(s), supervisor(s) and senior management of 3DMed Sichuan; and (iv) 3DMed Beijing retains 100% operational management rights of 3DMed Sichuan. Hence, the operating results of 3DMed Sichuan are included in our Group’s consolidated financial statements. We also have the decision-making power over the amount of profit before tax to be shared between the parties.

Based on the discussion with our management and the facts and circumstances set out by us as above, our Reporting Accountants concur that revenue from the sales of envafolimab in China will be recognised on gross basis and the sharing of profit payable to Alphamab Group is recorded as expenses in our Group’s consolidated financial statements.

Furthermore, the profit before tax generated from the sales of envafolimab in China takes into account the marketing service fees payable to Simcere Group. We are responsible for the preparation and audit of the financial statement to derive any such profit before tax.



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### *4. A Specific Arrangement in relation to 3DMed Sichuan*

As discussed above, considering previous and existing close and mutual beneficial cooperative business relationship which is critical to our Group as well as Alphamab Group, our Group also voluntarily assists and facilitates Alphamab Group’s development of non-oncology indications of envafolimab outside the scope of the Co-Development Agreements. Specifically, in October 2020, we entered into a memorandum of understanding with Alphamab Group setting out the terms of the transfer of 49% equity interest in 3DMed Sichuan (which was previously a wholly-owned subsidiary of our Group) to Alphamab Group at a nominal consideration. Under such memorandum of understanding, the parties agreed to designate 3DMed Sichuan as the entity to apply for envafolimab’s MAH (for both oncology and non-oncology indications). Considering that the parties’ co-ownership of the Co-Owned Patents under the Co-Development Agreements is limited to oncology or tumor therapy and NMPA had historically not granted separate MAH for different indications with respect to one drug at the time of the memorandum of understanding, the parties agreed that 3DMed Beijing would transfer 49% equity interest in 3DMed Sichuan to Jiangsu Alphamab for the higher of RMB1 or book net asset price as a guarantee for the potential interests of non-oncology indications of envafolimab which is outside the scope of the Co-Developments and not relevant to the Core Product. If Alphamab Group could successfully apply for separate MAHs for envafolimab’s non-oncology indications, Jiangsu Alphamab would transfer the 49% equity interest in 3DMed Sichuan back to 3DMed Beijing for the higher of RMB1 or book net asset price. Given that NMPA has granted separate MAHs for a drug’s different indications since February 2021, it is reasonably expected that Jiangsu Alphamab will potentially transfer the 49% equity interest in 3DMed Sichuan back to 3DMed Beijing for the higher of RMB1 or book net asset price.

To the best of our Directors’ knowledge, Alphamab Group has not made any application for separate MAH for envafolimab’s non-oncology indications as Alphamab Group’s IND application of such non-oncology indications was submitted in March 2019 and is still undergoing evaluation by the NMPA as of the Latest Practicable Date.

In the worst case, if Alphamab Group could not successfully apply for such separate MAH, we would inject additional capital into 3DMed Sichuan equal to royalties generated from envafolimab’s non-oncology indications. The commercial rationale for the transfer is that Alphamab Group has no voting rights or economics consolidation rights over 3DMed Sichuan upon the transfer at the nominal consideration and the parties agreed to the above-mentioned double-trigger mechanism whereby further capital could be injected into 3DMed Sichuan if it also becomes the MAH holder for non-oncology indications.

### **Collaboration with Alphamab Group and TRACON for Envafolimab**

In December 2019, we, Alphamab Group and TRACON entered into a collaboration and clinical trial agreement (the “**3D Alphamab TRACON Agreement**”) for the development of envafolimab for the treatment of sarcoma in the U.S., Canada, Mexico and each of their dependent territories (the “**TRACON Territory**”). TRACON is a biopharmaceutical company

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in the U.S., an Independent Third Party of our Group. We became acquainted with TRACON when our founder, CEO and Chairman, Dr. Gong, had a meeting in San Francisco with its CEO, Dr. Charles Theuer to discuss potential business collaboration in early 2019. Salient terms of the 3D Alphamab TRACON Agreement are summarized below:

**Allocation of  
Responsibility in  
General**

- The 3D Alphamab TRACON Agreement does not specify the respective roles of us and Alphamab Group with respect to envafolimab’s development. The two parties shall jointly bear all costs associated with the conduct of the pre-clinical studies and the preparation of chemical, manufacturing and control sections of an IND application for envafolimab. For details of our effective control of envafolimab, please refer to paragraphs headed “– Collaboration with Alphamab Group for Envafolimab – Effective Control over the Various Key Aspect of Our Core Product” in this section.

**Allocation of R&D  
Responsibility**

- Pursuant to the 3D Alphamab TRACON Agreement, TRACON is responsible for conducting and will bear the costs of any Phase I, Phase II, and Phase III or post-approval clinical trial in the TRACON Territory for envafolimab in the indications of refractory and first line treatment of sarcoma. We and Alphamab Group are responsible for conducting and will bear the costs of pre-clinical studies (other than those specific to the sarcoma indication) and the preparation of chemical, manufacturing and controls activities sections of an IND application for envafolimab. We and Alphamab Group have agreed to manufacture and supply, or to arrange for a third party manufacturer to manufacture and supply, envafolimab to TRACON at pre-negotiated prices that vary based on clinical or commercial use.

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- In light of the 3D Alphamab TRACON Agreement, our Group and the Alphamab Group jointly take responsibilities for the conduct of the pre-clinical studies and the preparing of chemical, manufacturing and control sections of the IND application as set out in the Co-Development Agreements. Under the Co-Development Agreement, we are responsible for the conduct of the pre-clinical studies, which Alphamab Group is responsible for the preparation of chemical, manufacturing and control sections of the IND application. For details, please refer to the paragraphs headed “– Collaboration Agreements – Collaboration with Alphamab Group for Envafolelimab – Effective Control over the Various Key Aspects of Our Core Product” in this section.
- With respect to the R&D roles and responsibilities other than the conduct of the pre-clinical studies and the preparing of chemical, manufacturing and control sections of the IND application, TRACON is fully responsible for conducting and will bear the costs of any Phase I, Phase II, and Phase III or post-approval clinical trial in the TRACON Territory for envafolimab in the indications of refractory and first line treatment of sarcoma.
- **Commercialization and Distribution of Revenue** TRACON will be responsible for commercializing envafolimab for sarcoma in the TRACON Territory, including booking of sales revenue, unless (a) envafolimab is first approved in the TRACON Territory for an indication other than sarcoma and launched in the TRACON Territory, or (b) envafolimab is first approved in the TRACON Territory for sarcoma and subsequently approved in the TRACON Territory for an additional non-orphan indication and sold commercially by us and/or Alphamab Group, or licensee, in which case we and Alphamab Group will be responsible for commercializing envafolimab for sarcoma in the TRACON Territory, including booking of sales revenue.

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- If TRACON has the responsibility for commercialization under the 3D Alphamab TRACON Agreement, we and Alphamab Group will be entitled to tiered double digit royalties on net sales of envafolimab for sarcoma in the TRACON Territory ranging from 15% to 40% depending on whether TRACON is the major stakeholder in the commercialization of envafolimab for sarcoma in the TRACON Territory. Under the 3D Alphamab TRACON Agreement, "net sales" is defined as the gross amounts received for sales or other dispositions by a party or any of its affiliates or licenses to third parties, less certain deductions actually incurred, allowed, paid, accrued or otherwise reasonably allocated in accordance with GAAP. Such royalties shall be split approximately evenly between us and Alphamab Group after accounting for all relevant costs and expenses. If we and Alphamab Group have responsibility for commercialization under the 3D Alphamab TRACON Agreement, TRACON will be entitled to (a) tiered double digit royalties on net sales of envafolimab for sarcoma in the TRACON Territory ranging from 15% to 40% if TRACON has elected to not co-market envafolimab in sarcoma or (b) a 50% on net sales of envafolimab for sarcoma in the TRACON Territory if TRACON has chosen to co-market envafolimab in sarcoma. Payment obligations under the 3D Alphamab TRACON Agreement continue on a country-by-country basis until the last to expire licensed patent covering envafolimab expires.

### **Intellectual Property (IP) Arrangements**

- Pursuant to the 3D Alphamab TRACON Agreement, TRACON was granted an exclusive and non-transferable license to develop and commercialize envafolimab for the treatment of sarcoma in the TRACON Territory.
- We and Alphamab Group retain the right to develop envafolimab in all territories outside of the TRACON Territory as well as within the TRACON Territory for all indications other than sarcoma.

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- According to our legal adviser as to U.S. intellectual property law, the completed Phase I clinical trial in the U.S. did not aim at developing treatment for sarcoma and no sarcoma patients were enrolled based on information provided by us. The clinical trial aimed at evaluating the safety and tolerability of envafolimab in advanced and metastatic solid tumors. Under the 3D Alphamab TRACON Agreement, TRACON was given an exclusive license to develop envafolimab in the U.S. for treating sarcoma. Based on the above, it is reasonably concluded that the completed Phase I clinical trial we conducted in the U.S. is not inconsistent with the scope of the exclusive license granted to TRACON pursuant to the 3D Alphamab TRACON Agreement.

- Term and Termination**
- The term of the 3D Alphamab TRACON Agreement continues until the later of the date the parties cease further development and commercialization of envafolimab for sarcoma in the TRACON Territory or the expiration of all payment obligations. The 3D Alphamab TRACON Agreement may be terminated earlier by a party in the event of an uncured material breach by the other party or bankruptcy of the other party, or for safety reasons related to envafolimab.

To the best of our Directors’ knowledge, there is no relationship between Alphamab Group and TRACON other than the contractual relationship under the 3D Alphamab TRACON Agreement.

### **Collaboration with Alphamab Group and Simcere Group for Envafolimab**

In March 2020, we entered into a tripartite collaboration agreement with Alphamab Group and Simcere Group, together with a separate marketing and promotion agreement with Simcere Group in respect of envafolimab (the “**Promotion Agreement**” and collectively, the “**3D Alphamab Simcere Agreements**”). Simcere Group is a company engaged in the R&D, production and commercialization of pharmaceuticals in China, a shareholder and an Independent Third Party of our Group. We became acquainted with Simcere Group when our founder, CEO and Chairman, Dr. Gong, visited Simcere in Nanjing and met with its founder, Dr. Ren Jinsheng, for business collaborations in 2009. Salient terms of the 3D Alphamab Simcere Agreements are summarized below:

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### **Allocation of Responsibility**

- The role of Simcere Group under the 3D Alphamab Simcere Agreements is to prepare a promotion plan and promote envafolimab in China in accordance with industry standards for the purpose of increasing its sales. The 3D Alphamab Simcere Agreements are silent on the role of the “distributors introduced by Simcere Group”. Once the distributors are introduced by Simcere Group, we work directly with them by entering into agreements and selling envafolimab.
- Pursuant to the 3D Alphamab Simcere Agreement, Simcere Group is mainly responsible for the preparation of promotion plan and promotion of envafolimab in China in accordance with industry standards for the purpose of increasing product sales, and its function is similar to a CSO with no right to exert any control over envafolimab. To facilitate sales and marketing and in line of with general practice in the industry, Simcere Group is entitled to decide on general matters with respect to the routine and day-to-day marketing of envafolimab in China but is not entitled to make any final decisions on specific matters that affect the commercial success of envafolimab such as its initial pricing and availability to centralized procurement or volume purchase catalogue.
- Furthermore, our wholly owned subsidiary, 3DMed Sichuan, is the sole MAH with respect to envafolimab and bears sole responsibility for the marketing and sales of envafolimab in China. For details, please see the paragraphs headed “– Collaboration Agreements – Collaboration with Alphamab Group for Envafolimab – Effective Control over the Various Key Aspects of Our Core Product” in this section. According to our advisers as to PRC law, subject to the 3D Alphamab Simcere Agreement, we therefore have the final decision-making power with respect to all matters of envafolimab granted to MAH holder under PRC law, including the right to select a CSO when carrying out the marketing and sales of envafolimab in China.

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- Sincere Group has agreed to undertake annual minimum promotion requirements starting from the fourth year of our collaboration and will re-negotiate such requirements with us and Alphamab Group upon the expiration of each consecutive four-year period thereafter. The “annual minimum promotion requirements” range from RMB200 million to RMB500 million starting from the fourth year of commercialization.
  - The reason why annual minimum promotion requirement is set as “starting from the fourth year” of the collaboration is that new drugs are possible to reach peak sales in the fourth year of commercialization, according to Frost & Sullivan, and the minimum promotion requirements setting a floor not only incentivizes Sincere Group to invest in promotion efforts in the first three years for the purpose of maximizing envafolimab’s sales potential but also requires Sincere Group to maintain such promotion efforts till envafolimab reaches its peak sales. For the above reasons, there is no minimum promotion requirement for the initial three-year period.
- Commercialization and Distribution of Revenue**
- Pursuant to the 3D Alphamab Sincere Agreements, Alphamab Group, as the exclusive manufacturer, will be responsible for supplying envafolimab to us at pre-negotiated prices and we will sell envafolimab to the relevant customers through Sincere Group, while Sincere Group will be entitled to receive the marketing service fees on a monthly basis calculated with reference to the total purchases made by distributors through Sincere Group and based on rates stipulated in the 3D Alphamab Sincere Agreements.
  - The “rates” of the marketing service fees specified in the 3D Alphamab Sincere Agreements equal to tiered percentage ranging from 55% to 70% with reference to the gross sales revenue minus product costs.

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- Intellectual Property (IP) Arrangements** • Under the 3D Alphamab Simcere Agreements, Simcere Group was granted an exclusive promotion right and the rights of first refusal for in-licenses or transfers of envafolimab in respect of oncology indications in China, subject to the terms and conditions of the 3D Alphamab Simcere Agreements.
  
- Right of First Refusal** • Simcere Group was granted the rights of first refusal for in-licenses or transfers of envafolimab in respect of oncology indications in China under this collaboration because our management team considered that it is in the best interest of us to grant Simcere Group such right of first refusal for the sake of continuous commercialization of envafolimab, given that Simcere Group’s strong sales force in the Chinese pharmaceutical market can generate potential synergies with our business and as our existing shareholder, it has a good understanding of the potentials of envafolimab.
  
- Term and Termination** • The agreement is silent on its duration and can be terminated by a non-breaching party if a breach has occurred but not resolved by negotiation.

In the view of the PRC Legal Advisers, the involvement of such designated distributors does not violate the Two-Invoice System. We intend to expand hospital coverage and promote our products to a larger group of hospitals in a cost-effective manner through the cooperation with Simcere Group. According to the 3D Alphamab Simcere Agreements, Simcere Group is responsible for the marketing and promotion of envafolimab including connecting and coordinating with various drug distributors or pharmacies scattered in different provinces. Our Company, as the MAH of envafolimab, will enter into distribution agreements with the distributors or pharmacies, including Simcere Group (i.e. the “designated distributors”). Our Company will issue invoice to the “designated distributors” as one invoice and the “designated distributors” will issue invoice to the hospitals and other medical service providers as the other invoice. Simcere Group will charge certain promotion service fees as stipulated in the 3D Alphamab Simcere Agreements. As such, our PRC Legal Advisers are of the view that the involvement of such “designated distributors” is not a violation of the “Two-Invoice System.”

To the best of our Directors’ knowledge, there is no relationship between Alphamab Group and Simcere Group other than the contractual relationship under the 3D Alphamab Simcere Agreement.



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### Collaboration with MRKDG for Envafolimab

In February 2022, we and Merck Healthcare KGaA (“**MRKDG**”) entered into a clinical trial collaboration and supply agreement (the “**3D MRKDG Agreement**”) for conducting a Phase II clinical pilot study in Greater China, in which envafolimab and cetuximab (Erbix<sup>®</sup>), a monoclonal antibody targeting epidermal growth factor receptor (EGFR) developed by MRKDG, would be dosed in combination (the “**Study**”). MRKDG is a biopharmaceutical company in Germany, an Independent Third Party of our Group. We became acquainted with MRKDG when our founder, CEO and Chairman, Dr. Gong, was introduced to Zezhi Yuan, the head of the oncology division of MRKDG’s China bio-pharmaceutical business in 2021. Salient terms of the 3D MRKDG Agreement are summarized below.

#### **Allocation of Responsibility**

- Under the 3D MRKDG Agreement, we shall act as the sponsor of the Study and shall at our own cost, among other things, design, conduct and monitor the Study, supply envafolimab for the Study, secure adherence to relevant regulatory standards and communicate with regulatory authorities, and maintain all related reports and documentation. MRKDG shall, among other things, advise on the design of the Study, and supply cetuximab needed for the Study without reimbursement.

#### **Intellectual Property (IP) Arrangements**

- All inventions achieved under the Study or through the clinical data relating solely to envafolimab shall be the sole and exclusive property of us, and those relating to cetuximab shall be the sole and exclusive property of MRKDG. Any other inventions shall belong to us while we grant a perpetual, sublicensable, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up license to use such inventions to MRKDG.

#### **Clinical Data**

- All clinical data generated from the Study shall be solely owned by us while we grant a sublicensable, irrevocable, non-exclusive, worldwide and perpetual right to use the clinical data to MRKDG to obtain and maintain the original label or label changes for cetuximab.
- Each party grants to the other party a non-exclusive and non-transferable “right of reference” with respect to the results of the Study.

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- Dispute Resolution**
- Each party shall appoint an alliance manager to resolve deadlocks or disputes. If an issue cannot be resolved by the alliance managers, the issue shall be elevated to our CEO (or his delegate) or the Head of Development of MRKDG (or his or her delegate). If failing to reach agreement, we shall have the right to make a final decision except that MRKDG shall have the final decision-making authority with respect to cetuximab-related safety issues and amount of cetuximab to be delivered.
- Term and Termination**
- The 3D MRKDG Agreement shall continue until the completion of all obligations of parties or terminated by either party.
  - Either party may terminate the 3D MRKDG Agreement in the event of (i) material breach by the other party, (ii) reasonable determination of material adverse patient safety impact, (iii) regulatory requirements, (iv) deviation from market forecast of the clinical trials determined by us, and (v) failure to perform obligations or breach of representations and warranties by the other party.
  - MRKDG may terminate the 3D MRKDG Agreement if it reasonably and in good faith believes an imminent danger to patients exists in the Study and we fail to incorporate changes or do not address such issue in good faith upon its written notice.

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### Collaboration with SELLAS Group for 3D189 and 3D059

In December 2020, we entered into an exclusive license agreement with SELLAS Group (the “**SELLAS Agreement**”). SELLAS is a biopharmaceutical company in the U.S., an Independent Third Party of our Group. Salient terms of the SELLAS Agreement are summarized below:

#### **License**

- Under the SELLAS Agreement, SELLAS Group granted us a sublicensable, royalty-bearing license, under certain intellectual property owned or controlled by SELLAS Group, to develop, manufacture and have manufactured, and commercialize galinpepimut-S (“**GPS**” or “**3D189**”) and heptavalent GPS (“**GPS+**” or “**3D059**”) product candidates (the “**SELLAS Licensed Products**”), for all therapeutic and other diagnostic uses (the “**SELLAS Licensed Field**”) in China, Hong Kong, Macau and Taiwan region (“**Greater China**”). MSK licensed certain know-how relating to 3D059 to SELLAS, which in turn sub-licensed the same to us. We are not obligated to pay any fee to SELLAS Group for granting sublicense of 3D059 to third parties. The tiered royalties we pay to SELLAS Group are based upon a percentage of the annual net sales of SELLAS Licensed Products in Greater China by us and any of our sublicenses. The license is exclusive, except with respect to certain know-how that has been non-exclusively licensed to SELLAS Group by MSK and is further sublicensed to us on a non-exclusive basis by SELLAS Group.
- We have the right, but not the obligation, to step-in to cure SELLAS’ breach in the event it fails to discharge its payment obligations under its license agreement with MSK. The maximum exposure with respect to the payment obligations include (i) running royalties calculated based on worldwide annual net sales, (ii) guaranteed minimum royalties, (iii) milestone payments upon the achievement of certain R&D milestone events, and (iv) share of any sublicensing incomes.

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### **Allocation of Responsibility**

- We are responsible for all costs related to developing, obtaining regulatory approval of and commercializing the SELLAS Licensed Products in the SELLAS Licensed Field in Greater China. We are required to use commercially reasonable best efforts to develop and obtain regulatory approval for, and upon receipt of regulatory approval, commercialize the SELLAS Licensed Products in the SELLAS Licensed Field in Greater China. We and SELLAS Group agreed to negotiate in good faith the terms and conditions of a clinical supply agreement, a commercial supply agreement, and related quality agreements pursuant to which SELLAS Group will manufacture or have manufactured and supply us with all quantities of the SELLAS Licensed Product necessary for us to develop and commercialize the SELLAS Licensed Products in the SELLAS Licensed Field in Greater China until we have received all approvals required for us or our designated contract manufacturing organization to manufacture the SELLAS Licensed Products in Greater China.

### **Intellectual Property (IP) Arrangements**

- SELLAS Group retains development, manufacturing and commercialization rights with respect to the SELLAS Licensed Products in the rest of the world.

### **Royalties**

- We agreed to pay tiered royalties based upon a percentage of annual net sales of SELLAS Licensed Products in Greater China ranging from 7% to 12%. The royalties are payable on a SELLAS Licensed Product-by- SELLAS Licensed Product and region-by-region basis commencing on the first commercial sale of a SELLAS Licensed Product in a region and continuing until the latest of (i) the date that is fifteen years from the receipt of marketing authorization for such SELLAS Licensed Product in such region and (ii) the date that is ten years from the expiration of the last valid claim of a licensed patent covering or claiming such SELLAS Licensed Product in such region (collectively, the “**SELLAS Royalty Term**”). The royalty rate is subject to reduction under certain circumstances, including when generic competition for a SELLAS Licensed Product exists in a particular region.

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### **Milestone Payments**

- In partial consideration for the rights granted by SELLAS Group, we agreed to pay to SELLAS Group (i) a one-time upfront cash payment of \$7.5 million in order to reimburse SELLAS Group for certain expenses incurred with respect to the development of the SELLAS Licensed Products prior to execution of the SELLAS Agreement, and such payment of \$7.5 million has been settled in December 2020, and (ii) milestone payments totaling up to \$194.5 million in the aggregate upon the achievement of certain technology transfer, development and regulatory milestones, as well as certain net sales thresholds of SELLAS Licensed Products in Greater China in a given calendar year.
- Under the SELLAS Agreement, milestone payments are triggered by two types of events: (i) development milestone events that mark important progress in the research and development of the SELLAS Licensed Products, and (ii) sales milestone events that mark the product reaching net sales thresholds of the SELLAS Licensed Products in Greater China in a given calendar year ranging from \$100 million to \$2,000 million.
- Under the SELLAS Agreement, development milestone events include (i) approval of the first IND for a SELLAS Licensed Product in China; (ii) agreement on the final version of a plan detailing the transfer of technology from SELLAS Group to us; (iii) completion of the technology transfer; (iv) initiation of the first Phase II clinical trial in Greater China for a SELLAS Licensed Product; (v) initiation of the first Phase III clinical trial in Greater China for a SELLAS Licensed Product; and (vi) approval of a marketing authorization application for a SELLAS Licensed Product by the NMPA for each of the first indication, second indication, third indication, and fourth indication.

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### **Decision-Making**

- Under the SELLAS Agreement, a joint steering committee will be established between us and SELLAS Group to coordinate and review the development, manufacturing and commercialization plans with respect to the SELLAS Licensed Products in Greater China. The joint steering committee is initially composed of four representatives, with each of the parties appointing two representatives, and the joint steering committee may change its size from time to time by mutual consent of the parties.
- In the event of deadlock, if the joint steering committee is unable to resolve the dispute within fifteen days, then either SELLAS Group or us may, by written notice to the other, have such matter referred to the President and CEO of the respective party. If such executive officer also fails to resolve such dispute within fifteen days, and provided that such matter (i) raises bona fide safety, efficacy and technical concerns, (ii) is inconsistent with the global development strategy for the SELLAS Licensed Products, or (iii) reasonably could be expected to have an adverse effect on the development or commercialization of any SELLAS Licensed Product outside Greater China, then mutual agreement by SELLAS Group and us will be required to make such decision. If the dispute does not involve any of the abovementioned matters, we shall have the final decision-making authority.

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- Term and Termination**
- The SELLAS Agreement will expire on a SELLAS Licensed Product-by- SELLAS Licensed Product and region-by-region basis on the date of the expiration of all of our payment obligations to SELLAS Group. Upon expiration of the SELLAS Agreement, the license granted to us will become fully paid-up, perpetual and irrevocable. Either party may terminate the SELLAS Agreement for the other party's material breach following a cure period or upon certain insolvency events. SELLAS Group may terminate the SELLAS Agreement if we or our affiliates or sublicensees challenge the validity or enforceability of the licensed patents or if we fail to timely pay the upfront payment. At any time following the two-year anniversary of the effective date, we have the right to terminate the License Agreement for convenience, provided that such termination is made upon (i) six months prior written notice to SELLAS Group if such notice is provided before the first sale to a third party of SELLAS Licensed Products in the China, Hong Kong, Macau or Taiwan; or (ii) twelve months prior written notice to SELLAS Group if such notice is provided after the first sale to a third party of SELLAS Licensed Products in China, Hong Kong, Macau or Taiwan. We may terminate the SELLAS Agreement upon prior notice to SELLAS Group if the grant of the license to us is prohibited or delayed for a period of time due to a change of U.S. export laws and regulations.

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- In the event of termination, depending on the reason for the termination, the consequences could be that (i) all licenses and other rights granted by SELLAS Group to us shall terminate, and all of our rights under the intellectual property with respect to the SELLAS Licensed Products shall revert to SELLAS Group; (ii) we shall cease any and all development, manufacture and commercialization activities relating to the SELLAS Licensed Products; (iii) we shall, at our own cost, wind down any of our ongoing clinical trials of the SELLAS Licensed Products or transfer such clinical trials to SELLAS Group.

### **Right to Remedies**

- MSK has the sole right to prosecute and maintain the patents sublicensed by MSK, while SELLAS has the first right to prosecute and maintain each of the licensed patents by SELLAS other than the patents sublicensed by MSK in relation to the SELLAS Agreement. SELLAS agrees to consult with us with respect to the prosecution and maintenance of the abovementioned patents in Greater China. We have the first right, but not the obligation, to enforce the MSK patents and the other licensed patents in the SELLAS Licensed Field in Greater China. Unless the parties otherwise agree in writing, each party shall have the right to defend itself against a suit that names it as a defendant with respect to the defense of claims brought by third parties.

The SELLAS Agreement includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature.

### **Collaboration with Aravive for 3D229**

In November 2020, we entered into a collaboration and license agreement (the “**Aravive Sub-Licensing Agreement**”) with Aravive, whereby Aravive granted us an exclusive sublicense to develop, manufacture and commercialize products that contain 3D229 as the sole drug substance, for the diagnosis, treatment or prevention of human oncological diseases, in Greater China. Please refer to “Risk Factors – If we are unable to obtain and maintain adequate patent protection for our product and 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 any of our future approved products or technologies would be materially adversely affected.” in this document for a description of



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relevant risks. Stanford licensed the technology that is used by Aravive to develop 3D229 and Aravive licensed 3D229 to us. Aravive is an oncology company in the U.S., an Independent Third Party of our Group. Salient terms of the Aravive Sub-Licensing Agreement are summarized below:

**Allocation of  
Responsibility**

- Under the terms and conditions of the Aravive Sub-Licensing Agreement, we will be solely responsible for the development and commercialization of licensed products in Greater China.

**Payments**

- Under the terms of the Aravive Sub-Licensing Agreement, Aravive received from us cash payments of \$12 million, which we have fully paid in November 2020, and is eligible to up to an aggregate of \$207 million in clinical development, regulatory and commercial milestone payments. Under the Aravive Sub-Licensing Agreement, milestone payments are triggered by two types of events: (i) development milestone events that mark important progress in the research and development of 3D229, and (ii) sales milestone events that mark the product reaching specific net sales thresholds of 3D229 in Greater China in a given calendar year. There can be no guarantee that any such milestones will in fact be met. Aravive is obligated to make certain payments to The Board of Trustees of the Leland Stanford Junior University (“**Stanford**”) based on certain amounts received from us under the Aravive Sub-Licensing Agreement pursuant to the existing exclusive license agreement by and between the Aravive and Stanford, dated January 25, 2012, and as amended to date (the “**Upstream Agreement**”).

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- Aravive will also be entitled to receive tiered royalties ranging from 10% to 16% on sales in Greater China, if any, of products containing 3D229. Royalties are payable with respect to each jurisdiction in Greater China until the latest to occur of: (i) the last-to-expire of specified patent rights in such jurisdiction in Greater China; (ii) expiration of marketing or regulatory exclusivity in such jurisdiction in Greater China; or (iii) ten (10) years after the first commercial sale of a product in such jurisdiction in Greater China. In addition, royalties payable under the Aravive Sub-Licensing Agreement will be subject to reduction on account of generic competition under certain specified conditions, with any such reductions capped at certain percentages of the amounts otherwise payable during the applicable royalty payment period.
- Representations and Warranties**
- Under the Aravive Sub-Licensing Agreement, Aravive represented and warranted that it has sufficient legal and/or beneficial title or ownership or license in relation to 3D229.
  - We are not entitled or obligated to step-in to cure Aravive's breach in the event Aravive fails to discharge its payment obligations under the Upstream Agreement. Under the Upstream Agreement, if the Upstream Agreement between Aravive and Stanford is terminated, Aravive is obligated to pay the royalties accrued or accruable, and any claim, accrued or to accrue, because of any breach or default by the other party.

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- Term and Termination**
- If either we or Aravive materially breaches the Aravive Sub-Licensing Agreement and does not cure such breach, the non-breaching party may terminate the Aravive Sub-Licensing Agreement in its entirety. Either party may also terminate the Aravive Sub-Licensing Agreement, upon written notice, if the other party files for bankruptcy, is dissolved or has a receiver appointed for substantially all of its property. Aravive may terminate the Aravive Sub-Licensing Agreement if we, our affiliates or our sublicensees challenges the validity or enforceability of any of Aravive's patents covering any of the licensed compounds or products or ceases substantially all development and commercialization of licensed products in Greater China for a specified period, subject to certain exceptions. We may also terminate the Aravive Sub-Licensing Agreement for convenience provided certain notice is provided to Aravive.
  - Under the Aravive Sub-Licensing Agreement, in the event of termination (i) all licenses and other rights granted by Aravive to us would terminate, and all of our rights under the licensed intellectual property in relation to 3D229 shall revert to Aravive; and (ii) we would, at our own cost, wind down any ongoing clinical trials for 3D229 or transfer such clinical trials to Aravive, unless the Aravive Sub-Licensing Agreement is terminated by us due to Aravive's material breach or bankruptcy, at Aravive's reasonable request.
- Right to Remedies**
- Aravive shall have the sole right to prosecute and maintain the patents sublicensed by Aravive in relation to the Aravive Agreement. Aravive shall have the first right, but not the obligation, to enforce the abovementioned patents, with a right for us to join such enforcement action. With respect to third party infringement claims, the party for which the infringement action is brought against shall have the right to direct and control the defense of such infringement action, provided the other party may participate in the defense and/or settlement.

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The Aravive Sub-Licensing Agreement contemplates that Aravive will enter in ancillary arrangements with us, including a clinical supply agreement and a manufacturing technology transfer agreement.

### **Collaboration with Haihe Biopharma for 3D185**

In June 2018 and September 2018 respectively, we entered into two patent license agreements with Haihe Biopharma and SIMM with respect to licenses of two patents in relation to 3D185 (the “**Haihe SIMM Collaboration Agreements**”). Haihe Biopharma is a leading innovation-driven biotechnology company in China and SIMM is a comprehensive research institution for drug discovery in China, each of which is an independent third party of our Group. Haihe Biopharma is a biotechnology company in China, an Independent Third Party of our Group. SIMM is a comprehensive research institution for drug discovery in China, also an Independent Third Party of our Group. Salient terms of the Haihe SIMM Collaboration Agreements are summarized below:

#### **Allocation of Responsibility**

- The agreement is silent on the relationship between Haihe and SIMM, and the role of SIMM in this collaboration. SIMM therefore has no specified role in this collaboration.
- We have rights to manage the clinical development and commercialization of 3D185 at our own discretion and shall retain intellectual property rights for any improvements we made on the licensed patents. Under the Haihe SIMM Collaboration Agreement, we have to manage the clinical development of 3D185 at our own cost.

#### **Intellectual Property (IP) Arrangements**

- Under the Haihe SIMM Collaboration Agreement, Haihe and SIMM jointly own the Chinese patents and international patents for 3D185.
- Pursuant to the Haihe SIMM Collaboration Agreements, we were granted exclusive licenses of the patents to develop, manufacture and commercialize 3D185 for oncology and pulmonary fibrosis treatment globally.

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### **Payments**

- Pursuant to the Haihe SIMM Collaboration Agreements, we fully paid upfront royalty fees of RMB18.75 million in June 2018 for the license, and are obligated to pay further royalty fees subject to achievements of development milestones. We are also obligated to pay 5% of net sales revenue to Haihe Biopharma and SIMM upon successful commercialization of 3D185, and “net sales” refers to the total amount of sale of 3D185 invoiced by us, any of our affiliates or any sublicensee to any third party, less the customary trade discount, refund, return, credit, tax and the costs for transportation, insurance and courier as shown on the aforementioned invoice.

### **Term and Termination**

- The Haihe SIMM Collaboration Agreements will expire upon the later of (a) the 10-year anniversary of the approval of the first indication of the licensed product, and (b) expiration of the licensed patents. The Haihe SIMM Collaboration Agreements may be terminated by us upon a 60-day advance written notice, and may be terminated by either party in the event of material breach by the other party.

### **Right to Remedies**

- We have a right to prosecute and maintain the relevant patents licensed by Haihe in relation to the Haihe SIMM Collaboration Agreements, with an obligation to notify and consult with Haihe Biopharma. The parties shall consult each other with respect to any infringement of third party patents.

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### Collaboration with Haihe Biopharma Group for 3D1001 and 3D1002

In October 2020 we entered into two patent license agreements (the “**Haihe License Agreement(s)**”) with Haihe Biopharma Group for 3D1001 and 3D1002, respectively. Salient terms of the Haihe License Agreement(s) are summarized below:

**Allocation of  
Responsibility**

- Pursuant to the Haihe License Agreements, we and Haihe Biopharma Group will establish a coordination committee for each of the Haihe Licensed Products, comprised of representatives of each party, to promote communication and coordination activities between the parties. The coordination committee will meet at least twice a year to discuss matters related to research and development progress and plan, intellectual property, regulatory approval, product labeling and research data. Under the Haihe License Agreements, the coordination committee shall be composed of representatives of each party. In the event of deadlock, the parties shall resolve such matter by lawsuit.
- Under the Haihe License Agreements, we will undertake pre-clinical and clinical trials related to the Haihe Licensed Products. Moreover, we will be responsible for applying for related clinical trials and becoming the Marketing Authorization Holder, with Haihe Biopharma Group using commercially reasonable efforts in providing assistance. We will solely assume the expenses associated with and have the decision-making authority on clinical development and commercialization of the Haihe Licensed Products. Moreover, we will use reasonable efforts in developing Haihe Licensed Products and formulate reasonable development plan.
- Under the Haihe License Agreement, we are not entitled or obligated to step-in to cure Haihe’s breach in the event Haihe fails to discharge its payment obligations under the AskAt Agreements. If Haihe fails to discharge its payment obligations under the AskAt Agreements, there will not be any material adverse impact on the development of 3D1001 and 3D1002 because both drug candidates have been fully transferred to us and our subsequent development will not rely on AskAt.

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### **Intellectual Property (IP) Arrangements**

- As between the parties, we will be the sole owner of any patents and intellectual property rights that are developed from our new research, data, information and other related technologies created by us while developing the Haihe Licensed Products. We agree to grant Haihe Biopharma Group a royalty-free, permanent and sublicensable license to use such intellectual properties for all uses outside China. Pursuant to the two license agreements entered into between Haihe Biopharma Group and AskAt (the “**AskAt Agreements**”), we will accordingly be granted a royalty-free and permanent license to use intellectual properties newly created by AskAt on AAT-076 and AAT-007. This is because Haihe was granted a royalty free license to the improvements of AAT-076 and AAt-007 within the territory in the AskAt Agreements. Furthermore, according to the Haihe License Agreements, we have been granted a royalty-free and permanent license to use IPs newly created by AskAt on AAT-076 and AAT-007, and as such, in the view of our PRC Legal Advisers, we can enjoy such new IPs.
- We will also have the initial right to enforce or defend the licensed patents against third parties in the Haihe Licensed Field in China, and Haihe Biopharma Group will use reasonable efforts in providing assistance if we so request. Haihe Biopharma Group will also have the step-in right to enforce or defend the licensed patents against third parties, should we fail to do so, and may require us to use our best efforts in joining such enforcement or defense and providing assistance.

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### License

- Under the Haihe License Agreement(s), Haihe Biopharma Group granted us an exclusive sub-license under specified patents and relevant know-hows to solely develop, manufacture, use, sell, promise to sell and import 3D1001 (a.k.a RMX1001 and AAT-076) and 3D1002 (a.k.a RMX1002 and AAT-007) (the “**Haihe Licensed Products**”), respectively, for the treatment of human pain (including but not limited to chronic or acute pain caused by tumor or inflammation, but excluding injection with respect to 3D1002) (the “**Haihe Licensed Field**”) in China, provided that AskAt Inc. (“**AskAt**”), the licensor that originally granted Haihe Biopharma Group the licenses concerning the Haihe Licensed Products, retained the right to develop, manufacture, use and export the Haihe Licensed Products within China for its export towards outside China. Under the Haihe License Agreements, 3D1001 and 3D1002 are out-licensed by AskAt Inc. to Haihe, who in turn sub-licensed 3D1001 and 3D1002 to us. We are granted a sublicense to solely manufacture 3D1001 and 3D1002 on one hand and a right to import the same products on the other hand since Haihe was granted both rights under its agreement with AskAt Inc and we succeed those rights under the Haihe License Agreements. We have never exercised and do not plan to exercise the right to import 3D1001 and 3D1002.

### Payments

- Under the Haihe License Agreements, for each of 3D1001 and 3D1002, Haihe Biopharma Group is eligible to receive an upfront payment of RMB500,000 and will be entitled to milestone payments amounting to US\$13.1 million plus RMB30 million, upon the achievement of certain development, regulatory and commercial milestones in respect of each of the Haihe Licensed Products. We confirm that the upfront payment of RMB500,000 for each Haihe License Agreement has been settled in January 2021. In addition, Haihe Biopharma Group will be entitled to royalties based upon a single-digit percentage of net sales in the range of 2% to 8% of each of the Haihe Licensed Products, on the basis of each indication, so long as intellectual rights currently held or to be held by Haihe Biopharma Group and AskAt are able to maintain exclusively with respect to the Haihe Licensed Products. Under the Haihe License Agreement, “net sales” refers to the total amount of sale of 3D1001 and 3D1002 invoiced by us, any of our affiliates or any sublicensee to third party, less the customary trade discount, refund, return, credit and tax.



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- Term and Termination**
- The Haihe License Agreements will be effective so long as we are commercializing the Haihe Licensed Products in China, unless terminated earlier or either of the AskAt Agreements is terminated earlier, in which case the respective Haihe License Agreement is deemed terminated simultaneously. The Haihe License Agreements may be terminated by us without cause by providing prior written notice, or by either party because of the other party's uncured material breach of the agreement or bankruptcy events.
- Right to Remedies**
- In accordance with the Haihe License Agreements, we will have the management right in the approved patents licensed to us, and will be responsible for all matters related to such patents, including but not limiting to administration, preparation, filing, prosecution, maintenance, defense and execution.
  - We have a right to prosecute and maintain the relevant patents licensed by Haihe in relation to the Haihe License Agreements, with an obligation to notify and consult with Haihe Biopharma. The parties shall consult each other with respect to any infringement of third party patents.

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### Collaboration with ImmuneOncia for 3D197

In March 2021, we entered into an exclusive license agreement with ImmuneOncia, pursuant to which we were granted an exclusive license for the development, manufacturing and commercialization of 3D197 (also known as IMC-002) in China, Hong Kong, Macau and Taiwan region in respect of oncology indications (the “**ImmuneOncia Agreement**”). ImmuneOncia is an immuno-oncology-centric biopharmaceutical company in South Korea, an Independent Third Party of our Group. Salient terms of the ImmuneOncia Agreement are summarized below:

#### Payments

- Under the ImmuneOncia Agreement, we shall make to ImmuneOncia an upfront payment of US\$8.0 million and, we have paid US\$5.0 million in April 2021, and US\$1.0 million in July 2021. For the remaining US\$2.0 million, we will pay US\$1.0 million upon each of the following events: (i) completion of transfer of all the IND submission dossier, data and materials, and approval of the first IND of 3D197 by NMPA; and (ii) completion of the technology transfer pursuant to the technology transfer plan. In addition, ImmuneOncia will be eligible to receive up to US\$462.5 million upon the achievement of all future development and commercial milestones, plus tiered royalties up to 10% on annual net sales of 3D197 in China, Hong Kong, Macau and Taiwan region.
- Under the ImmuneOncia Agreement, the 10% royalty rate will be adopted to calculate the royalty payments for the portion of annual net sale of 3D197 in China, Hong Kong, Macau and Taiwan region greater than US\$1 billion. “Net sales” means the gross amount received by us, any of our affiliates or any sublicensee for sale of 3D197 to independent third parties less the amounts to the extent actually incurred or paid by the selling party with respect to the sale of 3D197, as determined in accordance with IFRS.

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- Under the ImmuneOncia Agreement, milestone payments are made upon two types of events: (i) development milestone events that mark important progress in the research and development of the 3D197, and (ii) sales milestone events that mark the product reaching net sales thresholds of 3D197 in Greater China in a given calendar year ranging from \$100 million to \$5 billion.
  - Development milestone events include (i) initiation of the first Phase Ib clinical trial of 3D197; (ii) initiation of the first Phase II clinical trial or the first pivotal trial of 3D197, whichever occurs first; and (iii) issuance of market authorization application approval of 3D197 in Greater China by the corresponding regulatory authority for each of the first indication, second indication, third indication, and fourth indication.”
- Term and Termination**
- The ImmuneOncia Agreement will remain in effect until the later of (a) 15 years from the first commercial sale of 3D197, (b) 10 years from the expiration of last-to-expire claim of any related patent of ImmuneOncia, and (c) expiration of all applicable regulatory exclusivity period with respect to 3D197. The ImmuneOncia Agreement may be terminated by us upon a 30-day advance written notice, or by ImmuneOncia if we file any patent challenge proceeding against ImmuneOncia. The ImmuneOncia Agreement may also be terminated by either party in the event of the material breach by or insolvency of the other party.
  - Under the ImmuneOncia Agreement, in the event of termination, the consequences could be that (i) the license granted by ImmuneOncia to us would terminate; and (ii) we would terminate our ongoing clinical trial for 3D197 or, if ImmuneOncia agrees, transfer such clinical trial to ImmuneOncia.
  - Under the ImmuneOncia Agreement, after the expiration of the royalty term for 3D197 in a particular region among China, Hong Kong, Macau and Taiwan region, the licenses granted by ImmuneOncia to us shall continue and shall become non-exclusive, fully paid, royalty free, perpetual and irrevocable in such region.

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### **Right to Remedies**

- ImmuneOncia shall have the first right to prosecute and maintain all patents licensed by ImmuneOncia in relation to the ImmuneOncia Agreement, with an obligation to consult with and keep us reasonably informed of the status of the abovementioned patents in Greater China. Unless otherwise agreed by the parties, ImmuneOncia shall have the first right, but not the obligation, to enforce the abovementioned patents, and we have the right to be represented in such action by counsel of our choice at our own expense. The parties shall cooperate with each other in any defense of third party infringement claims by entering into a “common interest agreement” wherein the parties agree to their shared, mutual interest in the outcome of such potential dispute.

### **Collaboration with Y-Biologics for 3D057**

In December 30, 2020, we entered into a license agreement with Y-Biologics with respect to license of 3D057 (also known as YBL-013), a T cell bi-specific engager, pursuant to which we will obtain the exclusive right to develop, manufacture and commercialize 3D057 in therapeutic, palliative, prophylactic and diagnostic applications for all therapeutic areas (the “**Y-Biologics Field**”) based on Y-Biologics’ Antibody Like Cell Engager (ALiCE) platform technology in China, Hong Kong, Macau and Taiwan region (the “**Y-Biologics Agreement**”). Y-Biologics is a biotech company focusing on the discovery and development of novel antibody therapeutics in South Korea, an Independent Third Party of our Group. Salient terms of the Y-Biologics Agreement are summarized below:

#### **Allocation of Responsibility**

- Under the Y-Biologics Agreement, Y-Biologics will bear 50% of the 3D057 IND development costs, and we expect the total CMC costs to be borne by Y-Biologics not to exceed US\$4 million.

#### **Intellectual Property (IP) Arrangements**

- Y-Biologics shall own the residual intellectual property right in respect of 3D057 arising from the co-development in the ROW Territory and the U.S.

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- License**
- Under the Y-Biologics Agreement, we will obtain the exclusive right to develop, manufacture, and commercialize 3D057 in China, Hong Kong, Macau and Taiwan region for all therapeutic areas and will co-develop 3D057 with Y-Biologic in other regions in the world (excluding China, Hong Kong, Macau, Taiwan region, and Korea). Y-Biologics retains the exclusive right to develop, manufacture and commercialize 3D057 in Korea.
- Dispute Resolution**
- The dispute resolution authority for the co-development arrangement in other regions in the world is the joint development committee (“**JDC**”), each party is entitled to designate up to three members. If the JDC cannot resolve a matter presented to it despite reasonable discussion, such matter may be escalated by a party to the parties’ respective senior management for solution.
  - Under the Y Biologics Agreement, in the event that a matter could not be resolved after escalation to the parties’ respective senior management, the matter would be submitted for binding arbitration by the Singapore International Arbitration Centre.
- Right of First Refusal**
- Under the Y-Biologics Agreement, Y-Biologics has the sole discretion to conduct development and commercialization of 3D057 in all territories of the world other than Greater China, South Korea and the U.S. (“**ROW Territory**”), and if Y-Biologics contemplates to grant a license to a third party to conduct development or commercialization of 3D057 in a country in the ROW Territory, we shall have the right of first refusal.

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- If Y-Biologics chooses to pursue the development of 3D057 in the U.S., Y-Biologics shall first approach us with an offer to assist in conducting such development activities. If we and Y-Biologics agree that we shall assist in such development activities, such assistance shall be performed in the name and under the direction of Y-Biologics, and we shall cover all costs and expenses for the co-development in the U.S. We are entitled to tiered percentages, ranging from single digit to twenty, of the Y-Biologics's licensing revenue arising from licensing 3D057 to a third party in the ROW Territory and the U.S. depending on whether we assist in the IND filing or the Phase I clinical trials.
- If we inform Y-Biologics that we are not interested in or we and Y-biologics do not agree on our assistance in the U.S., Y-Biologics has the right to pursue the IND filing and Phase I clinical trials of 3D057 in the U.S. without us. In either case, we shall grant Y-Biologics a perpetual, irrevocable, royalty-bearing, sublicensable and exclusive license to use any intellectual property arising from our development on 3D057 in Greater China for the IND filing and Phase I clinical trials of 3D057 in the U.S. or the ROW Territory accordingly.

### Payments

- In addition, Y-Biologics is eligible to receive an upfront payment of US\$2 million which we have fully paid in March 2021, and will be eligible to receive up to an additional US\$83 million for additional development, regulatory, commercialization and sales milestone payments, and up to 14% royalties on net sales of 3D057 in the authorization regions. Under the Y-Biologics Agreement, milestone payments are made upon two types of milestone events: (i) development and regulatory milestone events that mark important progress in the research and development of the 3D057, and (ii) sales milestone events that mark the product reaching net sales thresholds of 3D057 in Greater China in a given calendar year ranging from \$500 million to \$1 billion.

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- In relation to development and regulatory milestone events, we should make milestone payments upon (i) the start of Phase II clinical trial after regulatory authority’s approval; (ii) the start of Phase III clinical trial after regulatory authority’s approval; (iii) the NDA approval by NMPA of the first indication of 3D057 in the Y-Biologics Field in Greater China; (iv) additional approval by NMPA of each of the second, third and fourth indication of 3D057 in the Y-Biologics Field in Greater China; and (v) additional approval by NMPA of the fifth or more indications of Licensed Product in the Field in the Territory.
- Under the Y-Biologics Agreement, “net sales” shall mean the gross amount received for sales or other dispositions of 3D057 by us or any of our affiliates or any sublicensee to third parties, less deductions actually incurred, allowed, paid, accrued or otherwise reasonably allocated to 3D057 by the selling party in accordance with IFRS.

### **Term and Termination**

- The Y-Biologics Agreement will remain in effect until the later of (a) 15 years after the first commercial sale by us of 3D057 in the Y-Biologics Field, and (b) 10 years from the expiration of all applicable patents of 3D057 in the Y-Biologics Field, unless prematurely terminated by us or Y-Biologics. The Y-Biologics Agreement may be terminated by either party in the event of material breach by or bankruptcy of the other party. The Y-Biologics Agreement may also be terminated by Y-Biologics if we file any patent action or proceeding against Y-Biologics.
- Under the Y-Biologics Agreement, in the event of termination, the consequences could be that (i) the license granted by the Y-Biologics to us would terminate and revert to Y-Biologics; (ii) unless our activities, rights and benefits under the Y-Biologics Agreement have been adversely affected by Y-Biologics’s breach, we would still pay the 50% development costs, upfront payment, milestone payments and royalty payments; and (iii) we would terminate the ongoing clinical trial of 3D057 or transfer such clinical trial to Y-Biologics or its designee.

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- Under the Y-Biologics Agreement, upon expiration of the agreement, we will not be granted a perpetual license in respect of 3D057 in the licensed regions as the license granted by the Y-Biologics to us would terminate and revert to Y-Biologics.
- Right to Remedies**
- Y-Biologics shall be responsible for, and shall have the sole right to prosecute and maintain the relevant patents licensed by Y-Biologics in relation to the Y-Biologics Agreement. We shall have the right to defend the abovementioned patents solely to the extent related to the such patents shall be creditable against the royalties otherwise payable by us to YBiologics, provided that such defence has been approved by Y-Biologics. The parties shall confer in good faith regarding strategy for abating any third party infringement claims, with us having the first right to bring an action for the infringement in Greater China.

Other than as stated above, we confirm that, during the Track Record Period, there is no any other relationship or arrangement (express or implied, formal or informal) with each of Alphamab Group, TRACON, Sincere Group, SELLAS Group, Aravive, Haihe Biopharma, SIMM, ImmuneOncia and Y-Biologics.

### **Collaboration with CROs**

In line with industry practice, we collaborate with contract research organizations (CROs) that manage, conduct and support our clinical trials in China, the U.S. and other jurisdictions. We selected our CROs taking into consideration various factors, such as their qualifications, academic and professional experience, industry reputation and service fees. Except for Sincere, none of our Directors and, to the best knowledge of our Directors, none of our Shareholders who owns more than 5.0% of the Shares in issue, nor any of their respective associates, had any interest in any of our CROs during the Track Record Period.

The CROs provide us with an array of products and services necessary for complex clinical trials. In addition to the scope, depth and quality of their service and product offerings, we place a high value on our CROs' ability to facilitate optimal site selection, timely patient recruitment and efficient conduct of complex clinical trials with high-quality standards. CROs generally provide a comprehensive suite of services to assist us in the implementation and management of clinical trials, including trial preparation, day-to-day site management, clinical safety management, data management, and report preparation.

Generally, we enter into a master service agreement with a CRO under which we execute a separate work order for each clinical research project, or we enter into a research and development contract with a CRO for an individual project. We closely supervise these



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third-party service providers to ensure that they perform their duties in a manner that complies with our protocols and applicable laws and regulations, and that protects the integrity of the data resulting from our trials. Below is a summary of the key terms of an agreement that we typically enter into with a CRO:

- **Services.** The CRO provides us with services such as the implementation of a clinical research project as specified in the master agreement or a work order.
- **Term.** The CRO is required to perform its services according to the prescribed timeframe set out in the master agreement or a work order.
- **Payment.** We are required to make payments to the CRO in accordance with the payment schedule agreed by the parties.
- **Confidentiality.** We and the CRO both agree to keep confidential any information in relation to the performance of the master agreement.
- **Intellectual Property.** We own all intellectual property derived from the clinical research project, and we are entitled to apply patent for such intellectual properties.
- **Termination.** Either party is entitled to terminate the agreement in case of a material breach of the other party.

We believe our ability to conduct, and to work closely with CROs to conduct multi-center and high-quality clinical trials enable us to shorten the time required for drug development by generating the requisite data reliably and efficiently.

## COMMERCIALIZATION

### Our Commercialization Force

We have been establishing our sales and marketing department dedicated to the commercialization of our pipeline products. Since we already received BLA approval for enavafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors on November 24, 2021, we have been building our qualified and capable sales and marketing department with rich experience in the commercialization of oncology treatment, and to be mainly responsible for product positioning, market strategy, promotional activity planning and patient assistance. As of the Latest Practicable Date, the leadership team of sales and marketing department was in place.

### Medical-Driven Marketing

Leveraging the expertise and industry connections of our team, we plan to market our products primarily through a physician-targeted marketing strategy, focusing on direct and interactive communication with key opinion leaders and physicians in the respective

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therapeutic areas to promote the differentiating clinical aspects of our products. Such marketing efforts have commenced several months before the approval for the commercialization of our product. In preparation for the sales of our future approved products, we are identifying a number of hospitals, clinics and physicians specialized in oncology treatment, and to visit the sites and physicians in person for pre-launch training and liaison. We are also marketing our products directly through introduction of physicians. Through the physician-targeted marketing strategy and utilizing our onsite efforts, we are seeking to get envafolimab marketed to hospitals in major cities in China and constantly improving the commercialization channels to increase the market share of envafolimab.

We plan to sponsor numerous investigator-led clinical trials to generate local clinical data and accumulate relevant clinical experience. With the focus on treating and managing cancer as a chronic disease, we plan to boost the efficiency of promoting envafolimab through academic-oriented marketing channels. We believe that these academic-oriented marketing efforts will be beneficial for improving alignment of expert opinions on, and promoting clinical use of, our product and drug candidates. We will also support leading experts to report the results of their researches at international and domestic conventions, symposia and other notable events to promote our brand at the forefront of the industry and to enhance the opportunities for envafolimab to be included in the relevant clinical guidelines of cancer diagnosis and treatment published by competent research societies. We believe the academic promotional efforts will help convey the advantages of envafolimab over other drug candidates to clinical experts, and lead them to apply envafolimab in the treatment of their patients in a safe and effective manner. Through academic marketing, we aim to educate future leading experts who may engage in determining the NRDL or provincial or local medical insurance catalogues for the National Medical Insurance Program, so as for envafolimab to seek entrance to the NRDL and other relevant catalogues. Moreover, we will actively organize academic conferences and seminars to publicize the clinical data and research results in relation of our product and drug candidates in order to raise our brand awareness and recognition. We expect that we will hold more than 1,000 academic conferences and seminars in 2022 in major cities in China. By hosting seminars and training sessions, presenting exhibitions and sharing our clinical results during such conferences, we are able to enhance physicians’ awareness of our products.

### **Our Sales Operations**

We provide our envafolimab to end-users through our collaborations with Simcere Group, and through distributors. We have established a robust sales and distribution network, covering 910 hospitals and 1,562 pharmacies across 201 cities and 30 provinces in China as of the Latest Practicable Date.

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The following table sets forth a breakdown of our revenue generated from sales through our collaborations with Simcere Group and through distributors:

	Year Ended December 31, 2021		Five Months Ended May 31, 2022	
	<i>RMB</i>	%	<i>RMB</i>	%
	<i>(in thousands, except for percentages)</i>			
Sales through our collaborations with Simcere Group	60,260	100.0	159,634	99.1
Sales through distributors	–	–	1,428	0.9
<b>Total</b>	60,260	100.0	161,062	100.0

### *Sales through our collaborations with Simcere Group*

As we commercially launched envafolimab in China only after we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors in November 2021, we primarily cooperated with Simcere Group with respect to the sales of envafolimab during the Track Record Period and up to the Latest Practicable Date.

We collaborate with Simcere Group in connection with the promotion of envafolimab. In March 2020, we entered into the Promotion Agreement with Simcere Group, together with a tripartite collaboration agreement with Alphamab Group and Simcere Group. Pursuant to the Promotion Agreement, we will sell envafolimab to the relevant customers through Simcere Group, while Simcere Group will be entitled to receive the marketing service fees on a monthly basis calculated with reference to the total purchases made by pharmacy stores and distributors through Simcere Group and based on rates stipulated in the Promotion Agreement. Simcere Group has agreed to undertake annual minimum promotion requirements starting from the fourth year of our collaboration and will re-negotiate such requirements with us and Alphamab Group upon the expiration of each consecutive four-year period thereafter. Please refer to the paragraph headed “Our Research and Development – Collaboration Agreements – Collaboration with Alphamab Group and Simcere Group for Envafolimab” for more details.

In November 2021, we entered into an agreement, as supplemented, with Simcere Group, to further agree on certain matters in connection with the promotion of envafolimab, pursuant to which, Simcere Group, as our business partner, agrees to provide various supports in relation to the sales of envafolimab. As of the Latest Practicable Date, we had just started the commercialization of envafolimab, and we had marketed envafolimab during the Track Record Period to our customers, i.e. pharmacy stores, primarily through our cooperation with Simcere Group.

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The price of envafolimab sold by us to pharmacy stores are within a range determined by us after taking into account factors such as our products’ costs, prices of competing products, and our target patients’ receptiveness to the products, as well as changes in market conditions and the regulatory environment. We also determine the suggested retail prices at which our products are sold by the pharmacy stores to patients. For details, please refer to the paragraph headed “Our Research and Development – Collaboration Agreements – Collaboration with Alphamab Group and Simcere Group for Envafolimab”.

We do not enter into long term agreement with pharmacy stores introduced by Simcere Group. The pharmacy stores generally placed orders through Simcere Group. We engage Simcere Group to assist the delivery of our products to the pharmacy stores through qualified vendor, while we, as the owner of the products, bear transportation costs for the delivery. The title and risk of loss for the products transfer from us to the pharmacy stores once the products arrive at the pharmacy stores.

We recognize revenue when the pharmacy stores and distributors receive our products and we grant a collection period of 70 days to Simcere Group who assists us with collecting payment from pharmacy stores and distributors. Our customers generally cannot return products unless that the products have quality defects. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material customer complaint, disputes or product returns.

### *Sales through distributors*

In addition, we cooperated with distributors who purchase envafolimab from us and resell to their customers, such as certain hospitals and pharmacies, during the Track Record Period and up to the Latest Practicable Date. Our distributors primarily engage in the pharmaceutical drugs distribution business whom we believe have the required qualifications and capabilities and are suited to our strategic marketing model. We have established and maintained resource sharing with our distributors to effectively execute our marketing strategies specifically tailored to each designated geographic location. We believe that our existing distributorship model is consistent with customary industry practice and serves to ensure efficient coverage of our sales network while controlling our cost of distribution.

Upon selecting distributors, we will first evaluate their qualifications. We select our distributors based on their experience in the pharmaceutical industry, particularly in anti-tumor drugs. In addition, they must possess the requisite business licenses and permits to sell drugs in the respective jurisdiction and have established relationships with hospitals, pharmacies and physicians within their designated territory. Before we appoint a distributor, we assess its average annual sales volume, ability to repay its business partners and past incidents of overdue payment, if any, its acceptable payment terms, and its sales staff and management to help ensure that they have the appropriate educational background and professional skills. We may also consult with hospitals or pharmacies regarding our choice of distributors. We perform

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annual qualifications of our distributors. During the Track Record Period, none of our distributors had any past or present relationship (business or otherwise) with our Group, our Shareholders, Directors, supervisors, senior management or any of their respective associates.

### *Rights and obligations relating to the sales of our products*

Our agreements with distributors typically include terms such as the term, designated distribution area, rebates, payment and credit terms. The typical principal terms are summarized below.

- |  |  |
|--|--|
| <b>Duration and option to renew</b>    | <ul style="list-style-type: none"><li>• The distribution agreements typically have a term of one year and may be renewed upon mutual consent.</li></ul>  |
| <b>Designated geographical regions</b> | <ul style="list-style-type: none"><li>• The geographical regions for which a distributor is responsible are designated. Generally, a distributor is prohibited from selling our products outside its designated geographical regions.</li></ul>  |
| <b>Target order amount</b>             | <ul style="list-style-type: none"><li>• We generally do not set a formal arrangement with our distributors for target order amount. Nevertheless, both us and the distributors agree to commit adequate internal resources to reach a target as discussed by the parties from time to time depending on market conditions.</li></ul>                                       |
| <b>Payment and credit terms</b>        | <ul style="list-style-type: none"><li>• We have granted credit terms to some distributors, typically up to 45 to 60 days, and in no event more than 90 days.</li></ul>   |
| <b>Termination</b>                     | <ul style="list-style-type: none"><li>• Both us and our distributors are entitled to terminate the agreement after 30 days of notification of non-fulfillment of the agreement by the other party, bankruptcy and liquidation of the other party, or in the event of <i>force majeure</i>, that the other party could not perform its obligations after 90 days.</li></ul> |

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We conduct annual review of our distributors, based on their business performance and regulatory compliance. Our distributors are generally required to comply with all applicable laws and regulations, such as anti-bribery and anti-kickback laws and regulations, and obtain relevant permits to sell and distribute pharmaceutical products. Distributors' business performance is primarily evaluated based on the distributors' sales performance, breach of payment and credit terms, if any, and feedbacks from the designated hospitals and pharmacies. We also review their compliance with applicable laws and regulations. Our sales and marketing team monitors, manages and supports the activities of our distributors to help ensure that they comply with our guidelines, policies and procedures. We generally do not grant any kinds of cash rebates to our distributors. We may grant different incentive and discount to our distributors on a case by case basis, such as giving discounts to our distributors for products they procured from us if they have, among other things, neither sold our products outside their designated geographical regions, nor made any late payments exceeding the credit terms as agreed. We retain the discretion to adjust their credit terms, renegotiate order price and certain other commercial terms with them based on the review results.

During the Track Record Period, we had maintained effective management and control over our distributors. We regularly communicate and conduct review with our distributors primarily regarding their inventory level, sales amount and marketing activities, as applicable. During the Track Record Period, our distributors did not materially breach our contract terms, and we did not have any disputes with our distributors relating to the settlement of trade receivables. As of the Latest Practicable Date, we were not aware of any potential abuse or improper use of our name by our distributors which could adversely affect our reputation, business operation or financial contribution.

### *Relationship with distributors*

As we had just started the commercialization of envafolimab in December 2021, we began evaluating distributors and entered into agreement with the first distributor in January 2022. As of the Latest Practicable Date, we had signed agreements with a total of 27 distributors. The following table sets forth the changes in the number of our distributors for the periods indicated:

	<b>For the Period From January 1, 2022 to the Latest Practicable Date</b>
As of the beginning of the period	–
Additions of new distributors	27
Termination of existing distributors	–
Net increase (decrease) in distributors	27
As of the end of period	27

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### *Return and Exchanges*

Once arrived at the destined place, the distributors shall bear all risks associated with the products. In general, We do not allow distributors to return any unsold products unless there are quality defects. In addition, given the unit price of our envafolimab is considerably high and it imposes strict temperature requirements for storage, our distributors only purchase from us the products they expect to sell to hospitals and pharmacies.

We may consider to allow return or exchange for defective products as ascertained by us, or for a batch of products with short in amount shipped to our distributors, accompanied with valid proof, as assessed on a case-by-case basis. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material product return from customers, which amounted to less than five units in total.

### *Pricing*

As of the Latest Practicable Date, there was no tender or bidding process or guidance price set by relevant PRC government authorities on our products. For both our sales through our collaborations with Simcere Group and through distributors, we negotiate the price with them on a case-by-case basis. They then sell to hospitals and pharmacies based on suggested prices as mutually agreed with us.

### **Inventory Management**

During the Track Record Period, our inventories consisted of finished products only. We regularly monitor our inventories to reduce the risk of overstocking. Our Core Product envafolimab generally have a shelf life of 18 months. We communicate frequently with Simcere Group and check with our distributors both quarterly and annually to understand the feedback from customers and anticipate their needs. We require Simcere Group and our distributors to provide to us details of the sales volume to customers to assess actual market demand for our products. Our Directors confirm that we did not experience any material shortage in supply or overstock of inventories during the Track Record Period and up to the Latest Practicable Date.

During the Track Record Period, We temporarily store all our inventories in Simcere Group’s warehouse. As of December 31, 2020, December 31, 2021 and May 31, 2022, we had inventories of nil, RMB13,000 and RMB1.5 million, respectively.

## **PRODUCTION AND QUALITY CONTROL**

### **Manufacturing**

During the Track Record Period and as of the Latest Practicable Date, Alphamab Group manufactured and supplied envafolimab to us pursuant to our collaboration with Alphamab Group. For details of the arrangements with Alphamab Group in connection with the

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manufacturing of envafolimab, please refer to the paragraph headed “Our Research and Development – Collaboration Agreements – Collaboration with Alphamab Group for Envafolimab”. In addition, we have been establishing our in-house manufacturing capability in Xuzhou, Jiangsu Province and work with qualified CMOs to manufacture and test drug candidates for pre-clinical and clinical supply. In the near future, we plan to continue outsourcing the manufacturing of our product and drug candidates, including commercial-scale manufacturing of our approved drugs, to qualified CMOs/CDMOs. We have adopted, and will continue to implement, robust procedures to ensure that the production qualifications, facilities and processes of our CMOs/CDMOs comply with the applicable regulatory requirements and our internal guidelines and quality standards. We may also engage additional qualified CMOs/CDMOs in the future to ensure that we will have sufficient supply of drug candidates for our clinical trials as well as for the commercial sales of our approved drugs. When selecting CMOs/CDMOs, we will focus on their qualifications, relevant expertise, production capacity, reputation, track record, product quality and production cost.

### **Quality Assurance and Control**

Our quality assurance (QA) and quality control (QC) function oversees the quality of our drug candidates and clinical study management, as well as the quality systems in research and development, manufacturing and commercialization of drug candidates and potential future commercial products. As of the Latest Practicable Date, our QA and QC team had 14 employees. The major responsibilities for our QA and QC function include the following: (i) establishing and maintaining a quality assurance system across the entire business, including document control and quality control evaluations; (ii) qualification of vendors and monitoring the product manufacturing process conducted by CMOs and the execution of clinical studies by the CRO; and (iii) validation of facilities and equipment, which includes laboratory tests to verify that a particular process, method, program, equipment or material works properly.

### **In-house Production Facilities and Future Expansions**

We have been building for our in-house production facilities in Xuzhou, Jiangsu province, with GMP-compliant manufacturing system and facilities throughout the drug development process, including chemical drugs and biologics, to meet stringent standards. In anticipation of large needs of our drugs upon commercialization, we purchased the use right to land in Xuzhou with an aggregate area of 65,637.97 square meters. We have obtained the construction permit and started construction of new manufacturing facilities in Xuzhou. We expect to complete building the facilities and commence operation by 2024. As of the Latest Practicable Date, our manufacturing facilities in Xuzhou did not have production capacity as we are still in the process of construction. We expect that their total production capacity will reach 6,000 L (3x2,000 L) by 2024 and we also plan to further expand the production capacity in the later stage, which will be sufficient to meet commercial manufacturing needs of all our pipeline products in the foreseeable future.



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### CUSTOMERS

We commercially launched envafolimab in China only after we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors in November 2021, and started to generate revenue from the sales of envafolimab to pharmacy stores, which we consider as our customers. As of the Latest Practicable Date, our customers covered 30 provinces and municipalities in China.

As of the Latest Practicable Date, we had just started the commercialization of envafolimab, and we had marketed envafolimab during the Track Record Period to our customers through our cooperation with Simcere Group, and through our distributors. For details of the arrangements with Simcere Group in connection with the commercialization of envafolimab, please refer to the paragraph headed “Commercialization – Our Sales Operations. Our five largest customers in 2021 and for the five months ended May 31, 2022, are China-based pharmaceutical companies. The revenue generated from our five largest customers in 2021 and for the five months ended May 31, 2022, was RMB14.6 million and RMB44.0 million, respectively, which accounted for 24.2% and 27.3% of our total revenue in 2021 and for the five months ended May 31, 2022, respectively. The revenue generated from our largest customer in 2021 and for the five months ended May 31, 2022, was RMB3.9 million and RMB13.7 million, respectively, which accounted for 6.4% and 8.5% of our total revenue in the same periods.

To the best knowledge of our Directors, each of our five largest customers in 2021 and for the five months ended May 31, 2022, is an Independent Third Party. None of our Directors and, to the best knowledge of our Directors, none of our Shareholders who owns more than 5.0% of the Shares in issue, nor any of their respective associates, had any interest in any of our five largest customers in 2021 and for the five months ended May 31, 2022.

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Customer	Length of relationship (since)	Customer background and principal business	Products sold	Credit term granted	Sale amount	Percentage of total sale
<b>For the five months ended May 31, 2022</b> <i>(RMB in thousands, except percentages)</i>						
Customer A	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	60 days	13,729.7	8.5%
Customer B	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	45 days	11,380.0	7.1%
Customer C	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	60 days	7,315.7	4.5%
Customer D	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	60 days	5,823.4	3.6%
Customer E	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	no credit term	5,791.6	3.6%
<b>Total</b>					<b>44,040.4</b>	<b>27.3%</b>

**BUSINESS**

Customer	Length of relationship (since)	Customer background and principal business	Products sold	Credit term granted	Sale amount	Percentage of total sale
<b>For the year ended December 31, 2021</b>						
<i>(RMB in thousands, except percentages)</i>						
Customer B	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	45 days	3,861.10	6.4%
Customer F	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	30 days	2,845.00	4.7%
Customer G	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	45 days	2,641.80	4.4%
Customer H	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	60 days	2,641.80	4.4%
Customer A	2021	A China-based pharmaceutical company engaged in the sales of drugs	Envofalimab	60 days	2,586.70	4.3%
<b>Total</b>					<b>14,576.40</b>	<b>24.2%</b>

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### RAW MATERIALS AND SUPPLIERS

During the Track Record Period, we primarily procured raw materials and equipment for the development and manufacture of product and our drug candidates from manufacturers and suppliers around the world. Our purchases mainly include third-party contracting services for research and development of our product and drug candidates and manufacturing of certain drug substances for clinical supply, as well as raw materials, consumables, machines and equipment. We also engage qualified CROs and CMOs to support our internal team in managing and conducting pre-clinical and clinical studies and of our pipeline candidates, as well as the manufacturing activities. During the Track Record Period, our purchases from our five largest suppliers in the aggregate in each year/period accounted for 78.5%, 49.6% and 75.4% of our total purchases (including value added tax), respectively.

To the best of our knowledge, each of our five largest suppliers in each year/period during the Track Record Period is an Independent Third Party. Except for Simcere, none of our Directors and, to the best knowledge of our Directors, none of our Shareholders who owns more than 5.0% of the Shares in issue, nor any of their respective associates, had any interest in any of our five largest suppliers in each year/period during the Track Record Period.

During the Track Record Period, we did not experience any significant fluctuations in raw material prices or delays that had a material impact on our results of operations or financial position. The raw materials for our product and drug candidates to be used in clinical trials as well as materials for our laboratory use are generally readily available in the market through many suppliers. We believe we have alternative sources of suppliers who that can provide us with substitutes with comparable quality and prices. Other than the agreements with certain CROs, we order supplies and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum purchase arrangements. We generally have credit periods of 30 to 60 days and make payments through bank remittance.

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The tables below set forth certain information about our five largest suppliers in each year/period during the Track Record Period in terms of purchase amount (in descending order) generated in the same year:

<u>Supplier</u>	<u>Length of relationship (since)</u>	<u>Supplier background and principal business</u>	<u>Services/ Goods sourced</u>	<u>Credit term granted</u>	<u>Purchase amount</u>	<u>Percentage of total purchase</u>
<b>For the five months ended May 31, 2022</b> <i>(RMB in thousands, except percentages)</i>						
Supplier M	2021	A China-based pharmaceutical company engaged in wholesales of drugs	clinical R&D service, sales and promotion service, channel and delivery service	25 days	97,417.4	40.2%
Supplier N	2021	A China-based company engaged in construction service	construction service (for Xuzhou facility)	7 days	40,809.3	16.8%
Supplier O	2016	A China-based biopharmaceutical company engaged in discovery, development, manufacturing and commercialization of biotherapeutics for cancer treatment	drug manufacture service	no credit term	28,093.4	11.6%
Supplier B	2021	A South Korea-based biopharmaceutical company engaged in drug development and antibody engineering	In-license of drug candidate	30 days	9,605.4	3.9%
Supplier C	2020	A U.S.-based pharmaceutical company engaged in novel cancer immunotherapeutics for a broad range of cancer indications	In-license of drug candidate	30 days	7,015.9	2.9%
<b>Total</b>					<b><u>182,941.4</u></b>	<b><u>75.4%</u></b>

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<u>Supplier</u>	<u>Length of relationship (since)</u>	<u>Supplier background and principal business</u>	<u>Services/ Goods sourced</u>	<u>Credit term granted</u>	<u>Purchase amount</u>	<u>Percentage of total purchases</u>
<b>For the year ended December 31, 2021</b> <i>(RMB in thousands, except percentages)</i>						
Supplier A	2020	A U.S.-based pharmaceutical company engaged in the development of treatments designed to halt progression of life-threatening diseases, including cancer and fibrosis	In-license of drug candidate	45 days	58,849.7	17.4%
Supplier M	2021	A China-based pharmaceutical company engaged in wholesales of drugs	clinical R&D service, sales and promotion service, channel and delivery service	25 days	44,901.0	13.3%
Supplier B	2021	A South Korea-based biopharmaceutical company engaged in drug development and antibody engineering	In-license of drug candidate	30 days	38,970.5	11.5%
Supplier C	2020	A U.S.-based pharmaceutical company engaged in novel cancer immunotherapeutics for a broad range of cancer indications	In-license of drug candidate	30 days	12,945.4	3.8%
Supplier N	2021	A China-based company engaged in construction service	construction service (for Xuzhou facility)	7 days	12,301.5	3.6%
<b>Total</b>					<b><u>167,968.1</u></b>	<b><u>49.6%</u></b>

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<u>Supplier</u>	<u>Length of relationship (since)</u>	<u>Supplier background and principal business</u>	<u>Services/ Goods sourced</u>	<u>Credit term granted</u>	<u>Purchase amount</u>	<u>Percentage of total purchases</u>
<b>For the year ended December 31, 2020</b> <i>(RMB in thousands, except percentages)</i>						
Supplier A	2020	A U.S.-based pharmaceutical company engaged in the development of treatments designed to halt progression of life-threatening diseases, including cancer and fibrosis	In-license of drug candidate	45 days	78,970.9	36.8%
Supplier C	2020	A U.S.-based pharmaceutical company engaged in novel cancer immunotherapeutics for a broad range of cancer indications	In-license of drug candidate	30 days	49,087.5	22.9%
Supplier D	2017	A China-based company principally engaged in CRO service	CRO (for clinical trial)	60 days	22,188.5	10.3%
Supplier F	2020	A South Korea-based biopharmaceutical company engaged in the discovery & development of novel antibody therapeutics	In-license of drug candidate	90 days	13,049.8	6.1%
Supplier G	2018	A China-based company principally engaged in CRO service	CRO (for clinical trial)	10 days	5,045.0	2.4%
<b>Total</b>					<b><u>168,341.7</u></b>	<b><u>78.5%</u></b>

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### AWARDS AND RECOGNITIONS

We have received various awards and recognitions including:

No.	Awards and Recognitions	Year	Issuer
1.	Small and Medium-Sized Technology Enterprise	2022	Jiangsu Provincial Department of Science and Technology
2.	Small and Medium-Sized Technology Enterprise	2022	Beijing Municipal Commission of Science and Technology
3.	Small and Medium-Sized Technology Enterprise	2022	Sichuan Provincial Department of Science and Technology
4.	Industry Build-Ecological Circle-and-Strengthen-Industry-Chain Leading Enterprise	2022	Communist Party Committee of Jinniu District, Chengdu and People’s Government of Jinniu District, Chengdu
5.	Beijing New Technology and New Product (Service)	2021	Beijing Municipal Science and Technology Commission, Beijing Municipal Commission of Development and Reform, Beijing Municipal Commission of Economy and Information, Beijing Municipal Administration of Market Supervision, Beijing Municipal Commission of Housing and Urban-Rural Development, Zhongguancun Management Committee
6.	Innovative Elite of Minhang District, Shanghai	2021	People’s Government of Minhang District, Shanghai
7.	Kunpeng Award of China’s Biopharmaceutical Industry Chain Innovation List	2020	Nanjing International Summit of Innovative Investment in New Medicine and Life Health Industry
8.	Beijing Small and Medium-sized Technology Enterprise	2020	Beijing Municipal Commission of Science and Technology



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No.	Awards and Recognitions	Year	Issuer
9.	Patent Pilot Enterprise of Beijing	2019	Beijing Municipal Intellectual Property Office
10.	State High-tech Enterprise	2019	Beijing Municipal Commission of Science and Technology, Beijing Municipal Finance Bureau, Beijing Municipal Tax Service State Taxation Administration
11.	Enterprise Science Association of Beijing Economic and Technological Development Zone	2019	Association for Science and Technology, Beijing Economic and Technological Development Zone
12.	Member of the Biomedical Industry Center of Beijing Capital Science and Technology Platform	2019	Beijing Municipal Commission of Science and Technology
13.	Beijing Zhongguancun High-tech Enterprise	2018	Zhongguancun Management Committee

## PERMITS, LICENSES AND OTHER APPROVALS

During the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations. The table below sets forth the relevant details of the material licenses we hold for our operation in China:

License/Permit	Holder	Issuing Authority	Issue Date	Expiration Date
Drug Manufacturing License (藥品生產許可證)	3DMed Sichuan	Sichuan Medical Products Administration	December 2, 2021	December 7, 2025
Drug Registration Certificate (藥品註冊證書)	3DMed Sichuan	National Medical Products Administration	November 24, 2021	November 23, 2026

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### RISK MANAGEMENT AND INTERNAL CONTROL

#### Risk Management

We are exposed to various risks in our business operations and we recognize that risk management is critical to our success. Please refer to the section headed “Risk Factors” for a discussion of various operational risks and uncertainties we face. We are also exposed to various market risks, in particular, credit, liquidity, interest rate and currency risks that arise in the normal course of our business. Please refer to the paragraphs headed “Financial Information – Quantitative and Qualitative Disclosure about Market Risk” in this document for a discussion of these market risks.

We have adopted a series of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an on-going basis. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors. Our audit committee, and ultimately our Directors supervise the implementation of our risk management policies.

To monitor the ongoing implementation of risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following risk management measures:

- Our audit committee will oversee and manage the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) reviewing and approving our corporate risk tolerance; (iii) monitoring the most significant risks associated with our business operation and our management’s handling of such risks; (iv) reviewing our corporate risk in the light of our corporate risk tolerance; and (v) monitoring and ensuring the appropriate application of our risk management framework across our Group.
- Our Board will be responsible for (i) formulating our risk management policy and reviewing major risk management issues of our Company; (ii) providing guidance on our risk management approach to the relevant departments in our Company; (iii) reviewing the relevant departments’ reporting on key risks and providing feedbacks; (vi) supervising the implementation of our risk management measures by the relevant departments; and (v) reporting to our audit committee on our material risks.
- The relevant departments in our Company, including but not limited to the finance department, the legal department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks

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relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) prepare a risk management report annually for our chief executive officer’s review; (iv) continuously monitor the key risks relating to their operation or function; (v) implement appropriate risk responses where necessary; and (vi) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

- Our R&D department will oversee and manage the overall risks associated with R&D by (i) performing risk assessment beforehand, (ii) setting acceptable indicators, (iii) preparing risk control measures, (iv) monitoring risks on a regular basis, and (v) monitoring the risk of patient safety.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

### **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 during the period from January 1, 2020 to December 31, 2020 of our Company and our major operating subsidiaries in certain aspects, including entity level control and operation control, such as sales and revenue control, procurement control and payroll control. The Internal Control Consultant performed the Internal Control Review in January 2021 and follow-up reviews in June 2021. 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 adopted various measures and procedures regarding each aspect of our business operation, such as related party transaction, risk management and protection of intellectual property. For more information, please refer to the paragraphs headed “– Intellectual Property.” We provide periodic training about these measures and procedures to our employees as part of our employee training program. Our internal audit department will conduct audit field work to monitor the implementation of our internal control policies, reports the weakness identified to our management and audit committee and follows up on the rectification actions.

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- Our Directors (who are responsible for monitoring the corporate governance of our Group) with help from our legal advisers, will also periodically review our compliance status with all relevant laws and regulations after 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 China Securities (International) Corporate Finance Company 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 Use of [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.
- We plan to provide various and continuing trainings to update our Directors, senior management, and relevant employees on the latest PRC laws and regulations from time to time with a view to proactively identify any concerns and issues relating to any potential non-compliance.
- We intend to maintain strict anti-corruption policies among our sales personnel and distributors in our sales and marketing activities and we believe we will therefore be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. We will also ensure that our sales and marketing personnel comply with applicable promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, also known as off-label use, and limitations on industry-sponsored scientific and educational activities.
- Prior to starting any project proposal for drug candidate or technology development, carrying out technological transformation, or evaluating potential in-licensed drug candidates, we would conduct a thorough search and analysis of public literature in accordance with our internal policy to detect potential IP disputes. We also engage external experts, such as legal advisers, when entering into collaborations to represent us with preparing and negotiating agreements. During the development of in-licensed drug candidates, we also regularly conduct follow-up searches to further mitigate risks of potential IP disputes.
- We have established procedures to protect the confidentiality of patients’ personal data. We issued clinical trial testee data protection policy which included personal information definition, confidentiality obligation, response to information leakage, data transfer management. Besides, according to company policy, it is forbidden for us to collect prescription and patient information by paying charges to HCPs.

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- Regarding anti-bribery and anti-kickback, we issued anti-bribery and anti-fraud policy which included compliance training for our personnel, adding anti-bribery clause in sales contracts, setting whistle-blowing system for non-compliance behavior and penalties for bribery and fraud cases. In current contract with CSO company, anti-bribery clause has already added in promotional agreement. Meanwhile, we plan to provide compliance training for CSO & distributor which includes specific requirements of laws and regulations and other company compliance requirements in 2022.

## INTELLECTUAL PROPERTY

Intellectual property, including patents, trade secrets, trademarks and copyrights, is critical to our business. Our success depends in part on our ability to obtain and maintain proprietary intellectual property protection for our product, drug candidates, novel discoveries, product development technologies, inventions and know-how. Our success also depends in part on our ability to defend and enforce our patents including any patent that we have or may issue from our patent applications, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of other parties. Our R&D team also regularly conducts patent search and searches of public literature before entering into collaboration or licensing arrangements, and during the course of development of the relevant drug candidates. Specifically, with respect to the collaboration with Alphamab Group, our R&D team conducted thorough patent searches and searches of public literature that are in line with industry practice as part of our due diligence prior to signing the Collaboration Agreement. We did not identify any red flags or risks during our due diligence. Furthermore, as a protective measure for us, Alphamab Group undertakes in the Collaboration Agreements that the Core Product did not infringe any intellectual property. Lastly, throughout the development of the Core Product and as of the date of this submission, we had not received or were aware of any actual, pending or threatened patent infringement claims with respect to the Core Product. Please refer to the paragraphs headed “Risk Factors – Other Risks Relating to Our Business – Risk Relating to Our Intellectual Property Rights” in this document for a description of risks related to our intellectual property.

We have an extensive portfolio of patents to protect our product, drug candidates and technologies. As of the Latest Practicable Date, we owned (including co-owned) (i) ten granted patents in China, (ii) 14 granted patents in other jurisdictions, and (iii) 20 pending patent applications, including five Chinese patent applications, one U.S. patent application and 14 patent applications in other jurisdictions, relating to certain of our product, drug candidates and technologies.

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The patent portfolio for our product and clinical-stage drug candidates as of the Latest Practicable Date is summarized below:

- **Envafolimab:** As of the Latest Practicable Date, we co-owned with Alphamab Group one granted Chinese patent, nine granted patents and ten patent applications in other jurisdictions related to envafolimab. As of the Latest Practicable Date, we were licensed by Alphamab Group two granted Chinese patents and, two granted patents and two patent applications in other jurisdiction related to envafolimab.
- **3D189 and 3D059:** As of the Latest Practicable Date, we were licensed by SELLAS Group with one granted Chinese patent, two Chinese patent applications, one granted patent and two patent applications in other jurisdictions related to 3D189 and 3D059.
- **3D229:** As of the Latest Practicable Date, we were licensed by Aravive with one granted Chinese patent, one Chinese patent application, and two granted patents and two patent applications in Hong Kong related to 3D229.
- **3D011:** As of the Latest Practicable Date, we owned two Chinese patent applications, five granted patents and five patent applications in other jurisdictions with respect to 3D011
- **3D185:** As of the Latest Practicable Date, we were licensed by Haihe Biopharma with one Chinese granted patent, 11 granted patents and one patent application in other jurisdictions related to 3D185.
- **3D1001:** As of the Latest Practicable Date, we were sub-licensed by Haihe Biopharma Group with two granted Chinese patents and one Chinese patent application related to 3D1001.
- **3D1002:** As of the Latest Practicable Date, we were sub-licensed by Haihe Biopharma Group with one granted Chinese patent related to 3D1002.
- **3D197:** As of the Latest Practicable Date, we were licensed by ImmuneOncia with one Chinese granted patent, one Chinese patent application and one patent application in other jurisdictions related to 3D197.
- **3D057:** As of the Latest Practicable Date, we were licensed by Y-Biologics with one Chinese patent application and four patent applications in other jurisdictions related to 3D057.

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The following table summarizes the details of the material granted patents and filed patent applications owned by us or shared with our collaboration partners in connection with our product, pre-clinical stage and clinical-stage drug candidates:

Product/ Product Candidate	Title	Jurisdiction	Status	Applicant(s)/ Registered Patentee(s)	Patent Type	Date of Application	Date of Approval	Date of Expiration <sup>1</sup>	Our Commercial Rights
Envafoлимab <sup>2</sup>	Single domain antibody and derivative proteins thereof against programmed death-ligand (PD-L1)	China	Granted	3DMed Beijing Jiangsu Alphamab	Invention	2016/8/1	2019/12/31	2036/8/1	All rights
		Hong Kong				2016/8/1	2021/1/15	2036/8/1	
		Macau				2016/8/1	2020/5/28	2036/8/1	
		South Korea				2016/8/1	2020/7/21	2036/8/1	
		Australia				2016/8/1	2020/1/23	2036/8/1	
		New Zealand				2016/8/1	2020/1/28	2036/8/1	
		Russia				2016/8/1	2020/3/2	2036/8/1	
		Indonesia				2016/8/1	2021/1/22	2036/8/1	
		Japan				2016/8/1	2021/9/17	2036/8/1	
	Canada	2016/8/1	2022/6/14	2036/8/1					
	Single domain antibody and derivative proteins thereof against programmed death-ligand (PD-L1)	EPO	Pending	3DMed Beijing Jiangsu Alphamab	Invention	2016/8/1	N/A	N/A	All rights
		Singapore				2016/8/1			
		Thailand				2016/8/1			
		Malaysia				2016/8/1			
		Mexico				2016/8/1			
Philippines		2016/8/1							
Egypt		2016/8/1							
Brazil		2016/8/1							
Vietnam	2016/8/1								
South Africa	2016/8/1								
3D011	Compound having anti-cancer effect, and preparation method therefor and use thereof	Taiwan region	Granted	3DMed Beijing	Invention	2018/3/6	2021/3/11	2038/3/5	All rights
		Japan				2018/3/6	2020/9/1	2038/3/5	
		U.S.				2017/11/17	2021/12/27	2037/11/17	
		U.S.				2017/11/17	2021/12/14	2037/11/17	
	Compound having anti-cancer effect, and preparation method therefor and use thereof	EPO	Pending	3DMed Beijing	Invention	2017/11/17	N/A	N/A	All rights
		U.S.				2017/11/17			
		China				2017/11/17			
		Thailand				2017/11/17			

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Product/ Product Candidate	Title	Jurisdiction	Status	Applicant(s)/ Registered Patentee(s)	Patent Type	Date of Application	Date of Approval	Date of Expiration <sup>1</sup>	Our Commercial Rights
Others	Synthesis and use of anti-tumor drug LQC-Y	China	Granted	3DMed Beijing	Invention	2011/3/9	2014/8/13	2031/3/9	All rights
	Synthesis and use of anti-tumor drug LQC-Y	China	Granted	3D Medicines		2011/3/9	2016/8/31	2031/3/9	
	Compound having anti-tumor effect, and method for preparation thereof and application thereof	China	Granted	3DMed Shanghai; 3D Medicines; 3DMed Beijing		2014/7/1	2018/10/16	2034/7/1	
	Synthesis method and use of anti-tumor drug X-TOA	China	Granted	3D Medicines		2014/10/29	2018/9/28	2034/10/29	
	Triterpenoid derivative TBA-X having anti-tumor effect, and method for preparation thereof and application thereof	China	Granted	3DMed Shanghai; 3DMed Beijing; 3D Medicines		2015/9/1	2018/10/16	2035/9/1	
	Compound having Anti-cancer effect, and method for preparation thereof and application thereof	China	Granted	3DMed Sichuan		2017/1/16	2020/9/1	2037/1/16	
	Compound having Anti-cancer effect, and method for preparation thereof and application thereof	China	Granted	3DMed Sichuan		2016/12/14	2021/1/8	2036/12/14	
	Pyridopyrimidine derivatives as inhibitors of KRAS G12D mutation	China	Pending	3D Medicines		2021/12/2	N/A	N/A	
	Thienopyrimidine derivatives and their use as pan-KRAS mutation inhibitors	China	Pending	3D Medicines; 3DMed Beijing		2022/1/20	N/A	N/A	
	Pan-KRAS inhibitors, preparation and application thereof	China	Pending	3D Medicines		2022/4/8	N/A	N/A	
	Tumor sampling device for easy isolation of tumors	China	Granted	3DMed Xuzhou		Utility Model	2021/8/3	2022/1/18	
	Effusion sampling device used in oncology	China	Granted	3DMed Xuzhou	2021/5/31		2022/1/14	2031/5/31	

Abbreviation: EPO = Europe Patent Office.



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*Notes:*

- (1) Patent expiration date is estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.
- (2) Under the Co-development Agreements, we agreed to co-own the patent rights under a PCT application and its multiple national phase applications (including the ones in China and the U.S.) covering the molecule of envafolimab with Alphamab Group. Please refer to the paragraphs headed “Our Research and Development – Collaboration Agreements – Collaboration with Alphamab Group for Envafolimab” in this section for more details.

The following table summarizes the details of the material granted patents and filed patent applications that licensed to us in connection with our product and clinical-stage drug candidates:

Product/ Product Candidate	Title	Jurisdiction	Status	Applicant(s)/ Registered Patentee(s)	Patent Type	Date of Application	Date of Approval	Date of Expiration <sup>1</sup>	Our Commercial Rights					
Envafolimab	Single domain antibody and derivative proteins thereof against programmed death-ligand (PDL1)	China	Granted	Suzhou Alphamab	Invention	2016/8/1	2019/12/31	2036/8/1	All rights					
		Japan				2016/8/1	2022/2/22	2036/8/1						
		U.S.				2016/8/1	2021/4/23	2036/8/1						
		EPO	Pending			2016/8/1	N/A	N/A						
		Hong Kong				2016/8/1								
3D189 and 3D059	Immunogenic WT-1 peptides and methods of use thereof	China	Granted	MEMORIAL SLOAN KETTERING CANCER CENTER	Invention	2014/1/15	2019/4/2	2034/1/15	Greater China					
		Macau				2014/1/15	2019/10/23	2034/1/15						
		China	Pending			2014/1/15	N/A	N/A						
		Hong Kong				2014/1/15								
	Multi-valent immunotherapy composition and methods of use for treating WT1-positive cancers	WIPO	Pending	SLSG LIMITED LLC; MEMORIAL SLOAN KETTERING CANCER CENTER	Invention	2020/4/10	N/A	N/A						
		China				2020/4/10								
3D229	Inhibition of AXL signaling in anti-metastatic therapy	China	Granted	Stanford University	Invention	2011/1/21	2017/3/15	2031/1/21	Greater China					
		Hong Kong	Pending			2011/1/21	N/A	N/A						
	Inhibition of AXL signaling in anti-metastatic therapy	Hong Kong	Pending	Stanford	Invention	2011/1/21	N/A	N/A						
		Modified AXL peptides and their use in inhibition of AXL signaling in anti-metastatic therapy	Hong Kong	Granted	Aravive; Stanford	Invention	2013/12/12	2021/10/8	2033/12/12					
							Antifibrotic activity of GAS6 inhibitor	Hong Kong	Granted	Aravive; Stanford	Invention	2015/12/17	2021/4/30	2035/12/17
							Methods of treating metastatic cancers using axl decoy receptors	China	Pending	Aravive	Invention	2018/11/5	N/A	N/A

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Product/ Product Candidate	Title	Jurisdiction	Status	Applicant(s)/ Registered Patentee(s)	Patent Type	Date of Application	Date of Approval	Date of Expiration <sup>1</sup>	Our Commercial Rights
3D185	Indazole compounds as FGFR kinase inhibitor, preparation and use thereof	China	Granted	Haihe Biopharma; Shanghai Institute of Materia Medica, CAS	Invention	2015/8/19	2019/11/12	2035/8/19	All rights
		U.S.				2015/8/19	2020/2/18	2035/8/19	
		EPO				2015/8/19	2021/10/6	2035/8/19	
		Japan				2015/8/19	2018/12/7	2035/8/19	
		South Korea				2015/8/19	2019/9/11	2035/8/19	
						2015/8/19	2020/10/8		
		Australia				2015/8/19	2018/6/28	2035/8/19	
		Canada				2015/8/19	2021/1/19	2035/8/19	
		Russia				2015/8/19	2020/4/17	2035/8/19	
		Mexico				2015/8/19	2021/4/28	2035/8/19	
		Malaysia				2015/8/19	2021/12/9	2035/8/19	
		Peru	2015/8/19			2022/4/28	2035/8/19		
	Brazil	Pending	2015/8/19	N/A	N/A				
3D1001	Salts and crystal forms	China	Granted	AskAt	Invention	2014/1/6	2017/7/18	2034/1/6	Mainland China
	Pharmaceutical composition	China	Granted			2012/10/18	2022/5/13	2032/10/18	
	Process for the differential solubility-driven asymmetric transformation of substituted 2h-chromene-3-carboxylic acids	China	Pending			2020/1/20	N/A	N/A	
3D1002	Crystal forms of an imidazole derivative	China	Granted		Invention	2006/3/1	2010/12/22	2026/3/1	Mainland China
3D197	Antibody therapeutics that bind CD47	China	Granted	SORRENTO THERAPEUTICS, INC.	Invention	2016/3/4	2022/2/8	2036/3/4	Greater China
		Taiwan region	Pending			2016/3/4	N/A	N/A	
		China				2016/3/4			
3D057	Cell engaging binding molecules	China	Pending	Y-BIOLOGICS INC.	Invention	2019/4/9	N/A	N/A	Greater China
		Hong Kong				2019/4/9			
		WIPO				2019/4/9			
	Multispecific fusion protein and use thereof	WIPO	Pending		Invention	2020/10/8	N/A	N/A	
		Taiwan region				2020/10/12			

*Note:*

- (1) Patent expiration date is estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

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As to the pending patent applications, the potential legal impediment in obtaining approval and the impact on the development and commercialisation of our drug candidates if we fail to obtain issued patent for each pending patent application are summarized as below:

According to Article 22 of the Patent Law of the People's Republic of China, effective as of June 1, 2021, inventions and utility models for which patent rights are to be granted shall be ones which are novel, creative and of practical use. Lack of or failure to satisfy any of the three requirements of novelty, inventive and practical use would result in rejection of any filed patent applications by the patent administration authorities.

According to our legal advisers as to intellectual property law who have taken a thorough review of the specifications and claims of the filed patent applications and the examination history of the US/EU/CN granted family patents, with the exceptions of CN110292575A, CN111565742A, WO2020210632A1, CN110167917A, and CN110167554A as further described below, there is no legal impediment for each of the filed patent applications in relation to the 10 drug products and candidates in our pipeline (i.e., envafolimab, 3D189, 3D059, 3D229, 3D1001, 3D1002, 3D185, 3D011, 3D057 and 3D197) of being granted, because it can satisfy the requirements of novelty, inventiveness and utility, provided that the examiner cites the same or similar prior arts which have been used in the patent family examination to evaluate the relevant pending claims, or our Company makes appropriate amendments or arguments to the claims where necessary, which is common in patent prosecution practice.

### **1. CN110292575A in relation to 3D-1001**

The likelihood of patent grant for CN110292575A in relation to 3D-1001 is not promising in light of the examination history of its corresponding CN, EU, and US counterparts. However, another patent grant, CN104870431B in relation to 3D-1001, which is stable according to our legal advisers as to intellectual property law, claims the crystal form of a potassium salt and therefore can provide appropriate protection for 3D-1001. Therefore, even if CN110292575A is ultimately rejected, CN104870431B ensures patent protection for 3D-1001.

### **2. CN111565742A in relation to 3D-229**

The likelihood of patent grant for CN111565742A is not promising in light of the examination history of its corresponding WO and EU counterparts. However, another patent grant, CN103154020B in relation to 3D-229, which is stable according to our legal advisers as to intellectual property law, claims a soluble AXL variant polypeptide and therefore can provide appropriate protection for 3D-229. Therefore, even if CN111565742A is ultimately rejected, CN103154020B ensures patent protection for 3D-229.

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### 3. WO2020210632A1 in relation to 3D-059

The likelihood of patent grant for CN111565742A after entering China is not promising in light of the Written Opinion of the International Search Bureau. However, another patent grant, CN105377291B in relation to 3D-059, which is stable according to our legal advisers as to intellectual property law, claims two individual peptides in 3D-059 and therefore can provide appropriate protection for 3D-059. Therefore, even if WO2020210632A1, after entering China, is ultimately rejected, CN105377291B ensures patent protection for 3D-059.

### 4. CN110167917A and CN110167554A in relation to 3D-011

In light of the disclosure of the patent application documents and the examination history of its corresponding EU and US counterparts, these two patent applications are likely to be granted with narrower scopes, provided that convincing observations and supplementary experimental data demonstrating the beneficial technical effects described in the Description are accepted by the examiner.

In the event that these pending patent applications are ultimately rejected, this would simply mean that the technology intended to be covered by such patent applications is not protected by patent rights. For more details, please refer to "Risk Factors – If we are unable to obtain and maintain adequate patent protection for our product and 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 any of our future approved products or technologies would be materially adversely affected." Practically, however, the loss of patent protection will not hinder us from developing and commercializing the drug candidates by using such technology. Further, as discussed above, there exist other patents which could provide appropriate patent protection for related drug products and candidates. In the absence of patent protection, we may also have extensive know-how in developing the drug products and candidates which enable us to maintain a competitive advantage in the market.

The term of individual patents may vary based on the countries in which they are obtained. In most countries in which we file patent applications, including China and the U.S., the term of an issued patent is generally 20 years from the filing date of the earliest non-provisional patent application on which the patent is based in the applicable country. In the U.S., a patent's term may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for administrative delays by the U.S. Patent and Trademark Office ("USPTO"), in excess of a patent applicant's own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly owned patent having an earlier expiration date.

In addition, with respect to any issued patents in the U.S. and Europe, we may be entitled to obtain an extension of the patent's term provided we meet the applicable requirements for obtaining such patent term extensions. For example, in the U.S., we may apply for a patent term

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extension of up to five years as compensation for the patent term lost during clinical trials and the U.S. FDA regulatory review process under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The exact duration of the extension depends on the time we spend in clinical studies, as well as getting a BLA approval from the FDA. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only once a 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. Furthermore, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In certain other foreign jurisdictions, similar extensions as compensation for regulatory delays are also available.

The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our owned or licensed pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our product and drug candidates and methods of manufacturing the same.

We may rely, in some circumstances, on trade secrets and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements or including confidentiality clauses in our agreements with consultants, scientific advisers and contractors, and developing a management system of such proprietary technology and process. We have entered into confidentiality agreements and non-competition agreements, or included confidentiality clauses and non-competition clauses in the employment agreements with our senior management and key members of our R&D team and other employees who have access to trade secrets or confidential information about our business.

These agreements may not provide sufficient protection of our trade secrets and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secrets and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential information may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

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We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. Please refer to the paragraphs headed “Risk Factors – Other Risks Relating to Our Business – Risk Relating to Our Intellectual Property Rights” in this document for a description of risks related to our intellectual property.

We conduct our business under the brand name of “3D Medicines” or “思路迪醫藥.” As of the Latest Practicable Date, we had registered 51 trademarks in China, five trademarks in Hong Kong and filed two trademark applications in other jurisdictions, respectively. As of the Latest Practicable Date, we were also the registered owner of one domain name.

We enter into collaboration agreements and other relationships with pharmaceutical companies and other industry participants to leverage our intellectual property and gain access to the intellectual property of others. Please refer to the paragraphs headed “– Our Research and Development – Collaboration Agreements” in this section.

During the Track Record Period and up to the Latest Practicable Date, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent. Our Directors confirm that we were not aware of any instances of infringement of any third parties’ intellectual property rights by us during the Track Record Period and up to the Latest Practicable Date.

Please refer to the paragraphs headed “Statutory and General Information – Further Information about Our Business – Intellectual Property Rights” in Appendix IV to this document for further information.

## COMPETITION

The pharmaceutical and biopharmaceutical industries are highly competitive and subject to rapid and significant change. While we believe that our pipeline of innovative product and drug candidates in clinical and pre-clinical trials, research and development capability, platform and leadership team provide us with competitive advantages, we face potential competition from many different sources working to develop therapies targeting the same indications against which we develop our products and drug candidates, in particular in the fields of oncology. These include major pharmaceutical companies as well as specialty pharmaceutical and biotechnology companies of various sizes, academic institutions, government agencies and research institutions. Any products and drug candidates that we successfully develop and commercialize will compete both with existing drugs and with any new drugs that may become available in the future. For more information on the competitive landscape of our product and drug candidates, please refer the paragraph headed “– Our Core Product and Other Drug Candidates.”

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### EMPLOYEES

As of the Latest Practicable Date, we had 253 employees in total and the following table sets forth the number of our employees categorized by function:

<b>Function</b>	<b>Number</b>	<b>% of Total</b>
Research and development	151	60%
Quality assurance, quality control and registration	29	11.5%
Commercial, operation and manufacturing	29	11.5%
General, administrative and others	44	17%
<b>Total</b>	<b>253</b>	<b>100.0%</b>

As of the Latest Practicable Date, among the 253 employees, 112 of our employees were stationed in Shanghai, 82 of our employees were stationed in Beijing, and 59 of our employees were based in other cities in China and the U.S. Notably, our R&D has a total of 151 employees, 82 of which have a master's degree or higher, including 17 with doctor's degrees.

We enter into individual employment contracts with our employees covering matters such as salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause and grounds for termination. We have entered into confidentiality agreements and non-competition agreements, or included confidentiality clauses and non-competition clauses in the employment agreements with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information about our business.

To maintain the quality, knowledge and skill levels of our workforce, we provide continuing education and training programs, including internal and external training, for our employees to improve their technical, professional or management skills. We also provide trainings programs to our employees from time to time to ensure their awareness and compliance with our policies and procedures in various aspects. Furthermore, we provide various incentives and benefits to our employees, including competitive salaries, bonuses and incentive schemes to our employees, particularly our key employees.

We have complied with the PRC law in all material aspects to make contributions to statutory employee benefit plans (including pension insurance, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance and housing funds) at a certain percentage of our employees' salaries during the Track Record Period and up to the Latest Practicable Date.

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None of our Company or any of our subsidiaries have any labor union. We consider our relations with our employees to be good. During the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes or labor disputes which had a material effect on our business.

### LAND AND PROPERTIES

#### Owned Properties

As of the Latest Practicable Date, we owned land use rights to one parcel of land in Xuzhou Economic and Development Area with an area of 65,637.97 square meters, of which we have obtained the property ownership. We have been building our in-house production facilities in Xuzhou, Jiangsu province, with GMP-compliant manufacturing system and facilities throughout the drug development process, including chemical drugs and biologics, to meet stringent standards.

#### Leased Properties

As of the Latest Practicable Date, we leased 14 properties with an aggregate GFA of approximately 19,050.45 square meters. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms to meet our future needs. We do not anticipate undue difficulty in renewing our leases upon their expiration.

The following table sets forth the details of our leased properties as of the Latest Practicable Date:

Entity	Location	Type of Property	Gross Floor Area (sq.m.)	Expiry Date
3D Medicines	Shanghai	Office	1,998.89	June 30, 2025
3D Medicines	Shanghai	Laboratories and office	1,975.16	August 31, 2025
3D Medicines	Shanghai	Office	1,811.04	October 31, 2026
3DMed Shanghai	Shanghai	Office	165.18	October 31, 2022
3DMed Shanghai	Guangzhou	Office	304.22	August 31, 2024
3DMed Shanghai	Guangzhou	Office	184.98	August 31, 2024
3DMed Beijing	Beijing	Office and laboratories	5,118	July 31, 2026
3DMed Sichuan	Sichuan	Office	133.32	May 3, 2023
3DMed Xuzhou	Xuzhou	Office	172	June 19, 2023
3DMed Xuzhou	Xuzhou	Office	41	May 23, 2023
Longteng Medicines	Xuzhou	Office and manufacturing factory	6,351.1	April 30, 2025
3DMed Xuzhou	Xuzhou	Employee dormitory	154	December 19, 2022
3DMed Xuzhou	Xuzhou	Employee dormitory	310.56	January 9, 2023
3DMed Xuzhou	Xuzhou	Employee dormitory	331	December 31, 2022



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Six of our leases are expiring in 2022. With respect to these leases, we are currently in the process of negotiating actively with the relevant lessors to renew such leases. Considering our stable cooperation relationship with the lessors, our Directors believe that we will be able to successfully renew the leases before the end term. Given our commercial interest, we may not renew all the expiring leases. However, given the nature of the usage under such leases (office), our Directors are of the view that there would not be any material impact on our operations.

We do not have any property interest with a carrying amount of 15% or more of our consolidated total assets as of May 31, 2022. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), this Document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to all of our interests in land or buildings.

### ENVIRONMENTAL MATTERS AND WORKPLACE SAFETY

We are committed to operate our business in a manner that protects environment and provides a safety workplace for our employees. We have implemented company-wide environmental, health and safety (EHS) manuals, policies and standard operating procedures. In particular, our environmental, health and safety protection measures include (i) strict compliance with the GMP qualification requirements and relevant pollutant emissions standards and pollutants management policies during our production process to reduce pollutant emissions of exhaust gas, sewage and hazardous solid waste; (ii) implementation of safety guidelines with respect to employee health and safety, environmental protection and operational and manufacturing safety in laboratories and manufacturing facilities, and closely monitor internal compliance with these guidelines; (iii) storage of hazardous substances in special warehouse and contract with qualified third parties for the disposal of hazardous materials and waste on a quarterly basis; (iv) conducting periodic environmental evaluations on exhaust gas detection and emissions, hazardous waste disposals, noise emissions, and waste water detection and emissions to make sure all operations are in compliance with the applicable laws and regulations, and (v) resource conservation policies to reduce the levels of resource consumption. The cost of compliance with relevant environmental protection laws and regulations incurred by us in 2020, 2021 and for the five months ended May 31, 2022, was approximately RMB37,500, RMB298,200 and RMB56,009, respectively.

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We closely monitor the below metrics in relation to the formulation and implementation of our pollutants management and resource conservation policies as appropriate:

### *Pollutants emission*

- *Exhaust gas discharge.* During the Track Record Period, based on our best estimates, exhaust gas discharge levels were approximately 6 kilograms and 8.45 kilograms in aggregate in 2021 and for the five months ended May 31, 2022, respectively.
- *Sewage discharge.* During the Track Record Period, based on our best estimates, sewage discharge levels were approximately 10 tons and 42 tons in aggregate in 2021 and for the five months ended May 31, 2022, respectively.
- *Hazardous solid waste discharge.* During the Track Record Period, based on our best estimates, hazardous solid waste discharge levels were approximately 1.5 tons and 0.3 ton in aggregate in 2021 and for the five months ended May 31, 2022, respectively.
- *Hazardous liquid waste discharge.* During the Track Record Period, based on our best estimate, hazardous liquid waste discharge levels were 0.2 ton and 0.5 ton in aggregate in 2021 and for the five months ended May 31, 2022, respectively.

### *Resource consumption*

- *Electricity consumption.* In 2020, 2021 and for the five months ended May 31, 2022, electricity consumption levels were approximately 95.30 thousand kWh, approximately 615.62 thousand kWh and approximately 431.68 thousand kWh in aggregate, respectively.
- *Water consumption.* In 2020, 2021 and for the five months ended May 31, 2022, water consumption levels were approximately 490 tons, 3,141 tons and 4,527.6 tons in aggregate, respectively.

We will continue to monitor our pollutants emission and resource consumption levels, and will strive to operate in an environmentally friendly way. We have also adopted greenhouse gases reduction measures (including using cleaner energy source and formulating policies to conserve electricity and reuse paper), to gradually reduce our resource consumption and greenhouse gases emissions in the future.

During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental and occupational health and safety laws and regulations in all material aspects and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or results of operations during the period.

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### **INSURANCE**

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our principal insurance policies cover property loss due to accidents or natural disasters, employee benefits liability and personal injury. We currently maintain insurance for adverse events in clinical trials. We currently do not maintain insurance for environmental liability. Please refer to the section headed “Risk Factors – Risks Relating to our Operations – We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources” in this document.

We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made, or been the subject of, any material insurance claims.

### **LEGAL PROCEEDINGS AND COMPLIANCE**

During the Track Record Period and up to the Latest Practicable Date, we were not a party to any actual or threatened legal or administrative proceedings which would have a material and adverse impact on our business, financial condition or results of operations. We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business. Please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Operations” in this document for a description of risks related to legal or administrative claims and proceedings arising in the ordinary course of business.

Our PRC Legal Advisers confirmed that during the Track Record Period and up to the Latest Practicable Date, we had complied with applicable PRC laws and regulations in all material aspects. Our Directors confirmed that we were not involved in any material or systematic non-compliance incidents.

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*You should read the following discussion and analysis in conjunction with our audited consolidated financial statements and the accompanying notes included in the Accountants’ Report set forth in Appendix I to this document. Our consolidated financial statements have been prepared in accordance with IFRSs, which may differ in material aspects from generally accepted accounting principles in other jurisdictions. Potential investors should read the whole of the Accountants’ Report set forth in Appendix I and not rely merely on the information contained in this section.*

*The following discussion and analysis contain forward-looking statement 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. In evaluating our business, you should carefully consider the information provided in the section headed “Risk Factors” in this document.*

### OVERVIEW

Founded in 2014, we are a bio-pharmaceutical company with research and development capabilities. We are committed to the development and commercialization of oncology therapies with differentiated clinical profile in response to the trend of treating cancer as a chronic disease.

Our core business model is to discover, research, develop and commercialize oncology products and drug candidates by building a pipeline of innovative products and drug candidates with a potential to create significant synergy as combination therapies to address unmet medical needs through a combination of in-house discovery, co-development and in-licensing. Our management team has extensive industry experience at reputable organizations including FDA and leading pharmaceutical companies, and has led us to build end-to-end capabilities from discovery to commercialization with proven track record and strong growth potentials.

We have incurred operating losses during the Track Record Period, with RMB635.4 million, RMB1,461.8 million and RMB293.4 million for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, respectively. Substantially all of our operating losses resulted from research and development expenses, administrative expenses and fair value losses on preferred shares. Our liabilities are primarily related to the preferred shares.

We expect to incur an increased amount of operating expenses, in particular increasing research and development expenses, selling and marketing expenses and administrative expenses, for at least the next several years as we conduct further pre-clinical research, continue the clinical development of, seek regulatory approval for and manufacturing of, our drug candidates, launch and promote our pipeline products, and add personnel necessary to

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operate our business. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a public company. We expect that our financial performance will fluctuate from period to period affected by the development status of our drug candidates, regulatory approval timeline and commercialization of our product and drug candidates after approval.

### **BASIS OF PRESENTATION**

Our Company was incorporated as an exempted company with limited liability in the Cayman Islands on January 30, 2018. Our Company, as the holding company of our business, directly or indirectly owns all of our subsidiaries that are primarily engaged in developing, manufacturing and commercializing our approved products and drug candidates for cancer treatment. For more details, please refer to the section headed “History, Development and Corporate Structure” in this document.

The consolidated financial information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board (“IASB”). All IFRSs effective for the accounting period commencing from January 1, 2022, together with the relevant transitional provisions, have been adopted by us in the preparation of the consolidated financial information throughout the Track Record Period.

The consolidated financial information has been prepared under the historical cost convention except for certain financial instruments which have been measured at fair value for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022. The consolidated financial information is presented in RMB and all values are rounded to the nearest thousand except where otherwise indicated.

### **MAJOR FACTORS AFFECTING OUR RESULTS OF OPERATIONS**

We believe that our results of operations and financial condition are principally affected by the following factors:

#### **Commercialization of Product and Our Drug Candidates**

Our business and results of operations will be dependent on our receipt of regulatory approval for and successful commercialization of our drug candidates. By strategically adopting a combination of in-house discovery, co-development and in-licensing of highly innovative products, we have assembled and developed a portfolio of differentiated therapies for cancer as a chronic disease with twelve product and drug candidates in total, consisting of one approved product, seven drug candidates at the clinical stage and four selected drug candidates at pre-clinical stage in our pipeline. Our Core Product envafolimab is a subcutaneously-injectable PD-L1 antibody that has the potential to address an unmet medical need for the treatment of cancer as a chronic disease. On November 24, 2021, we received BLA approval for envafolimab for previously treated microsatellite instability-high (MSI-H)/mismatch repair deficiency (dMMR) advanced solid tumors from the NMPA and we

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are the marketing authorization holder (MAH). It has been approved in China for the treatment of previously treated MSI-H/dMMR advanced solid tumors. In addition, we also have multiple drug candidates at clinical stage, which we own the exclusive rights to develop and commercialize. For more details of our product and drug candidates, please refer to the paragraphs headed “Business – Our Core Product and Other Drug Candidates” in this document.

We had one commercialized product as of the Latest Practicable Date, and we expect to commercialize more of our pipeline products in the coming years as they move towards the final stages of development. Our commercialization strategy includes leveraging our commercialization resources with our reputable and resourceful partners, adopting a localized commercial approach, focusing on expert-driven promotion strategies, and establishing suitable commercialization strategy based on each product or drug candidate’s characteristics and market coverage. Once our product and drug candidates are commercialized, our business and results of operations will be driven by the market acceptance and sales of our commercialized drugs and by production capacity to meet the commercial demand. However, the commercialization may require significant marketing efforts before we are able to achieve profitability from product sales. If we fail to achieve the degree of market acceptance, we may not be able to generate revenue as expected. For more details on our commercialization strategy and relevant risks, please refer to the paragraphs headed “Business – Our Strategies” and paragraphs headed “Risk Factors – Other Risks Relating to Our Business – Risks Relating to the Development of Our Drug Candidates – Risks Relating to Commercialization of Our Products” in this document.

### **Clinical Trial Progress of Our Product and Drug Candidates**

Our financial performance is affected by whether the clinical trial of our product and drug candidates can be successfully progressed. However, due to the inherent complexity and uncertainty related to drug research and development, our drug candidates may be unsuccessful or the clinical trial progress may be delayed. If the clinical trial progress is delayed due to technical or other issues, we will need to spend more time and effort on such research and development. For more details on the relevant risks, please refer to the paragraphs headed “Risk Factors – Other Risks Relating to Our Business – Risks Relating to the Development of Our Drug Candidates” in this document.

As of the Latest Practicable Date, we had one approved product, envafolimab, and seven drug candidates at the clinical stage, including 3D189, 3D229, 3D011, 3D185, 3D1001, 3D1002 and 3D197. Envafolimab has undergone clinical trials with almost 1,000 patients enrolled for multiple tumor indications in the U.S., China and Japan (with the first-in-human trial in the U.S.). On December 17, 2020, the NMPA accepted the BLA for envafolimab in the treatment of advanced solid tumors with MSI-H/dMMR, and our BLA was granted priority review. In November 2021, we received BLA approval for envafolimab for the treatment of previously treated MSI-H/dMMR advanced solid tumors. Our 3D189 is currently being evaluated by our partner SELLAS in an ongoing global Phase III pivotal trial in acute myeloid leukemia (AML). The FDA has permitted a Phase III trial to evaluate our 3D229 in PROC

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which is carried out by our partner Aravive. In addition, our 3D011, 3D1001, 3D1002 and 3D197 have received the IND approval from the NMPA in January 2021, February 2019, July 2018 and January 2022, respectively. Furthermore, we had four selected drug candidates at pre-clinical stage in our pipeline. For more details on the development status of our various product and drug candidates, please refer to the paragraphs headed “Business – Our Core Product and Other Drug Candidates” in this document.

### Our Cost Structure

Our results of operations are significantly affected by our cost structure, which primarily consisted of research and development expenses, selling and marketing expenses, administrative expenses, and other expenses.

We have focused on our research and development activities, such as conducting pre-clinical studies, clinical trials and activities related to regulatory filings for our product candidates, which are essential to our business. We are of the opinion that the primary factor affecting our long-term competitiveness and future growth is our ability to successfully develop drug candidates. However, developing high-quality drug candidates requires a significant investment of resources over a prolonged period of time. We incurred research and development expenses of RMB264.0 million, RMB371.2 million and RMB138.3 million for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, respectively. We expect our research and development expenses to continue to increase for the foreseeable future as our development programs progress.

Our administrative expenses mainly consisted of employee benefit expenses and professional service expenses incurred by our administrative departments. We incurred administrative expenses of RMB40.5 million, RMB151.0 million and RMB46.6 million for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, respectively. We also anticipate our administrative expenses, in particular, expenses in legal, compliance, accounting, and investor and public relations areas, will increase as we operate as a public company following the completion of the [REDACTED].

Our selling and marketing expenses mainly comprised of the marketing service fees incurred for the commercialization of our Core Product envafolimab since its approval in November 2021. We incurred a total of RMB42.8 million and RMB103.6 million for the year ended December 31, 2021 and the five months ended May 31, 2022. We also expect our selling and distribution expenses to increase in the future to support our product development efforts and commercialization activities with respect to our product candidates if they are approved. Given our near-commercial stage product candidates, we are in the process of gradually enhancing sales and marketing efforts in anticipation of the commercialization of our products.

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### **Our Present and Future Collaborations**

We have strategically integrated industry resources by securing collaboration with long-term partners with complementary resources. We have formed collaborations with reputable domestic and multinational pharmaceutical and biotech companies, such as Alphamab Group, Simcere, TRACON, SELLAS, Aravive, Haihe Biopharma, Y-Biologics and ImmuneOncia. In particular, our collaboration programs with Alphamab Group and Simcere with respect to envafohimab will help maximize its clinical and commercial value through quick deployment of production and commercialization resources. For more details, please refer to the paragraphs headed “Business – Our Research and Development – Collaboration Agreements” in this document. We believe that leveraging our partners’ manufacturing, sales and marketing expertise, business networks and experienced teams will help us efficiently gain coverage in and capture a substantial share of the oncology market.

In addition, we may continue to enter into collaborations with reputable pharmaceutical and biotech companies in the future to maintain our forward-looking multi-stream strategy. Therefore, for any such future possible collaborations, we may incur substantial expenses, including but not limited to upfront payments, milestone payments and royalties, and recognize revenue from potential license-out and commercialized products. The timing of these payments and the mix of future product sales will have an effect on our profitability.

### **Funding for Our Operations**

During the years ended December 31, 2020 and 2021, and the five month ended May 31, 2022, we funded our operations primarily through our financing in the form of preferred shares. Going forward, with the continuing expansion of our business and our product pipeline, we may require further funding through our financing in the form of preferred shares, debt financing, collaborations, licensing arrangements or other sources. In the event of successful commercialization of one or more of our product candidates, we expect to fund our operations in part with revenue generated from sales of our products. Any fluctuation in our ability to fund our operations will impact our cash flow and our results of operations.

### **Fair Value Change in Our Financial Instruments**

We raised private equity financings through the issuance of preferred shares. We classified the financial instruments as financial liabilities measured at fair value through profit and loss. The fair value is established by using valuation techniques. Although our Preferred Shares will be automatically converted to Ordinary Shares upon the closing of the [REDACTED], to the extent we need to reevaluate the preferred shares prior to the closing of the [REDACTED], any change in fair value will result in non-cash gains or losses, which could materially affect our financial positions and results of operations.



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### CRITICAL ACCOUNTING POLICIES, JUDGEMENTS AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based on our financial information, which have been prepared in accordance with accounting principles that conform with IFRSs issued by the IASB. The preparation of these financial information requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

We consider an accounting policy significant if it: (i) requires management to make judgments and estimates about matters that are inherently uncertain; and (ii) is important to the understanding of our financial condition and operating results. We believe the following accounting policies are most significant to our business operations and to an understanding of our financial condition and results of operations, and reflect the more significant judgments and estimates used in the preparation of our consolidated financial statements. Our significant accounting policies and estimates are summarized below. Please refer to note 2.4 and note 3 to the Accountants’ Report set out in the Appendix I to this document for a detailed description of our significant accounting policies, estimates, assumptions and judgments, which are important for understanding our financial condition and results of operations.

#### Significant Accounting Policies

##### *Revenue recognition*

###### *Revenue from contracts with customers*

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.

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.

When the contract contains a financing component which provides the customer with a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between us and the

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customer at contract inception. When the contract contains a financing component which provides us with a significant financial benefit for more than one year, revenue recognized under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

(a) Sales of products

Revenue from the sale of products is recognized at the point in time when control of the product is transferred to the customer, generally when the products are delivered and accepted by the customers.

During the year ended December 31, 2021 and the five months ended May 31, 2022, 100% and 99% of the sales of products were made through Jiangsu Simcere Pharmaceutical Co., Ltd. (“Jiangsu Simcere”) to pharmacy stores and distributors which are our customers. Jiangsu Simcere acted as our service provider and the service fees retained by Jiangsu Simcere are recognized as selling expenses.

*Other income*

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Research service income is recognized at the point in time when the research report is delivered and accepted by the customers.

*Fair value measurement*

We measure our certain financial instruments at fair value at the end of each of reporting period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by us. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

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A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

We use valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly;
- Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

For assets and liabilities that are recognized in the consolidated financial information on a recurring basis, we determine whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of reporting period.

### ***Financial liabilities***

#### *Initial recognition and measurement*

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, or payables, as appropriate.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

Our financial liabilities include trade payables, other payables and accruals, interest-bearing bank and other borrowings, loans from related parties, amounts due to related parties and preferred shares.

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### *Subsequent measurement*

The subsequent measurement of financial liabilities depends on their classification as follows:

#### Financial liabilities at amortised cost (loans and borrowings)

After initial recognition, trade payables, other payables and accruals, interest-bearing bank and other borrowings, loans from related parties and amounts due to related parties, are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognized in statement of profit or loss when the liabilities are derecognized as well as through the effective interest rate amortization process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortization is included in finance costs in the statement of profit or loss and other comprehensive income.

#### Financial liabilities at FVTPL

Financial liabilities measured at FVTPL include preferred shares which are designated upon initial recognition as at fair value through profit or loss.

Financial liabilities designated upon initial recognition as at fair value through profit or loss are designated at the initial date of recognition, and only if the criteria in IFRS 9 are satisfied. Gains or losses on liabilities designated at fair value through profit or loss are recognized in profit or loss, except for the gains or losses arising from the Group’s own credit risk which are presented in other comprehensive income with no subsequent reclassification to the statement of profit or loss.

### *Derecognition of financial liabilities*

A financial liability is derecognized when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognized in profit or loss and other comprehensive income.

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### *Property, plant and equipment and depreciation*

Property, plant and equipment are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalized in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, we recognize such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used for this purpose are as follows:

Leasehold improvements	shorter of remaining lease terms and estimated useful lives
Office equipment	19% to 32%
Laboratory equipment	19% to 32%
Transportation equipment	24%

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at the end of each of reporting period.

An item of property, plant and equipment including any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognized in profit or loss in the year the asset is derecognized is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress represents a building under construction, which is stated at cost less any impairment losses, and is not depreciated. Cost comprises the direct costs of construction during the period of construction. Construction in progress is reclassified to the appropriate category of plant and equipment when completed and ready for use.

### *Leases*

We assess at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

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### *The Group as a lessee*

We apply a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. We recognize lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

We recognize right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Where applicable, the cost of a right-of-use asset also includes an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Office and laboratory	2 to 5 years
Leasehold land	40 years

If ownership of the leased asset transfers to us by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

(b) Lease liabilities

Lease liabilities are recognized at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by us and payments of penalties for termination of a lease, if the lease term reflects us exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognized as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, we use our incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there

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is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

(c) Short-term leases and leases of low-value assets

We apply the short-term lease recognition exemption to its short-term leases of office (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the recognition exemption for leases of low-value assets to leases of office equipment that are considered to be of low value. Lease payments on short-term leases and leases of low-value assets are recognized as an expense on a straight-line basis over the lease term.

### *Intangible assets (other than goodwill)*

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least at the end of each of the reporting period.

Intangible assets are amortized on the straight-line basis over the following useful economic lives:

Software	10 years
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### *Research and development costs*

We charge all research costs to profit or loss as incurred. Expenditure incurred on projects to develop new products is capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, our intention to complete and our ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

### *Share-based payments*

3D Medicines and its immediate holding company before the Business Restructuring (the “**Predecessor Holdco**”) operated share award schemes for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. The share award schemes of 3D Medicines and the Predecessor Holdco were terminated in June

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2021 and we adopted a share incentive scheme in June 2021. Our employees (including directors) receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (“**equity-settled transactions**”).

We measure the cost of equity-settled transactions with employees by reference to the fair value at the date on which they are granted. The fair value of share award is determined using the back-solve method or binomial model. For more details of our share award scheme, please refer to note 30 of the Accountants’ Report set forth in Appendix I to this document.

We recognize the cost of equity-settled transactions in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognized for equity-settled transactions at the end of 2020 and 2021, respectively, until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The charge or credit to profit or loss for a period represents the movement in the cumulative expense recognized as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group’s best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognized. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognized as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognized for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognized for the award is recognized immediately. This includes any award where non-vesting conditions within the control of either the Group or the



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employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

When the equity-settled award is exercised, the amount previously recognized in equity-settled share-based reserve will be transferred to share premium. When the equity-settled award is forfeited after the vesting date or are still not exercised at the expiry date, the amount previously recognized in equity-settled share-based reserve will be transferred to retained earnings.

### *Inventories*

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the weighted average method basis and, in the case of work in progress and finished goods, comprises direct materials, direct labour and an appropriate proportion of overheads. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

### *Government grants*

We recognize government grants at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, we recognize it as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed. When the grant relates to expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future costs and obligations, it is recognized in profit or loss in the period in which it becomes receivable.

Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to profit or loss over the expected useful life of the relevant asset by equal annual instalments or deducted from the carrying amount of the asset and released to profit or loss by way of a reduced depreciation charge.

## **Significant Accounting Judgements and Estimates**

### *Judgements*

In the process of applying our accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognized in the consolidated financial information:

### *Research and development expenses*

All research expenses are charged to the statement of profit or loss as incurred. Expenses incurred on each pipeline to develop new products are capitalized and deferred only when (i) we can demonstrate the technical feasibility of completing the intangible asset so that it will

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be available for use or sale; (ii) our intention to complete and our ability to use or sell the asset; (iii) how the asset will generate future economic benefits; (iv) the availability of resources to complete the project; and (v) the ability to measure reliably the expenditure during the development. Research expenses which does not meet these criteria is expensed when incurred. Determining whether research and development expense should be expensed or capitalized requires the application of judgements and estimation.

### *Estimation uncertainty*

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of 2020 and 2021 and the five months ended May 31, 2022, respectively, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

### *Provision for expected credit losses on trade receivables*

We use a provision matrix to calculate ECLs for trade receivables. The provision rates are based on internal credit ratings as groupings of debtors that have similar loss patterns.

The provision matrix is initially based on the credit loss rate of similar companies in the market as we have not had sufficient credit loss data. We will calibrate to adjust the expected loss rate with forward-looking information. The expected loss rate will be back-tested against observed default rates in the future and changes in the forward-looking estimates will be analyzed.

The assessment of the correction among credit loss rates of comparable companies, forecast economic conditions and ECLs is a significant estimate. The amount of ECLs is sensitive to changes in circumstances and forecast economic conditions. Our expected credit loss rate and forecast of economic conditions may also not be representative of a customer's actual default in the future. The information about the ECLs on our trade receivables is disclosed in note 18 to the Historical Financial Information.

### *Recognition of income taxes and deferred tax assets*

Determining income tax provision involves judgement on the future tax treatment of certain transactions and when certain matters relating to the income taxes have not been confirmed by the local tax bureau. Management evaluates tax implications of transactions and tax provisions are set up accordingly. We recognize the tax treatments of such transactions periodically to take into account all changes in tax legislation.

We recognize deferred tax assets for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgement is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and level of future taxable profits together with future tax planning strategies.

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### *Fair value of preferred shares measured at FVTPL*

We determine the fair value of the preferred shares measured at FVTPL using valuation techniques, including the discounted cash flow method, the back-solve method and the equity allocation model. Such valuation requires key assumptions include the risk-free interest rate, discounts for lack of marketability (“**DLOM**”) and volatility, which are subject to uncertainty. Improper application of such parameters might result in material differences from the actual results. For more details, please refer to note 26 of the Accountants’ Report set forth in Appendix I to this document.

### *Fair value of share-based payment transactions*

Estimating fair value of share-based payment transactions requires determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. This estimate also requires determination of the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them.

For the measure for the fair value of share-based payment transactions with employees at the grant date, we use a binomial model. The assumptions and models used for estimating fair value for share-based payment transactions are disclose in note 30 of the Accountants’ Report set forth in Appendix I to this document.

### *Leases – Estimating the incremental borrowing rate*

We cannot readily determine the interest rate implicit in a lease, and therefore, it uses an incremental borrowing rate (“**IBR**”) to measure lease liabilities. The **IBR** is the rate of interest that we would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The **IBR** therefore reflects what we “would have to pay”, which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when it needs to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary’s functional currency). We estimate the **IBR** using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates (such as the subsidiary’s stand-alone credit rating).

### *Impairment of non-financial assets (other than goodwill)*

We assess whether there are any indicators of impairment for all non-financial assets (including right-of-use assets) at the end of 2020 and 2021 and the five months ended May 31, 2022, respectively. The non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm’s length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

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### DESCRIPTION OF CERTAIN KEY ITEMS OF CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

The following table summarizes our consolidated statements of profit or loss and other comprehensive income for the periods indicated:

	Year Ended December 31,		Five Months Ended May 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>	<i>RMB'000</i>
Revenue	–	60,260	–	161,062
Cost of sales	–	(4,277)	–	(11,458)
Gross profit	–	55,983	–	149,604
Other income and gains	2,337	19,637	1,494	21,480
Research and development expenses	(263,970)	(371,162)	(129,940)	(138,259)
Administrative expenses	(40,528)	(150,956)	(26,757)	(46,631)
Selling and marketing expenses	–	(42,834)	–	(103,567)
Royalty expenses	–	(7,153)	–	(17,364)
Other expenses	(5,929)	(8,940)	(1,371)	(14,224)
Finance costs	(8,058)	(1,528)	(365)	(740)
Fair value losses on preferred shares	(319,232)	(954,742)	(647,031)	(143,642)
Impairment losses on financial assets, net	–	(130)	–	(74)
<b>Loss before tax</b>	(635,380)	(1,461,825)	(803,970)	(293,417)
Income tax expenses	–	–	–	–
<b>Loss and total comprehensive loss for the year/period</b>	<u>(635,380)</u>	<u>(1,461,825)</u>	<u>(803,970)</u>	<u>(293,417)</u>
Attributable to:				
Owners of the parent	(635,380)	(1,434,092)	(803,970)	(280,379)
Non-controlling interests	–	(27,733)	–	(13,038)
	<u>(635,380)</u>	<u>(1,461,825)</u>	<u>(803,970)</u>	<u>(293,417)</u>

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### Non-IFRS Measure

In order to supplement our consolidated statements of profit or loss and other comprehensive income which are presented in accordance with IFRS, we use adjusted loss and total comprehensive loss as an additional financial measure, which is not required by, or presented in accordance with IFRS. Our adjusted loss and total comprehensive loss represents our loss and total comprehensive loss for the year/period, adjusted to add back fair value losses on preferred shares and share-based payment expenses. We believe that such measure provides investors and other persons with useful information to understand and evaluate our consolidated results of operation in the same manner as it helps our management. However, adjusted net loss presented by us may not be comparable to the similar financial measure presented by other companies. There are limitations to the non-IFRS measure used as an analytical tool, and you should not consider it in isolation or regard it as a substitute for our results of operation or financial position analysis that is presented in accordance with IFRS.

The following table sets forth our loss and total comprehensive loss and adjusted loss and total comprehensive loss for the year/period, which is adjusted by adding back fair value losses on preferred shares and share-based payment expenses, for the periods indicated:

	<b>Year Ended</b>		<b>Five Months Ended</b>	
	<b>December 31,</b>		<b>May 31,</b>	
	<b>2020</b>	<b>2021</b>	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Loss and total comprehensive loss for the year/period	(635,380)	(1,461,825)	(803,970)	(293,417)
Add:				
Fair value losses on preferred shares <sup>(1)</sup>	319,232	954,742	647,031	143,642
Share-based payment expenses <sup>(2)</sup>	416	164,659	94	55,435
<b>Adjusted loss and total comprehensive loss for the year/period</b>	<b><u>(315,732)</u></b>	<b><u>(342,424)</u></b>	<b><u>(156,845)</u></b>	<b><u>(94,340)</u></b>

*Notes:*

- (1) Fair value losses on preferred shares consist of fair value losses on preferred shares we issued, during the Track Record Period. We will cease to recognize fair value losses on preferred shares upon the [REDACTED].
- (2) Share-based payment expenses mainly represent share award schemes and share incentive scheme adopted by our Group for the purpose of providing incentives to eligible participants. Share-based payment expenses are not expected to result in future cash payments (a non-cash item).

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### Revenue

During the Track Record Period, all of our revenue was generated from the sales of commercialized Core Product to pharmacy stores and distributors through Simcere Group. In the future, we will expand our sales channel and sell our commercialized products through more distributors.

### Cost of sales

During the Track Record Period, the cost of sales were purchase prices of our Core Product we paid to Alphamab Group, which served as our contract manufacturer for the manufacturing of our Core Product. We and Alphamab Group agreed that the pricing of envafolimab provided by Alphamab Group to us is based on a cost-plus arrangement plus applicable value tax. Our cost of sales amounted to nil, RMB4.3 million and RMB11.5 million in 2020, 2021 and the five months ended May 31, 2022, respectively, as we only began sales of envafolimab in December 2021. For more information, please refer to paragraphs headed “Business – Collaboration Agreements – Collaboration with Alphamab Group and Simcere Group for Envafolimab,” and “Business – Collaboration Agreements – Effective Control over the Various Key Aspects of Our Core Product – CMC and Manufacturing.”

### Gross Profit and Gross Profit Margin

Our gross profit represents our revenue less our cost of sales. Our gross profit margin represents our gross profit as a percentage of our revenue. During the Track Record Period, our gross profit amounted to nil, RMB56.0 million and RMB149.6 million in 2020, 2021 and the five months ended May 31, 2022, respectively, while our gross profit margin reached nil, 92.9% and 92.9% during the same periods, as we only began sales of envafolimab in December 2021. As of the Latest Practicable Date, our Core Product had not been included in the NRDL, and the price of our Core Product might be influenced if our Core Product is included in the NRDL in the future, which in turn may affect our gross profit and gross profit margin.

### Other Income and Gains

During the Track Record Period, we did not generate any revenue from product sales. Our other income and gains primarily consisted of (i) government grants income; (ii) interest income; and (iii) research service income. For the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, we recorded other income and gains of RMB2.3 million, RMB19.6 million and RMB21.5 million, respectively.

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The following table sets forth a breakdown of our other income and gains for the periods indicated:

	Year Ended December 31,		Five Months Ended May 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Government grants income	571	8,423	330	746
Investment income on other investments classified as financial assets at FVTPL	156	424	–	593
Interest income	1,610	5,502	1,164	2,311
Research service income	–	5,110	–	–
	<u>2,337</u>	<u>19,459</u>	<u>1,494</u>	<u>3,650</u>
<b>Other gains</b>				
Foreign exchange gain, net	–	–	–	17,809
Fair value gains on other investments classified as financial assets at FVTPL	–	178	–	21
	<u>2,337</u>	<u>19,637</u>	<u>1,494</u>	<u>21,480</u>

The government grants mainly represent subsidies received from the local governments for the purpose of compensation of expenses spent on research and clinical trial activities, allowances for new drug development. There were no unfulfilled conditions or contingencies relating to the grants.

Interest income primarily includes bank interest income from increased bank balance arising from the receipt of proceeds from our financing in the form of preferred shares. Our research service income was generated from the provision of pre-clinical CRO services to independent third parties.

### Research and Development Expenses

During the Track Record Period, our research and development expenses primarily consisted of (i) employee benefit expenses including salaries, social insurance, pension, bonus, and share-based expenses related to our research and development personnel; (ii) third-party contracting expenses paid to service providers; and (iii) upfront and milestone fee associated with the exclusive development rights in designated regions of our in-licensed drug candidates.

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For the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, we recorded research and development expenses of RMB264.0 million, RMB371.2 million and RMB138.3 million, respectively. In particular, the research and development expenses incurred for our Core Product amounted to RMB92.4 million, RMB118.0 million and RMB39.7 million, for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, respectively. The research and development expenses in relation to the services provided by third-party contract research organizations amounted to RMB67.3 million, RMB60.6 million and RMB38.9 million, for the years ended December 31, 2020, 2021 and the five months ended May 31, 2022, respectively.

The following table sets forth a breakdown of our research and development expenses for the periods indicated:

	Year Ended December 31,				Five Months Ended May 31,			
	2020		2021		2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Employee benefit expenses	47,052	17.8	181,178	48.8	28,308	21.8	77,900	56.3
Depreciation and amortisation	2,517	1.0	7,781	2.1	2,553	2.0	6,063	4.4
Third-party contracting expenses	67,270	25.5	60,647	16.3	18,077	13.9	38,944	28.2
Upfront and milestone fee	141,915	53.8	110,461	29.8	78,374	60.3	12,990	9.4
Others <sup>(1)</sup>	5,216	1.9	11,095	3.0	2,628	2.0	2,362	1.7
	263,970	100.0	371,162	100.0	129,940	100.0	138,259	100.0

*Note:*

(1) Primarily include (i) traveling expenses; (ii) advisory service expenses; and (iii) office expenses.

### Administrative Expenses

During the Track Record Period, our administrative expenses primarily consisted of (i) employee benefit expenses including salaries, social insurance, pension, bonus, and share-based expenses related to our administrative personnel; (ii) [REDACTED] expenses in connection with the [REDACTED]; and (iii) professional service expenses mainly paid to the financial advisors in relation to financing activities. For the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, we recorded administrative expenses of RMB40.5 million, RMB151.0 million and RMB46.6 million, respectively.



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The following table sets forth a breakdown of our administrative expenses for the periods indicated:

	Year Ended December 31,				Five Months Ended May 31,			
	2020		2021		2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Employee benefit expenses	12,097	29.8	90,727	60.1	11,084	41.4	35,074	75.2
Depreciation	854	2.1	4,699	3.1	905	3.4	2,711	5.8
Traveling expenses	2,423	6.0	3,259	2.2	1,492	5.6	1,224	2.6
Professional service expenses	17,897	44.2	21,940	14.5	3,006	11.2	2,602	5.6
Office and other expenses	3,070	7.6	4,766	3.2	1,471	5.5	1,478	3.2
[REDACTED] expenses	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
	40,528	100.0	150,956	100.0	26,757	100.0	46,631	100.0

### Selling and Marketing Expenses

During the Track Record Period, our selling and marketing expenses were marketing service fees retained by Simcere Group, which acted as a contract sales organization, on monthly basis calculated with reference to the total purchases and rates stipulated in the 3D Alphamab Simcere Agreements. The role of Simcere Group under the 3D Alphamab Simcere Agreements is to prepare a promotion plan and promote envafolimab in China in accordance with industry standards for the purpose of increasing its sales. For the years ended December 31, 2020 and 2021, and the five months ended May 31, 2022 we recorded selling and marketing expenses of nil, RMB42.8 million and RMB103.6 million, respectively, as we only began sales of envafolimab since December 2021. For more information, please refer to paragraphs headed “Business – Collaboration Agreements – Collaboration with Alphamab Group and Simcere Group for Envafolimab.”

### Royalty Expenses

As agreed under the Co-Development Agreements, upon the approval and commercialization of envafolimab, we are entitled to 51% while Alphamab Group is entitled to 49% of the profit before tax generated from the sales of envafolimab in China. During the Track Record Period, profit before tax from the sales of envafolimab were paid by us by proportion to Alphamab Group in the form of royalty expenses. For the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, we recorded royalty expenses of nil, RMB7.2 million and RMB17.4 million, respectively, as we only began sales of

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envafolimab since December 2021. For more information, please refer to paragraphs headed “Business – Collaboration Agreements – Effective Control over the Various Key Aspects of Our Core Product – Commercialization and Economic Interests.”

### Impairment Losses on Financial Assets, net

During the Track Record Period, our impairment losses on financial assets represented expected credit losses on our trade receivables. For the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, we recorded impairment losses on financial assets of nil, RMB130.0 thousand and RMB74.0 thousand, respectively.

### Other Expenses

During the Track Record Period, our other expenses primarily consisted of (i) foreign exchange losses; (ii) research service cost; (iii) loss on disposal of property, plant and equipment; and (iv) donations. For the years ended December 31, 2020, 2021 and the five months ended May 31, 2022, we recorded other expenses of RMB5.9 million, RMB8.9 million and RMB14.2 million, respectively.

The following table sets forth a breakdown of our other expenses for the periods indicated:

	Year Ended December 31,				Five Months Ended May 31,			
	2020		2021		2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%
					<i>(unaudited)</i>			
Foreign exchange losses, net	5,927	99.9	3,699	41.4	1,371	100.0	–	–
Research service cost	–	–	2,538	28.4	–	–	–	–
Loss on disposal of property, plant and equipment	2	0.1	959	10.7	–	–	–	–
Donations	–	–	1,424	15.9	–	–	14,224	100.0
Others	–	–	320	3.6	–	–	–	–
	<u>5,929</u>	<u>100.0</u>	<u>8,940</u>	<u>100.0</u>	<u>1,371</u>	<u>100.0</u>	<u>14,224</u>	<u>100.0</u>

The foreign exchange losses arose from the fluctuations in exchange rate between RMB, our functional currency, and U.S. dollar.

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The Group manages its foreign exchange risk by closely monitoring the movement of the foreign currency rates, the Group did not commit to any financial instruments to hedge its exposure to foreign currency risk.

We donated envafohimab and cash to a non-profit charity organization which provides support to cancer patients for public welfare purposes.

### Finance Costs

During the Track Record Period, our finance costs consisted of (i) interest on loans from related parties; (ii) interest on bank loans, and other borrowings; and (iii) interest on lease liabilities. For the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, we recorded finance costs of RMB8.1 million, RMB1.5 million and RMB0.7 million, respectively.

The following table sets forth a breakdown of our finance costs for the periods indicated:

	Year Ended December 31,				Five Months Ended May 31,			
	2020		2021		2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%
	<i>(unaudited)</i>							
Interest on loans from a related party	641	8.0	-	-	-	-	-	-
Interest on bank loans and other borrowings	7,107	88.2	46	3.0	46	12.6	-	-
Interest on lease liabilities	310	3.8	1,482	97.0	319	87.4	740	100.0
	<u>8,058</u>	<u>100.0</u>	<u>1,528</u>	<u>100.0</u>	<u>365</u>	<u>100.0</u>	<u>740</u>	<u>100.0</u>

During the Track Record Period, interest on loans from a related party mainly related to our loan from Aves Capital, LLC. The loan from Aves Capital, LLC, born an interest rate at 8% per annum, was settled in November 2020. As of December 31, 2020, all of the loans from related parties had been fully settled. For more details of our loans, please refer to the paragraphs headed “Indebtedness – Borrowings from Related Parties” in this section, and note 34 of the Accountants’ Report set forth in Appendix I to this document.

During the Track Record Period, interest on bank loans and other borrowings mainly related to bank loans with an aggregate drawdown amount of RMB5.7 million, each with an effective interest rate of approximately 3.9% per annum, and other borrowings with an aggregate drawdown amount of RMB1.2 million, each with an effective interest rate of approximately 4.5% per annum.

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## FINANCIAL INFORMATION

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Interest on lease liabilities mainly related to interest expenses we recognized with the application of IFRS16 for our leasing of office buildings.

### **Fair Value Losses on Preferred Shares**

For the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, we recorded fair value losses on preferred shares of RMB319.2 million, RMB954.7 million and RMB143.6 million, respectively. Fair value losses on preferred shares consist of fair value losses on Series Seed Preferred Shares, Series A Preferred Shares, Series A+ Preferred Shares, Series B Preferred Shares, Series B+ Preferred Shares, Series C Preferred Shares, Series D Preferred Shares, Series D+ Preferred Shares and Series E Preferred Shares, which we issued during the Track Record Period. For more details, please refer to the paragraphs headed “History, Development and Corporate Structure – Pre-[REDACTED] Investments” in this document. The Preferred Shares are designated as financial liabilities at fair value through profit or loss on the consolidated balance sheet. They are initially recognized at fair value and the increases in the fair value are recognized as fair value losses on the consolidated statements of comprehensive loss. We expect to continue to recognize fair value losses on preferred shares for the period from May 31, 2022 to the [REDACTED] or at such time prior to the [REDACTED] as may be required to give effect to the [REDACTED] pursuant to applicable listing rules of Hong Kong Stock Exchange. Upon such conversion date, all Preferred Shares will automatically convert to Ordinary Shares and we do not expect to recognize any loss or gain on fair value changes of preferred shares thereafter. For more details, please refer to note 26 of Appendix I to this document. For certain risks relating to our preferred shares, please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Financial Position and Need for Additional Capital – Fair Value Changes in our Financial Instruments Issued to Investors and Related Valuation Uncertainty may Materially Affect our Financial Condition and Results of Operations” in this document.

### **Income Tax Expense**

#### ***Cayman Islands***

Our Company was incorporated in the Cayman Islands as an exempted company with limited liability under the Cayman Companies Act, and has not been subject to any taxation in the Cayman Islands during the Track Record Period.

#### ***British Virgin Islands***

Our subsidiary incorporated in the British Virgin Islands is exempted from any income tax in the British Virgin Islands.

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### *Hong Kong*

Our subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at a rate of 16.5% during the Track Record Period. We have not earned or derived any taxable profit in Hong Kong since its incorporation, and as such has not been subject to Hong Kong profits tax.

### *PRC*

Generally, pursuant to the Corporate Income Tax Law of the PRC, our PRC subsidiaries are subject to a standard corporate income tax rate of 25% on taxable income, except for 3DMed Beijing, which was qualified as a “High and New Technology Enterprise” to enjoy a preferential income tax rate of 15% from 2019 to 2021. The related tax authorities review the “High and New Technology Enterprise” status every three years. 3DMed Beijing is currently preparing for renewal of the qualification and we expect 3DMed Beijing to continue to qualify as a “High and New Technology Enterprise” for the foreseeable future.

### *United States*

Among our subsidiaries, 3D Medicines USA, Inc. was subject to statutory U.S. federal corporate income tax at a rate of 21%. It is also subject to the state income tax in Delaware at a rate of 8.7% during the Track Record Period.

Our Directors confirm that during the Track Record Period, we had made all the required tax filings and had paid all outstanding tax liabilities with the relevant tax authorities in the relevant jurisdictions and we are not aware of any outstanding or potential disputes with such tax authorities.

## PERIOD TO PERIOD COMPARISON OF RESULTS OF OPERATIONS

### **Five Months Ended May 31, 2022 Compared to Five Months Ended May 31, 2021**

#### *Revenue*

Our revenue significantly increased from nil for the five months ended May 31, 2021 to RMB161.1 million for the five months ended May 31, 2022, because the Company only started to sell envafolimab in PRC market after December 2021.

#### *Cost of sales*

Our cost of sales increased from nil for the five months ended May 31, 2021 to RMB11.5 million for the five months ended May 31, 2022, resulted from purchase prices of envafolimab we paid to Alphamab Group since December 2021.

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### *Gross Profit and Gross Profit Margin*

As a result of the foregoing, our gross profit increased from nil for the five months ended May 31, 2021 to RMB149.6 million for the five months ended May 31, 2022, and our gross profit margin increased from nil to 92.9% during the same periods.

### *Other Income and Gains*

Our other income and gains significantly increased from RMB1.5 million for the five months ended May 31, 2021 to RMB21.5 million for the five months ended May 31, 2022. The increase was mainly attributed to an increase in the foreign exchange gain of RMB17.8 million resulted from the appreciation of the U.S. dollar against RMB, which is our functional and reporting currency.

### *Research and Development Expenses*

Our research and development expenses increased from RMB129.9 million for the five months ended May 31, 2021 to RMB138.3 million for the five months ended May 31, 2022. This increase was primarily the net effect of (i) an increase in employee benefit expenses of RMB49.6 million mainly resulted from the increased number of our R&D personnel; (ii) an increase in third-party contracting expenses of RMB20.9 million mainly resulted from our engagement of CROs and advancement of clinical trials in 2022; and (iii) a decrease in upfront and milestone fee of RMB65.4 million mainly because we made huge amount of down payment associated with the exclusive development rights in designated regions of our in-licensed drug candidates in 2021.

### *Administrative Expenses*

Our administrative expenses increased from RMB26.8 million for the five months ended May 31, 2021 to RMB46.6 million for the five months ended May 31, 2022. This increase was primarily due to an increase in employee benefit expenses of RMB24.0 million mainly resulted from the increased number of our administrative personnel, partially offset by a decrease in [REDACTED] expenses of RMB5.3 million associated with the [REDACTED].

### *Selling and Marketing Expenses*

Our selling and marketing expenses increased from nil for the five months ended May 31, 2021 to RMB103.6 million for the five months ended May 31, 2022, resulted from the commercialization of envafolimab in the PRC market since December 2021.

### *Royalty Expenses*

Our royalty expenses increased from nil for the five months ended May 31, 2021 to RMB17.4 million for the five months ended May 31, 2022, in line with the commercialization of envafolimab since December 2021.

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### *Other Expenses*

Our other expenses increased from RMB1.4 million for the five months ended May 31, 2021 to RMB14.2 million for the five months ended May 31, 2022. This increase was primarily due to an increase in donations of RMB14.2 million worth of envafolimab and cash we made to a non-profit charity organization, which supports cancer patients for public welfare purposes.

### *Finance Costs*

Our finance costs increased from RMB0.4 million for the five months ended May 31, 2021 to RMB0.7 million for the five months ended May 31, 2022, which was primarily due to an increase in interest on lease liabilities of RMB0.4 million mainly due to the new leases for our offices and laboratories in Beijing and new leases for our offices in Shanghai.

### *Fair Value Losses on Preferred Shares*

Our fair value losses on preferred shares significantly decreased from RMB647.0 million for the five months ended May 31, 2021 to RMB143.6 million for the five months ended May 31, 2022 primarily due to the fair value change of existing Preferred Shares.

### *Impairment Losses on Financial Assets, net*

Our impairment losses on financial assets increased from nil for the five months ended May 31, 2021 to RMB0.1 million for the five months ended May 31, 2022 primarily due to an increase in our trade receivables from the customers since December 2021.

### *Total Comprehensive Loss for the Period*

For the reasons described above, our total comprehensive loss for the period decreased from RMB804.0 million for the five months ended May 31, 2021 to RMB293.4 million for the five months ended May 31, 2022.

## **Year Ended December 31, 2021 Compared to Year Ended December 31, 2020**

### *Revenue*

Our revenue significantly increased from nil for the year ended December 31, 2020 to RMB60.3 million for the year ended December 31, 2021, due to the sales of envafolimab in PRC market since December 2021.

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## FINANCIAL INFORMATION

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### *Cost of sales*

Our cost of sales increased from nil for the year ended December 31, 2020 to RMB4.3 million for the year ended December 31, 2021, resulted from purchase prices of envafolimab we paid to Alphamab Group since December 2021.

### *Gross Profit and Gross Profit Margin*

As a result of the foregoing, our gross profit increased from nil for the year ended December 31, 2020 to RMB56.0 million for the year ended December 31, 2021, and our gross profit margin increased from nil to 92.9% during the same periods.

### *Other Income and Gains*

Our other income and gains significantly increased from RMB2.3 million for the year ended December 31, 2020 to RMB19.6 million for the year ended December, 2021. The increase was mainly attributed to (i) an increase in the government grants income of RMB7.9 million from local government for the compensation of expenses for our research and development activities; (ii) an increase in our interest income of RMB3.9 million mainly resulted from an increase in our bank balances following the receipt of proceeds from our financing in 2021; and (iii) an increase in our research service income of RMB5.1 million mainly resulted from the CRO service we provided to independent third parties.

### *Research and Development Expenses*

Our research and development expenses increased from RMB264.0 million for the year ended December 31, 2020 to RMB371.2 million for the year ended December 31, 2021. This increase was primarily the net effect of an increase in employee benefit expenses of RMB134.1 million resulted from the increased number of research and development personnel and share-based payment made to research and development personnel; and a decrease of upfront and milestone fee of RMB31.5 million associated with the exclusive development rights in designated regions of our in-licensed drug candidates, which mostly occurred in 2020 rather than 2021.

### *Administrative Expenses*

Our administrative expenses increased from RMB40.5 million for the year ended December 31, 2020 to RMB151.0 million for the year ended December 31, 2021. This increase was primarily due to (i) an increase in employee benefit expenses of RMB78.6 million resulted from the increased number of our administrative personnel and share-based payment made to our administrative personnel; and (ii) an increase in the [REDACTED] expense of RMB21.4 million in relation to the [REDACTED].



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### *Selling and Marketing Expenses*

Our selling and marketing expenses increased from nil for the year ended December 31, 2020 to RMB42.8 million for the year ended December 31, 2021, due to an increase in the marketing service fees of RMB42.8 million resulted from the commercialization of envafolimab in the PRC market since December 2021.

### *Royalty Expenses*

Our royalty expenses increased from nil for the year ended December 31, 2020 to RMB7.2 million for the year ended December 31, 2021, in line with the commercialization of envafolimab since December 2021.

### *Other Expenses*

Our other expenses increased from RMB5.9 million for the year ended December 31, 2020 to RMB8.9 million for the year ended December 31, 2021. This increase was primarily due to (i) an increase in research service cost of RMB2.5 million incurred for our CRO services made to third parties; and (ii) an increase in donations of RMB1.4 million including the donations of envafolimab and cash we made to a non-profit charity organization, which supports cancer patients for public welfare purposes.

### *Finance Costs*

Our finance costs decreased from RMB8.1 million for the year ended December 31, 2020 to RMB1.5 million for the year ended December 31, 2021, which was primarily the net effect of a decrease of interest on bank loans and other borrowings of RMB7.1 million mainly due to the repayment of our outstanding bank loans and an increase in interest on lease liabilities of RMB1.2 million mainly due to the new leases for our offices and laboratories in Beijing and new leases for our offices in Shanghai.

### *Fair Value Losses on Preferred Shares*

Our fair value losses on preferred shares significantly increased from RMB319.2 million for the year ended December 31, 2020 to RMB954.7 million for the year ended December 31, 2021 primarily due to (i) the fair value change of existing preferred shares; and (ii) the issuance of new preferred shares.

### *Impairment Losses on Financial Assets, net*

Our impairment losses on financial assets increased from nil for the year ended December 31, 2020 to RMB0.1 million for the year ended December 31, 2021 primarily due to an increase in our trade receivables from the customers in 2021.

### *Total Comprehensive Loss for the Year*

For the reasons described above, our total comprehensive loss for the year increased from RMB635.4 million for the year ended December 31, 2020 to RMB1,461.8 million for the year ended December 31, 2021.

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### DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

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

	As of December 31,		As of
	2020	2021	May 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>2022</i> <i>RMB'000</i>
<b>Non-current assets</b>			
Property, plant and equipment	10,864	52,246	97,401
Intangible assets	–	929	887
Right-of-use assets	15,937	66,293	62,333
Other non-current assets	7,660	18,384	10,878
Amounts due from related parties	–	3,214	3,254
<b>Total non-current assets</b>	<b>34,461</b>	<b>141,066</b>	<b>174,753</b>
<b>Current assets</b>			
Trade receivables	–	65,004	101,889
Prepayments, other receivables and other assets	41,122	29,654	29,510
Amounts due from related parties	372	–	–
Financial assets at FVTPL	–	50,178	50,021
Pledged deposits	6,000	–	–
Restricted bank balances	–	72	72
Cash and bank balances	414,261	774,306	660,231
Inventories	–	13	1,545
<b>Total current assets</b>	<b>461,755</b>	<b>919,227</b>	<b>843,268</b>
<b>Current liabilities</b>			
Trade payables	2,416	3,742	2,650
Other payables and accruals	88,340	137,431	193,404
Interest-bearing bank borrowings	3,522	–	–
Amounts due to a related party	1,702	150	150
Preferred shares	215,237	3,093,968	3,233,922
Lease liabilities	3,791	12,754	13,701
<b>Total current liabilities</b>	<b>315,008</b>	<b>3,248,045</b>	<b>3,443,827</b>

## FINANCIAL INFORMATION

	As of December 31,		As of
	2020	2021	May 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
<b>Net current assets/(liabilities)</b>	146,747	(2,328,818)	(2,600,559)
<b>Total assets less current liabilities</b>	181,208	(2,187,752)	(2,425,806)
<b>Non-current liabilities</b>			
Deferred income	7,579	–	–
Lease liabilities	13,061	45,987	41,512
Preferred shares	1,430,383	38,823	42,511
<b>Total non-current liabilities</b>	1,451,023	84,810	84,023
<b>Net liabilities</b>	(1,269,815)	(2,272,562)	(2,509,829)
<b>Equity</b>			
Equity attributable to owners of the parent			
Share capital	37	57	57
Treasury shares	–	(27)	(27)
Deficits	(1,269,852)	(2,238,041)	(2,467,519)
	(1,269,815)	(2,238,011)	(2,467,489)
Non-controlling interests	–	(34,551)	(42,340)
<b>Total deficit</b>	(1,269,815)	(2,272,562)	(2,509,829)

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The following table sets forth our current assets and current liabilities as of the dates indicated:

	As of December 31,		As of May 31,
	2020	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
<b>Current Assets</b>			
Inventories	–	13	1,545
Trade receivables	–	65,004	101,889
Prepayments, other receivables and other assets	41,122	29,654	29,510
Amounts due from related parties	372	–	–
Financial assets at FVTPL	–	50,178	50,021
Pledged deposits	6,000	–	–
Restricted bank balances	–	72	72
Cash and bank balances	414,261	774,306	660,231
<b>Total current assets</b>	<b>461,755</b>	<b>919,227</b>	<b>843,268</b>
<b>Current liabilities</b>			
Trade payables	2,416	3,742	2,650
Other payables and accruals	88,340	137,431	193,404
Interest-bearing bank borrowings	3,522	–	–
Amounts due to a related party	1,702	150	150
Preferred shares	215,237	3,093,968	3,233,922
Lease liabilities	3,791	12,754	13,701
<b>Total current liabilities</b>	<b>315,008</b>	<b>3,248,045</b>	<b>3,443,827</b>
<b>Net current assets/(liabilities)</b>	<b>146,747</b>	<b>(2,328,818)</b>	<b>(2,600,559)</b>

Our net liabilities increased from RMB1,269.8 million as of December 31, 2020 to RMB2,272.6 million as of December 31, 2021, mainly reflecting changes in equity comprising (i) total comprehensive loss of RMB1,461.8 million; (ii) capital contribution from a non-controlling shareholder of a subsidiary of RMB321.1 million; and (iii) recognition of equity-settled share-based payments of RMB164.7 million. Our net liabilities further increased

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to RMB2,509.8 million as of May 31, 2022, mainly reflecting changes in equity comprising total comprehensive loss for the period of RMB293.4 million. For more information, please refer to consolidated statements of changes in equity included in the Accountants’ Report in Appendix I to this document.

### Property, Plant and Equipment

During the Track Record Period, our property, plant and equipment primarily consisted of (i) leasehold improvements; (ii) office equipment; (iii) laboratory equipment; (iv) transportation equipment; and (v) construction in progress. The following table sets forth a breakdown of our property, plant and equipment as of the dates indicated:

	As of December 31,		As of
	2020	2021	May 31,
	<i>RMB’000</i>	<i>RMB’000</i>	<i>2022</i>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Leasehold improvements	9,100	19,615	25,308
Office equipment	532	2,016	2,132
Laboratory equipment	693	1,841	2,009
Transportation equipment	539	618	534
Construction in progress	–	28,156	67,418
	10,864	52,246	97,401

Our property, plant and equipment increased from RMB10.9 million as of December 31, 2020 to RMB52.2 million as of December 31, 2021, which was mainly attributable to (i) an increase in leasehold improvements of RMB10.5 million mainly due to the renovation of our offices in Beijing and Shanghai in 2021; and (ii) an increase in construction in progress of RMB28.2 million due to the renovations of our offices in Beijing and Shanghai in 2021, as well as the construction costs for our manufacturing facilities in Xuzhou.

Our property, plant and equipment further increased to RMB97.4 million as of May 31, 2022, mainly due to (i) an increase in construction in progress of RMB39.3 million due to the construction for our manufacturing facilities in Xuzhou; and (ii) an increase in leasehold improvements of RMB5.7 million due to the renovations of our offices in Beijing and Shanghai in 2022.

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### Right-of-use Assets

Our right-of-use assets are primarily related to our land use rights and leased buildings during the Track Record Period. Our right-of-use assets significantly increased from RMB15.9 million as of December 31, 2020 to RMB66.3 million as of December 31, 2021 mainly due to the newly acquired land in Xuzhou and new lease of buildings in Beijing and Shanghai in 2021. Our right-of-use assets slightly decreased to RMB62.3 million as of May 31, 2022, mainly due to the depreciation and amortization of the right-of-use assets.

### Intangible Assets

Our intangible assets mainly consisted of software. Our intangible assets was nil as of December 31, 2020, and increased to RMB0.9 million as of December 31, 2021, primarily due to the purchase of software. Our other intangible assets remained stable at RMB0.9 million as of May 31, 2022.

### Inventories

During the Track Record Period, our inventories consisted of finished goods, namely, envafolimab.

Our inventories increased from nil as of December 31, 2020 to RMB13,000 as of December 31, 2021, which was in line with our commercialization of envafolimab since December 2021. Our inventories significantly increased to RMB1.5 million as of May 31, 2022, mainly due to an increase in the stock of envafolimab since the commercialization. Our Directors confirm that our inventory control system and policies have been effective and we did not experience any material shortage in supply or overstock of inventory during the Track Record Period and up to the Latest Practicable Date. For more details, please refer to the paragraphs headed “Business – Inventory Management” in this document.

### Trade Receivables

During the Track Record Period, our trade receivables consisted of (i) trade receivables; and (ii) impairment. We grant a collection period of 70 days to Simcere Group, which serves as our service provider, to reconcile and settle payments of envafolimab from the customers for us on a monthly basis. Pursuant to our agreements with Simcere Group, we sell envafolimab to the relevant customers through Simcere Group, while Simcere Group is entitled to receive the marketing service fees on a monthly basis calculated with reference to the total purchases made by pharmacy stores and distributors through Simcere Group and based on rates stipulated in the agreements. In addition, we grant a credit period of 45-70 days to our distributors. We recognize revenue when the pharmacy stores and distributors receive the products. For details

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of the arrangements with Simcere Group, please refer to the paragraph headed “Business – Our Sales Operation.” The following table sets forth a breakdown of our trade receivables as of the dates indicated:

	As of December 31,		As of May 31,
	2020	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade receivables	–	65,134	102,093
Impairment	–	(130)	(204)
	–	65,004	101,889

As of the Latest Practicable Date, approximately RMB81.3 million or 79.7%, of our trade receivable outstanding as of May 31, 2022 was subsequently settled.

The following table sets forth the ageing analysis of our trade receivables as of December 31, 2020 and 2021 and May 31, 2022, based on the invoice date and net of loss allowance:

	As of December 31,		As of May 31,
	2020	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Within 3 months	–	65,004	101,889

The Company has a credit control department to manage and minimize credit risks. Overdue balances are reviewed regularly by senior management team. The Company does not hold any collateral or other credit enhancements over its trade receivable balances. All trade receivables are non-interest-bearing. As of May 31, 2022, nearly all trade receivables were due from Simcere Group.

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### Prepayments, Other Receivables and Other Assets

Our prepayments, other receivables and other assets consisted of (i) value-added tax recoverable; (ii) deferred [REDACTED] expenses; (iii) prepayments; and (iv) other receivables during the Track Record Period. The following table sets forth the breakdown of prepayments, other receivables and other assets as of the dates indicated:

	As of December 31,		As of
	2020	2021	May 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>2022</i>
			<i>RMB'000</i>
Value-added tax recoverable	9,100	5,993	–
Deferred [REDACTED] expenses	[REDACTED]	[REDACTED]	[REDACTED]
Prepayments	29,500	12,226	16,385
Other receivables	1,126	1,294	1,261
	41,122	29,654	29,510

Our prepayments, other receivables and other assets decreased from RMB41.1 million as of December 31, 2020 to RMB29.7 million as of December 31, 2021, primarily due to (i) a significant decrease in prepayments because the prepaid preferred shares repurchase payment of RMB24.5 million made by the Company to certain existing shareholders for the redemption of their preferred shares in the Company was incurred in 2020 and settled in 2021; (ii) a decrease in value-added tax recoverable of RMB3.1 million resulted from the generation of sales tax after the commercialization of envafolimab, partially offset by an increase in deferred [REDACTED] expenses of RMB8.7 million associated with the [REDACTED]. Our prepayments, other receivables and other assets remained relatively stable at RMB29.5 million as of May 31, 2022. For details of the repurchase of Preferred Shares from certain existing shareholders, please refer to section headed “History, Development and Corporate Structure – Corporate Development – Major Shareholding Changes” for details.

### Financial Assets at FVTPL

During the Track Record Period, our financial assets at FVTPL represented wealth management products issued by banks in Mainland China. Such wealth management products comprised short-term and low-risk financial products issued by commercial banks in China. The expected but not guaranteed rates of return ranged from 1.6% to 3.4% per year. In accordance with our risk management and investment strategy, we managed and evaluated the performance of these investments on a fair value basis and therefore these investments are designated as financial assets at FVTPL. Our financial assets at FVTPL increased from nil as of December 31, 2020 to RMB50.2 million as of December 31, 2021, primarily due to purchase



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of new wealth management products in 2021. Our financial assets at FVTPL remained relatively stable at RMB50.0 million as of May 31, 2022. For more details, please refer to note 20 of the Appendix I to this document.

We purchase wealth management products as an supplemental mean to improve utilization of our cash on hand on a short-term basis. We believe that making such investments is in the best interest of the Company, and we can make better use of our cash by utilizing low-risk wealth management products, to enhance our income without interfering with our business operations or capital expenditures. Although the purchases of wealth management products were not subject to approval of the Board of the Company during the Track Record Period, the purchases were carefully reviewed and assessed by staff in our finance department, who have financial management or accounting background, and such decisions were subject to the further review and approval of the management team. Additionally, we have established a set of risk management and capital preservation investment policy, and have implemented a series of internal control measures regarding our investment in wealth management products. These policies and measures include:

- our investment decisions are made on a case-by-case basis and after due and careful consideration of a number of factors, such as the duration of the investment and the expected returns;
- we only purchase low-risk wealth management products issued by qualified financial institutions, and in any given period, we make investments in products provided by multiple issuers to mitigate concentration risks;
- our finance department, subject to the review and approval of our management team, is responsible for the overall execution of our investments, including risk assessment; and
- after making an investment, we closely monitor its performance and fair value on a regular basis to ensure that the purpose of such investment is to preserve capital and liquidity until free cash is used in our primary business and operation.

In the future, we may continue to purchase low-risk wealth management products with a short maturity period based on surplus cash situation to maximize our capital utilization efficiency. Our investments in wealth management products will be subject to the compliance with the requirements under Chapter 14 of the Listing Rules.

## FINANCIAL INFORMATION

### Cash and Bank Balances, Pledged Deposits and Restricted Bank Balances

The following table sets forth the breakdown of our cash and bank balances, pledged deposits and restricted cash balances denominated in RMB, USD and HKD as of the dates indicated:

	As of December 31,		As of
	2020	2021	May 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>2022</i>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Cash and bank balances	414,261	774,306	660,231
Pledged deposits	6,000	–	–
Restricted bank balances	–	72	72
Denominated in			
RMB	293,751	315,779	222,133
USD	126,506	457,727	437,966
HKD	4	872	204
	420,261	774,378	660,303

Our cash and bank balances consisted of cash and bank balances denominated in RMB, USD and HKD. Our cash and bank balances increased from RMB414.3 million as of December 31, 2020 to RMB774.3 million as of December 31, 2021, primarily due to the net effect of receipt of proceeds from financing in 2021, which was partially offset by operating expenses in 2021. Our cash and bank balances decreased to RMB660.2 million as of May 31, 2022, primarily because we did not have equity financing in 2022 but continuously had cash expenditures in relation to the operating activities.

Our pledged deposits related to bank balance as a performance guarantee in the amount of RMB6.0 million which was paid to a commercial bank in 2020. The pledged bank balances decreased from RMB6.0 million as of December 31, 2020 to nil as of December 31, 2021 due to the discharge of the pledge. The pledged bank balances remained nil as of May 31, 2022

Our restricted bank balances represent the restricted portion of the interests of investment proceeds received from a minority shareholder of a subsidiary of the Group, which amount was under escrow. The principal of the investment proceeds had been withdrawn from the account in 2021.

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### Trade Payables

Our trade payables mainly related to our purchase of third-party contracting services. Our credit terms on trade payables were up to 90 days. Our trade payables increased from RMB2.4 million as of December 31, 2020 to RMB3.7 million as of December 31, 2021, for additional procurement of third-party contracting services. Our trade payables decreased to RMB2.7 million as of May 31, 2022, mainly due to the settlement of certain trade payable obligations in 2022. We did not have any material defaults in payment of trade payables during the Track Record Period and up to the Latest Practicable Date.

The following table sets forth an aging analysis of our trade payables based on the invoice date as of the dates indicated:

	As of December 31,		As of
	2020	2021	May 31, 2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Within 3 months	1,948	3,732	2,086
3 to 6 months	468	–	562
6 months to 1 year	–	10	2
	<u>2,416</u>	<u>3,742</u>	<u>2,650</u>

### Other Payables and Accruals

Our other payables and accruals mainly consisted of accrued marketing service fees, accrued research and development expenses, payroll payables, interest payables, accrued [REDACTED] expenses, and payables to precedent investors. The following table sets forth a breakdown of other payables and accruals as of the dates indicated:

	As of December 31,		As of
	2020	2021	May 31, 2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Accrued marketing service fees	–	38,281	60,922
Accrued royalty expenses	–	7,153	6,826
Accrued research and development expenses	60,498	43,087	47,245
Payroll payable	12,093	21,944	15,250
Accrued [REDACTED] expenses	[REDACTED]	[REDACTED]	[REDACTED]
Other tax payables	638	1,425	3,047
Payables for property, plant and equipment	1,141	4,423	35,801
Payables for financing services	8,949	710	741
Payables to precedent investors	1,143	12,692	13,260
Other payables	2,132	356	338
	<u>88,340</u>	<u>137,431</u>	<u>193,404</u>

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Our other payables and accruals increased from RMB88.3 million as of December 31, 2020 to RMB137.4 million as of December 31, 2021, primarily due to the net effect of (i) an increase in accrued marketing service fees of RMB38.3 million resulted from the commercialization of our Core Product since December 2021; (ii) an increase in payroll payable of RMB9.9 million mainly resulted from the increase in the number of employees; (iii) an increase in payables to precedent investors of RMB11.5 million primarily due to an increase in the amount withheld by the Group to be released to the precedent investors when they confirm the completion of their tax filings. To be specific, as approved by the Board in October 2020, the Company decided to repurchase Preferred Shares owned by certain precedent investors of the Company, for the purpose of issuing the same number of Preferred Shares to new investors afterwards. The Company withheld 10% of the preferred share transfer consideration in order to make sure that the transferors duly made their tax filings associated with the preferred share transfers. The total transferred number of preferred shares and total transfer consideration was higher in 2021 than in 2020. After confirming that the tax filings are completed, the Company will then release such 10% withheld consideration to the transferors; and (iv) a decrease in accrued research and development expenses of RMB17.4 million mainly resulted from the completion of certain research and development programs at the end of 2020.

Our other payables and accruals further increased to RMB193.4 million as of May 31, 2022, mainly due to the net effect of (i) an increase in payables for property, plant and equipment of RMB31.4 million incurred for the construction of our manufacturing facilities in Xuzhou city; and (ii) an increase in accrued marketing service fees of RMB22.6 million incurred for the commercialization of our Core Product.

### **Interest-Bearing Bank Borrowings**

Our interest-bearing bank borrowings consisted of secured bank loans, unsecured bank loans, secured other loans and unsecured other loans. It decreased from RMB3.5 million as of December 31, 2020 to nil as of December 31, 2021. Our interest-bearing bank borrowings remained nil as of May 31, 2022. For more details, please refer to the paragraphs headed “Indebtedness – Interest-Bearing Bank and Other Borrowings” in this section.

### **Amounts due From Related Parties**

Amounts due from related parties mainly arose from (i) rental deposits paid for our leased properties to Simcere Shanghai; (ii) the reimbursable expenses incurred by Dr. Gong, which was prepaid by our Group; and (iii) loans to our senior management members. Except for the amounts due from Simcere Shanghai, all other amounts due from related parties were non-trade in nature. Our amounts due from related parties increased from RMB0.4 million as of December 31, 2020 to RMB3.2 million as of December 31, 2021, primarily due to the new unsecured loans borrowed by two senior management members, Dr. Lin Yihui and Ms. Zhang Jing, each bearing an interest rate of 3.0% per annum, and the loan term of three years and two years, respectively. The outstanding balances of the loans are expected to be settled by maturity of such loans. Our amounts due from related parties remained relatively stable at RMB3.3 million as of May 31, 2022.

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### Amounts due to a Related Party

Amounts due to a related party mainly arose from subsidies, which were non-trade in nature and applied on behalf of the Company, but were intended to be paid to Dr. Gong. Our amounts due to a related party decreased from RMB1.7 million as of December 31, 2020 to RMB0.2 million as of December 31, 2021, because the Company transferred the subsidies to Dr. Gong. The amounts due to a related party remained at RMB0.2 million as of May 31, 2022. For more details, please refer to the paragraphs headed “Related Party Transactions” in this section. The outstanding balance is expected to be settled before the [REDACTED].

### Deferred Income

Our deferred income consisted of deferred income on government grants, which mainly related to the subsidies received from the local government for the purpose of compensation for expenses arising from research activities and clinical trial, award for new drugs development and capital expenditure incurred on our projects. The subsidies will be recognized in profit or loss after the Company fulfills certain project acceptance requirements set by the local government. Our deferred income decreased from RMB7.6 million as of December 31, 2020 to nil as of December 31, 2021 due to the completion of the project acceptance and reclassification of such government grants to other income and gains. Our deferred income remained nil as of May 31, 2022.

### Preferred Shares

Preferred shares represents the fair value of Preferred Shares we issued for the financing, to be specific, Series Seed Preferred Shares, Series A Preferred Shares, Series A+ Preferred Shares, Series B Preferred Shares, Series B+ Preferred Shares, Series C Preferred Shares, Series D Preferred Shares, Series D+ Preferred Shares, and Series E Preferred Shares. We classified the Preferred Shares as financial liabilities measured at fair value through profit and loss. We recorded fair value of Preferred Shares of RMB1,645.6 million, RMB3,132.8 million and RMB3,276.4 million as of December 31, 2020 and 2021 and May 31, 2022, respectively. The increase was primarily resulted from the evaluation of all then existing Preferred Shares and the new issuance of Series E Preferred Shares in 2021. For more details on our Preferred Shares, please refer to the paragraphs headed “History, Development and Corporate Structure – Pre-[REDACTED] Investments.” in this document. For details on the fair value determination of our Preferred Shares, please refer to the paragraphs headed “Critical Accounting Policies, Judgements and Estimates – Significant Accounting Judgments and Estimates – Estimation Uncertainty – Fair Value of Preferred Shares Measured at FVTPL” in this section and note 26 of the Accountants’ Report set forth in Appendix I to this document.

In relation to the valuation of our Group’s financial liabilities measured at FVTPL categorized within level 3 of fair value measurement, our Group had: (i) engaged an external appraiser, and reviewed the valuation methods and assumptions adopted by such appraiser; and (ii) reviewed relevant agreements and supporting documents, including investment agreements, shareholders’ agreement, memorandum of association, among others, to understand the

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detailed underlying terms and conditions that may affect the valuation of the financial instruments. Based on the aforementioned work, our management is satisfied with the categorization within level 3 of fair value measurement pursuant to the SFC’s “Guidance note on directors’ duties in the context of valuations in corporate transactions.”

The Joint Sponsors had conducted the following due diligence work in relation to the Group’s financial liabilities measured within level 3 fair value measurement:

- discussing with the Directors with a view to understand the work done by the Directors in discharging their duties in relation to reviewing the fair value measurement of level 3 financial liabilities of the Group;
- understanding from the Company the nature and details of the financial liabilities and obtaining and reviewing the list of the financial liabilities during the Track Record Period;
- obtaining and reviewing the terms of the relevant agreements and documents regarding the financial liabilities;
- reviewing the disclosures in relevant notes to the Accountants’ Report;
- understanding from the Company the key bases, assumptions and methodologies used in the valuation of the financial liabilities;
- discussing with the reporting accountants to understand the work it has performed in relation to the fair value measurements of level 3 financial liabilities of the Group for the purpose of reporting on the historical financial information of the Group as a whole.

Based on the due diligence conducted by the Joint Sponsors as stated above, and having considered the confirmations from the Directors and the discussions with the reporting accountants, nothing material has come to the Joint Sponsors’ attention that indicates that the Company has not undertaken independent and sufficient investigation and due diligence on such level 3 financial liabilities.

Details of the fair value measurement of financial liabilities, particularly the fair value hierarchy, the valuation techniques and key inputs, including significant unobservable inputs, the relationship of unobservable inputs to fair value are disclosed in Note 26 to the Accountant’s Report set out in Appendix I to this document, which was reported on by the reporting accountant in accordance with Hong Kong Standards on Auditing (“HKSA”) 540 (Revised) and other related HKSA’s issued by the Hong Kong Institute of Certified Public Accountant. The reporting accountant’s opinion on the historical financial information of our Group for the Track Record Period as a whole is set out in Appendix I to this document.

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### LIQUIDITY AND CAPITAL RESOURCES

#### Working Capital

Our uses of cash primarily compose of pre-clinical research and development expenses, clinical development expenses, and license-in related expenses. During the Track Record Period, we primarily funded our working capital requirements through capital contributions from our shareholders, private equity financing and other borrowings. We monitor and maintain a level of cash and cash equivalents deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. Our net cash used in operating activities was RMB278.3 million, RMB377.1 million and RMB112.9 million for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, respectively. As our business develops and expands, we expect to generate net cash from our operating activities, through the sales revenue of our future commercialized products. Going forward, we believe our liquidity requirements will be satisfied by using funds from a combination of our cash equivalents and cash and net [REDACTED] from the [REDACTED]. As of May 31, 2022, we had cash and cash equivalents of RMB660.2 million.

Our cash burn rate refers to the average monthly aggregate amount of (i) net cash used in operating activities, including research and development expenses; (ii) payment for property, plant and equipment; (iii) interest paid; (iv) purchase amount of intangible assets; and (v) lease payment. Assuming that the average cash burn rate going forward of 1.9 times the level in 2021, which is primarily based on the difference between the average monthly burn rate in 2022 and the nine months ended September 30, 2023, we estimate that our cash and cash equivalents as of May 31, 2022 will be able to maintain our financial viability for approximately 9.6 months or, if we also take into account the estimated net [REDACTED] (based on the low-end of the indicative [REDACTED]) from the [REDACTED], for approximately 33.3 months. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

#### Cash Flows

Since our inception, we have incurred net losses and negative cash flows from our operations. Our primary uses of cash are to fund the research and development of our drug pipeline, our clinical trials, administrative expenses and other recurring expenses. Our net cash used in operating activities amounted to RMB278.3 million, RMB377.1 million and RMB112.9 million for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022, respectively. As our business develops and expands, we expect to generate cash from our operating activities mainly through sales of our products.

During the Track Record Period and up to the Latest Practicable Date, we primarily funded our working capital needs through equity and debt financing. Our management monitors and maintains a level of cash and cash equivalents deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. Going forward, we believe our liquidity requirements will be mainly satisfied from a combination of our cash and cash

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equivalents, cash flow from operating activities with products gradually commercialized in the market, bank borrowings, net [REDACTED] from the [REDACTED] and other financing activities. We expect that our existing cash, cash equivalents and available financing facilities will enable us to fund our operating expenses and capital expenditures requirements for at least the next 12 months of the date of this document. As of May 31, 2022, we had cash and cash equivalents of RMB660.2 million.

The following table provides information regarding our cash flows for the periods indicated:

	Year Ended December 31,		Five Months Ended May 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Cash flows from operating activities before movements in working capital	(300,140)	(337,200)	(152,972)	(105,445)
Changes in working capital	21,811	(39,879)	24,979	(7,451)
Net cash flows used in operating activities	(278,329)	(377,079)	(127,993)	(112,896)
Net cash flows used in investing activities	(20,480)	(98,871)	(16,711)	(13,166)
Net cash flows from financing activities	607,387	840,082	104,380	(6,335)
Net increase in cash and cash equivalents	308,578	364,132	(40,324)	(132,397)
Cash and cash equivalents at beginning of year/period	112,156	414,261	414,261	774,306
Effect of foreign exchange rate changes, net	(6,473)	(4,087)	(1,370)	18,322
<b>Cash and cash equivalents at end of the year/period</b>	<b>414,261</b>	<b>774,306</b>	<b>372,567</b>	<b>660,231</b>



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### Net Cash Flows Used in Operating Activities

We had net cash outflows in operating activities during the Track Record Period. Our primary uses of cash are to fund the development of both our internally and in-licensed developed drug candidates, our clinical trials and for the purchase of equipment, administrative expenses and other recurring expenses. We shall continue to advance our late stage clinical assets into NDA stage and commercialization which will bring incremental cash flow to fund our operation in the foreseeable future.

For the five months ended May 31, 2022, our net cash flows used in operating activities was RMB112.9 million, which was primarily attributable to our loss before tax of RMB293.4 million. Negative adjustments for non-cash and non-operating items primarily included (i) fair value losses on preferred shares of RMB143.6 million; and (ii) equity-settled share-based payments of RMB55.4 million. The amount was then adjusted positively by changes in working capital, primarily included an increase in trade receivables of RMB37.0 million, partially offset by an increase in other payables and accruals of RMB23.4 million.

For the year ended December 31, 2021, our net cash flows used in operating activities was RMB377.1 million, which was primarily attributable to our loss before tax of RMB1,461.8 million. Negative adjustments for non-cash and non-operating items primarily included fair value losses on preferred shares of RMB954.7 million. The amount was then adjusted positively by changes in working capital, primarily included an increase in trade receivables of RMB65.1 million, partially offset by an increase in other payables and accruals of RMB34.1 million.

For the year ended December 31, 2020, our operating activities used RMB278.3 million, primarily as a result of an increase in payments for clinical stage research and developments. Negative adjustments for non-cash and non-operating items primarily include fair value losses of preferred shares. The amount was then further adjusted negatively by changes in working capital, primarily included (i) a decrease in prepayments and other receivables of RMB17.2 million; (ii) a decrease in other non-current assets of RMB9.3 million; and (iii) an increase in other payables and accruals of RMB8.9 million, partially offset by a decrease in trade payables of RMB13.3 million.

### Net Cash Flows Used in Investing Activities

For the five months ended May 31, 2022, our net cash flows used in investing activities was RMB13.2 million, primarily as a result of (i) purchase of items of property, plant and equipment of RMB16.2 million; and (ii) purchase of financial assets at FVTPL of RMB100.0 million, partially offset by proceeds from disposal of financial assets at FVTPL of RMB100.8 million.

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For the year ended December 31, 2021, our net cash flows used in investing activities was RMB98.9 million, primarily as a result of (i) purchase of items of property, plant and equipment of RMB43.9 million; and (ii) purchase of financial assets at FVTPL of RMB100.0 million, partially offset by proceeds from disposal of financial assets at FVTPL of RMB50.4 million.

For the year ended December 31, 2020, our net cash flows used in investing activities was RMB20.5 million, primarily as a result of (i) purchases of items of property, plant and equipment; (ii) payment for acquisition of subsidiaries in the Business Restructuring; and (iii) loans provided to a third party; partially offset by repayment of loans from a third party.

### **Net Cash Flows From Financing Activities**

For the five months ended May 31, 2022, our net cash flows used in financing activities was RMB6.3 million, primarily as a result of (i) principal portion of lease payments of RMB5.0 million; and (ii) [REDACTED] expenses paid of RMB1.1 million.

For the year ended December 31, 2021, our net cash flows from financing activities was RMB840.1 million, primarily as a result of proceeds from issuance of preferred shares of RMB1,614.4 million, partially offset by the payments for repurchase of onshore investments of RMB843.0 million.

For the year ended December 31, 2020, our net cash flows from financing activities was RMB607.4 million, primarily as a result of proceeds from issue of preferred shares.

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### CASH OPERATING COSTS

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

	Year Ended		Five Months Ended	
	December 31,		May 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
<b>Research and development costs</b>				
<i>Research and development costs for our Core Product</i>				
– Clinical trial expenses	64,666	39,089	12,835	12,383
– Staff costs	25,762	28,963	12,276	16,024
– Raw material costs	1,324	1,248	788	905
– Others	1,210	4,783	1,047	2,290
<i>Research and development costs for our other product candidates</i>				
– License in expenses	129,101	127,308	52,563	26,384
– Clinical trial expenses	11,100	21,475	3,686	9,153
– Staff costs	9,469	37,593	18,321	24,780
– Raw material costs	157	7,397	1,007	4,395
– Others	3,221	11,550	5,912	7,214
<b>Workforce employment costs<sup>(1)</sup></b>	21,566	30,527	14,024	19,323
<b>Product marketing costs</b>	–	–	–	74,754
<b>Non-income taxes, royalties and other governmental charges</b>	157	817	525	441
<b>Contingency allowances<sup>(2)</sup></b>	–	–	–	–
	<u>267,733</u>	<u>310,750</u>	<u>122,984</u>	<u>198,046</u>

*Note:*

- (1) Workforce employment costs represent general and administrative staff costs mainly including salaries and benefits.
- (2) We did not have any contingency allowances during each of the Track Record Period.

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### WORKING CAPITAL CONFIRMATION

Our Directors are of the opinion that, taking into account the financial resources available to our Group, including cash and cash equivalents, internally generated funds and the estimated net [REDACTED] from the [REDACTED], we have sufficient working capital to cover at least 125% of our costs, including research and development expenses, distribution costs, administrative expenses, and other operating costs, for at least the next 12 months from the date of this document.

### INDEBTEDNESS

The following table sets forth the components of our indebtedness as of the dates indicated:

	<u>As of December 31,</u>		<u>As of</u>
	<u>2020</u>	<u>2021</u>	<u>May 31,</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>2022</i>
			<i>RMB'000</i>
Interest-bearing bank borrowings	3,522	–	–
Lease liabilities			
Current	3,791	12,754	13,701
Non-current	13,061	45,987	41,512
	<u>20,374</u>	<u>58,741</u>	<u>55,213</u>

### Interest-Bearing Bank Borrowings

Our interest-bearing bank borrowings consisted of secured bank loans and unsecured bank loans.

As of December 31, 2020 and 2021 and May 31, 2022, the outstanding balance of our interest-bearing bank borrowings was RMB3.5 million, nil and nil, respectively, among which, RMB2.3 million was secured bank loan with an effective interest rate of one year LPR+5bp, secured by the Group's deposits of RMB6,000,000; RMB1.2 million was unsecured bank loan with an effective interest rate of one year LPR+65bp. Such loans were fully repaid as of December 31, 2021.

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### Lease Liabilities

Since IFRS 16 was adopted by our Group throughout the Track Record Period, we recognized right-of-use assets and the corresponding lease liabilities in respect of all leases, except for short-term leases. Our total lease liabilities increased from RMB16.9 million as of December 31, 2020 to RMB58.7 million as of December 31, 2021 primarily resulted from the new lease of offices and laboratory buildings in Beijing, as well as new lease of offices in Shanghai. Our total lease liabilities decreased to RMB55.2 million as of May 31, 2022, mainly due to the decrease of long-term (more than a year) lease liabilities of RMB4.5 million. The following table sets forth our lease liabilities as of the dates indicated:

	<b>As of December 31,</b>		<b>As of</b>
	<b>2020</b>	<b>2021</b>	<b>May 31,</b>
	<i>RMB'000</i>	<i>RMB'000</i>	<b>2022</b>
			<i>RMB'000</i>
Current portion	3,791	12,754	13,701
Non-current portion	13,061	45,987	41,512
	16,852	58,741	55,213

Save as otherwise disclosed under the paragraphs headed “Indebtedness” in this section, our Directors confirm that, we had no material defaults in bank and other borrowings, nor did we breach any covenants during the Track Record Period and up to the Latest Practicable Date. We did not have any unutilized credit facilities as of the Latest Practicable Date.

Except as otherwise disclosed in the paragraphs headed “Indebtedness” in this section, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of May 31, 2022. Since May 31, 2022 and up to the Latest Practicable Date, there had not been any material adverse change to our indebtedness.

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### CAPITAL EXPENDITURE

We regularly incur capital expenditures to expand our operations and optimize our operating efficiency in order to enhance our development capabilities and expand our business operations, including the construction of our facility in Xuzhou city. Historically, we have funded our capital expenditures mainly through financing in the form of preferred shares and borrowings. The following table sets forth our capital expenditures for the periods indicated:

	Year ended December 31,		Five Months Ended May 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Purchases of items of property, plant and equipment	11,147	43,872	5,617	16,248
Payment for acquisition of a land use right	—	11,492	11,492	—
	<u>11,147</u>	<u>55,364</u>	<u>17,109</u>	<u>16,248</u>

We expect to incur capital expenditures in the next few years primarily in relation to the construction of our Xuzhou facility, which we expect to fund primarily through cash generated from operations, bank facilities and net [REDACTED] to be received from the [REDACTED]. To the extent we require additional funding for major capital expenditures, we will consider additional equity and debt financings. The sufficiency of such funding will in turn depend on prevailing market conditions, as well as investors' willingness to invest in our Company. We may adjust our budgeted capital expenditures for any given period according to our development plans or in light of market conditions and other factors we believe to be appropriate.

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### CONTRACTUAL COMMITMENTS

#### Capital Commitments

We had capital commitments contracted for but not provided of nil as of December 31, 2020, RMB126.3 million as of December 31, 2021 and RMB109.6 million as of May 31, 2022, mainly related to our facility in Xuzhou city. The following table sets forth our capital commitments as of the dates indicated:

	<b>As of December 31,</b>		<b>As of</b>
	<b>2020</b>	<b>2021</b>	<b>May 31,</b>
	<i>RMB'000</i>	<i>RMB'000</i>	<b>2022</b>
			<i>RMB'000</i>
Contracted, but not provided for:			
Purchase of items of property, plant and equipment	–	126,260	109,628

### CONTINGENT LIABILITIES

Save as disclosed in the paragraphs headed “Contractual Commitments” in this section, we did not have any material contingent liabilities as of the Latest Practicable Date.

### OFF-BALANCE SHEET ARRANGEMENTS

We had not entered into any off-balance sheet transactions as of the Latest Practicable Date.

### KEY FINANCIAL RATIO

The following table sets forth the components of our key financial ratio as of the dates indicated:

	<b>As of December 31,</b>		<b>As of</b>
	<b>2020</b>	<b>2021</b>	<b>May 31,</b>
			<b>2022</b>
Current ratio <sup>(1)</sup>	1.5	0.3	0.2

*Note:*

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

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Our current ratio decreased from 1.5 as of December 31, 2020 to 0.3 as of December 31, 2021 primarily due to the reclassification of preferred shares from non-current liabilities to current liabilities and an increase in the fair value of the preferred shares. In addition, our current ratio decreased to 0.2 as of May 31, 2022, mainly due to (i) a decrease in cash and bank balances of RMB114.1 million primarily because we did not have equity financing in 2022 but continuously incurred cash expenditures in relation to our operating activities in the meantime; (ii) an increase in other payables and accruals of RMB56.0 million primarily due to the increased accrued marketing service fees of RMB22.6 million in line with our sales activities, and increased payables for property, plant and equipment of RMB31.4 million in relation to the renovations of our offices and construction of our manufacturing facilities; and (iii) an increase in Preferred Shares classified as current liabilities of RMB140.0 million primarily due to the fair value increase of such Preferred Shares.

### RELATED PARTY TRANSACTIONS

The following table sets forth our transactions with related parties for the periods indicated:

	Year ended		Five Months Ended	
	December 31,		May 31,	
	2020	2021	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Repayment of loans from a related party	11,948	–	–	–
Preferred share issuance	–	165,920	66,178	–
Expenses for utilities	–	693	269	–
Expenses for research and development	–	3,660	–	–
Interest income on loans to related parties	–	14	–	40
Interest expenses on loans from a related party	641	–	–	–



## FINANCIAL INFORMATION

The following table sets forth our outstanding balances with related parties as of the dates indicated:

	As of December 31,		As of
	2020	2021	May 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>2022</i>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Amounts due from related parties	372	3,214	3,254
Amounts due to a related party	1,702	150	150
Lease liabilities arising from rent from a related party	16,198	–	–

For more details, please refer to note 34 to Accountants’ Report set forth in Appendix I to this document. Our Directors are of the view that each of the related party transactions was conducted in the ordinary course of business and on an arm’s length basis and with normal commercial terms between the relevant parties. Our Directors are also of the view that our related party transactions during the Track Record Period would not distort our track record results or make our historical results not reflective of our future performance.

### QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

#### Foreign Currency Risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between RMB and other currencies in which we conduct business may affect our financial condition and results of operations.

## FINANCIAL INFORMATION

The following table demonstrates the sensitivity at the end of the reporting period to a reasonably possible change in foreign currency exchange rates, with all other variables held constant, of our loss before tax (due to changes in the fair value of monetary assets and liabilities) and our equity:

	<b>Increase/ (decrease) in rate of foreign exchange</b>	<b>Increase/ (decrease) in loss before tax</b>	<b>Increase/ (decrease) in equity</b>
	<i>%</i>	<i>RMB'000</i>	<i>RMB'000</i>
<b>December 31, 2020</b>			
If RMB weakens against the US\$	5	76,013	(76,013)
If RMB strengthens against the US\$	(5)	(76,013)	76,013
<b>December 31, 2021</b>			
If RMB weakens against the US\$	5	133,753	(133,753)
If RMB strengthens against the US\$	(5)	(133,753)	133,753
<b>May 31, 2021 (unaudited)</b>			
If RMB weakens against the US\$	5	111,919	(111,919)
If RMB strengthens against the US\$	(5)	(111,919)	111,919
<b>May 31, 2022</b>			
If RMB weakens against the US\$	5	141,923	(141,923)
If RMB strengthens against the US\$	(5)	(141,923)	141,923

### Liquidity Risk

Liquidity risk is the risk that we will encounter difficulty in meeting financial obligations due to shortage of funds. We monitor and maintain a level of cash and cash equivalents deemed adequate by the management of our Group to finance the operations and mitigate the effects of fluctuations in cash flows. For more details, please refer to note 37 to Accountants' Report set forth in Appendix I to this document.

### Capital Management

The primary objectives of our Group's capital management are to safeguard our abilities to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximize shareholders' value.

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## FINANCIAL INFORMATION

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We manage our capital structure and make adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, we may return capital to shareholders or issue new shares. We are not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital as of the end of each of the reporting period.

### 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.

We may need dividends and other distributions on equity from our subsidiaries to satisfy our liquidity requirements, including those incorporated in the PRC. Current PRC regulations permit our PRC subsidiaries to pay dividends to us only out of their distributable profits. Distributable profits are our PRC subsidiaries' after-tax profits, less any recovery of accumulated losses and appropriations to statutory and other reserves that our PRC subsidiaries are required to make. In addition, our PRC subsidiaries are required to set aside at least 10% of their respective after-tax profits each year to fund statutory reserve until the total amount set aside reaches 50% of their respective registered capital. Where the aggregate balance of statutory reserve is insufficient to cover loss in the previous financial year, the current financial year's profits shall first be used to cover the loss before any statutory reserve is set aside. Our PRC subsidiaries may also allocate a portion of their after-tax profits to discretionary reserve where our PRC subsidiaries have set aside statutory reserve from their after-tax profits, subject to a resolution of the shareholders. These reserves are not distributable as cash dividends. Furthermore, if our PRC subsidiaries incur debt on their own behalf, the instruments governing such debt may restrict their ability to pay dividends or make other payments to us.

### DISTRIBUTABLE RESERVES

As of May 31, 2022, we did not have any distributable reserves.

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## FINANCIAL INFORMATION

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### [REDACTED] EXPENSES

[REDACTED] expenses represent professional fees, [REDACTED] commissions and other fees incurred in connection with the [REDACTED]. [REDACTED] expenses to be borne by us are estimated to be approximately RMB[REDACTED] (HK\$[REDACTED]) (assuming the [REDACTED] is not exercised and based on the [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the [REDACTED] range), including (i) [REDACTED]-related expenses, including [REDACTED] commissions and fees of approximately RMB[REDACTED] million (HK\$[REDACTED] million), and (ii) non-[REDACTED]-related expenses of approximately RMB[REDACTED] (HK\$[REDACTED]), comprising (a) fees and expenses of legal advisors and reporting accountants of approximately RMB[REDACTED] (HK\$[REDACTED]) and (b) other fees and expenses of approximately RMB[REDACTED] (HK\$[REDACTED]).

Our [REDACTED] expenses as a percentage of gross [REDACTED] estimated to be received by us from the [REDACTED] is [REDACTED]%, assuming an [REDACTED] of HK\$[REDACTED] per Share (being the mid-point of the indicative [REDACTED] range stated in this document) and assuming that the [REDACTED] is not exercised. In 2020 and 2021 and the five months ended May 31, 2022, the [REDACTED] expenses charged to profit or loss were RMB[REDACTED], RMB[REDACTED] and RMB[REDACTED], respectively. After May 31, 2022, we estimate that additional [REDACTED] expenses of approximately RMB[REDACTED] will be incurred by our Company, approximately RMB[REDACTED] of which is expected to be charged to our consolidated statements of profit or loss, and approximately RMB[REDACTED] of which is expected to be recognized directly as a deduction from equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

### NO MATERIAL ADVERSE CHANGE

Our Directors confirm that, after performing all the due diligence work which our Directors consider appropriate, that, as of the date of this document, there has been no material adverse change in our financial or trading position or prospects since May 31, 2022 and up to the date of this document.

### IMPACT OF THE COVID-19 OUTBREAK

Since December 2019, the outbreak of a novel strain of coronavirus causing coronavirus disease 2019 (COVID-19) has materially and adversely affected the global economy. Since late July 2021, the COVID-19 has recurred in the form of the Delta variant in China and overseas, and since November 2021, another variant designated as Omicron (together with the Delta variant, the “COVID-19 Variants”) has also been discovered in many cases over the globe (the “Recurrences”). Recently, the Chinese government has implemented emergency measures in certain cities or regions, including Shanghai, in response to the Recurrence, including travel restrictions, mandatory cessations of business operations, mandatory quarantines, and limitations on social and public gathering and lockdowns.

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## FINANCIAL INFORMATION

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While we experienced delays in the patient enrollment process and data entry for certain of our clinical trials in China (including the temporary delays in the patient enrollment in Shanghai since March 2022), the outbreak of COVID-19 and the Recurrences have not caused any early termination of our clinical trials or necessitated removal of any patients enrolled in our clinical trials. We have employed various measures to mitigate any impact the COVID-19 outbreak and the Recurrences may have on our ongoing clinical trials in China, including providing alternative methods for safety and efficacy assessment, continuing patient visit through remote access, supplying enrolled patients with study medication through monitored delivery process, and engaging necessary communications with our investigators to identify and address any issues that may arise. For our U.S. and Japan trials, we did not experience any material difficulties arising from the outbreak of COVID-19 and the Recurrences in our patient enrollment and trial management, and the progress of those trials is generally in line with our trial development plan despite minor delays. Based on the foregoing, we currently expect that our ongoing clinical trials will not be significantly affected by the outbreak of COVID-19 and the Recurrences. We may adjust our current clinical development plan covering multiple jurisdictions to the extent necessary depending on the status of the COVID-19 outbreak and the Recurrences worldwide. Currently, we do not expect it to have any material long-term impact on data quality of our clinical trials or our overall clinical development plans.

Our Directors have carried out a holistic review of the impact of the COVID-19 outbreak and the Recurrences on our operations, and confirmed that the COVID-19 outbreak and the Recurrences did not have any long-term material adverse impact on our business operation and financial performance as of the Latest Practicable Date, mainly because (i) the Recurrences are less severe in terms of its lower modality rate and higher curability rate than the early outbreak and (ii) the Chinese government authorities have responded quickly to the COVID-19 and the Recurrences and made controlling efforts timely. However, due to the prevalence of the Recurrences in Shanghai since March 2022, as of the Latest Practicable Date, we had experienced temporary delays in the patient enrollment in Shanghai and our sales activities in Shanghai had been temporarily affected. We have mobilized and will continue to mobilize internal and external resources and leveraged our operating capabilities to minimize the impact on our operations caused by the COVID-19 outbreak and the Recurrences.

The above analyses are made by our management based on currently available information concerning COVID-19 and the Recurrences. It is uncertain whether the continuance or future recurrence of the COVID-19 outbreak in China, the U.S., Japan or the rest of the world will have a material adverse effect on our results of operations, financial position or prospects. For example, with the ongoing COVID-19 outbreak and the Recurrences around the world, we cannot assure you that our clinical development plan covering multiple jurisdictions including the China, the U.S. and will not be adversely affected. For more details, please refer to the paragraphs headed “Risk Factors – Risks Relating to Our Operations – We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control, including the COVID-19 outbreak, which may have a material adverse effect on our business, financial condition and results of operations” in this document. We will continue to monitor and evaluate any impact of the COVID-19 outbreak and the Recurrences on us and adjust our precautionary measures according to the latest developments of the outbreak.

## FINANCIAL INFORMATION

### UNAUDITED PRO FORMA STATEMENT OF ADJUSTED NET TANGIBLE ASSETS

The following unaudited pro forma adjusted consolidated net tangible assets of our Group prepared in accordance with paragraph 4.29 of the Listing Rules and with reference to Accounting Guideline 7 *Preparation of Pro Forma Financial Information for Inclusion in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants for illustration purposes only, and is set out here to illustrate the effect of the [REDACTED] on the consolidated net tangible assets of our Group attributable to owners of the parent as if the [REDACTED] had taken place on May 31, 2022.

The unaudited pro forma statement of adjusted consolidated net tangible assets of our Group has been prepared for illustrative purpose only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of our Group to owners of the parent had the [REDACTED] been completed as of May 31, 2022 or as at any future dates.

	Consolidated net tangible liabilities of the Group attributable to owners of the Company as at May 31, 2022	Estimated net [REDACTED] from the [REDACTED]	Estimated impact to the consolidated net tangible liabilities upon the conversion of preferred shares	Unaudited pro forma adjusted consolidated net tangible assets as at May 31, 2022	Unaudited pro forma adjusted consolidated net tangible assets per Share as at May 31, 2022	
	<i>RMB'000</i> <i>(Note 1)</i>	<i>RMB'000</i> <i>(Note 2)</i>	<i>RMB'000</i> <i>(Note 3)</i>	<i>RMB'000</i>	<i>RMB</i> <i>(Note 4)</i>	<i>HK\$</i> <i>(Note 5)</i>
Based on an [REDACTED] of HK\$[REDACTED] per Share	(2,510,716)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Based on an [REDACTED] of HK\$[REDACTED] per Share	(2,510,716)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Based on an [REDACTED] of HK\$[REDACTED] per Share	(2,510,716)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

*Notes:*

- (1) The consolidated net tangible liabilities of our Group attributable to our equity holders as of May 31, 2022 was arrived at after deducting intangible assets of RMB887,000 from the consolidated net liabilities attributable to our owners as of May 31, 2022 of RMB2,509,829,000 set out in the Accountants' Report in Appendix I to this document.

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## FINANCIAL INFORMATION

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- (2) The estimated net [REDACTED] from the [REDACTED] are based on an [REDACTED] of HK\$[REDACTED] per Share, HK\$[REDACTED] per Share and HK\$[REDACTED] per Share, after deduction of the [REDACTED] fees and other related expenses payable by our Company and do not take into account any Shares which may be issued upon the exercise of the [REDACTED].
- (3) Upon the [REDACTED] and the completion of the [REDACTED], all Preferred Shares will be automatically converted into Ordinary Shares. The Preferred Shares will then be transferred from liabilities to equity. Accordingly, for the purpose of the unaudited pro forma financial information, the unaudited pro forma adjusted net tangible liabilities attributable to owners of the parent will be decreased by RMB3,276,433,000 being the carrying amounts of the preferred shares as of May 31, 2022.
- (4) The unaudited pro forma adjusted consolidated net tangible assets per Share is arrived at after adjustments referred to notes 2 and 3 above and on the basis that (i) [REDACTED] Shares are in issue, assuming the [REDACTED] has been completed on May 31, 2022, and (ii) 32,693,837 Shares allotted and issued to three BVI entities, namely Immunal Medixin US Limited, Immunal Medixin Cino L. Limited and Immunal Medixin Cino Limited were not included in the calculation since they were recognized as treasury shares in the Accountants’ Report.
- (5) The unaudited pro forma adjusted consolidated net tangible assets per Share is converted into HK\$ at an exchange rate of HK\$1.00 to RMB0.8592 prevailing on July 18, 2022.
- (6) No adjustment has been made to the unaudited pro forma adjusted consolidated net tangible assets to reflect any trading results or other transactions of our Group entered into subsequent to May 31, 2022.

### DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, except as otherwise disclosed in this document, as of the Latest Practicable Date, there was no circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

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## **RELATIONSHIP WITH OUR SINGLE LARGEST SHAREHOLDER**

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### **OUR SINGLE LARGEST SHAREHOLDER**

As of the Latest Practicable Date, the equity interest of our Company was controlled as to 31.06% in aggregate by Dr. Gong through (i) Dragon Prosper Holdings Limited, his holding entity, and (ii) the share incentive platforms, namely Immunal Medixin US Limited, Immunal Medixin Cino L. Limited and Immunal Medixin Cino Limited, which are managed by a trustee who shall exercise voting rights in accordance with Dr. Gong’s instructions. Please refer to the paragraphs headed “History, Development and Corporate Structure – Share Incentive Scheme” for more details.

Immediately following the completion of the [REDACTED], Dr. Gong will be interested in approximately [REDACTED] of our issued share capital, assuming the [REDACTED] is not exercised. Therefore, Dr. Gong is our single largest Shareholder upon [REDACTED].

### **NO COMPETITION AND CLEAR DELINEATION OF BUSINESS**

Dr. Gong has confirmed that, as of the Latest Practicable Date, he did not have any interest in any business, other than our business, which compete, or is likely to compete, either directly or indirectly, with our business and would require disclosure under Rule 8.10 of the Listing Rules.

### **INDEPENDENCE FROM OUR SINGLE LARGEST SHAREHOLDER**

Having considered the following factors, our Directors are satisfied that we are capable of carrying on our business independently from Dr. Gong after the [REDACTED].

#### **Management Independence**

Our Directors are of the view that our Board as a whole, together with our senior management team, is able to perform the managerial role in our Group independently for the following reasons:

- (a) upon [REDACTED], our Board of Directors will consist of seven Directors, including Dr. Gong as an executive Director, three non-executive Directors and three independent non-executive Directors. Dr. Gong has not exerted any influence on the decision-making of any other Directors on the management of the Board. Each Director is aware of his fiduciary duties as a director which require, among other things, that he acts for the benefit and in the interest of our Company and does not allow any conflict between his duties as a Director and his personal interests;
- (b) our daily management and operations are carried out by a senior management team. Our senior management team has substantial experience in the industry in which our Company is engaged, and will therefore be able to make business decisions that are in the best interests of our Group;



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## RELATIONSHIP WITH OUR SINGLE LARGEST SHAREHOLDER

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- (c) we have three independent non-executive Directors and certain matters of our Company must always be referred to the independent non-executive Directors for review;
- (d) in respect of any contract or arrangement or any other proposal whatsoever in which a Director or any of his close associates (or, if required by the Listing Rules, his other associates) has any material interest, such Director shall abstain from voting on the resolutions and shall not be counted towards the quorum for the voting;
- (e) where a Shareholders' meeting is held to consider a proposed transaction in which Dr. Gong has a material interest, Dr. Gong shall abstain from voting on the resolutions and shall not be counted towards the quorum for the voting; and
- (f) our Company has appointed China Securities (International) Corporate Finance Company Limited as our compliance adviser, which will provide advice and guidance to our Group in respect of compliance with the applicable laws and Listing Rules including various requirements relating to Directors' duties and corporate governance.

Based on the above, our Directors are satisfied that our Board as a whole together with our senior management team is able to perform the managerial role in our Group independently.

### **Operational Independence**

We have full rights to make business decisions and to carry out our business. On the basis of the following reasons, our Directors consider that our Company will continue to be operationally independently after [REDACTED]:

- (a) we are not reliant on trademarks owned by Dr. Gong;
- (b) we are the holder of all relevant licenses material to the operation of our business and have sufficient capital, equipment and employees to operate our business independently;
- (c) we have our own administrative and corporate governance infrastructure, including our own accounting, legal and human resources departments;
- (d) other than engaging Dr. Gong as our executive Director, our Directors do not expect that there will be any connected transactions between our Group and Dr. Gong or his associates upon or shortly after [REDACTED]; and
- (e) Dr. Gong does not have any interest which competes or is likely to compete with the business of our Group.

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## RELATIONSHIP WITH OUR SINGLE LARGEST SHAREHOLDER

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### Financial Independence

We have independent internal control and accounting systems. We also have an independent finance department responsible for discharging the treasury function. We are capable of obtaining financing from third parties, if necessary, without reliance on Dr. Gong. As of December 31, 2021, the amounts due to Dr. Gong were approximately RMB150,000. The aforesaid amounts due to Dr. Gong is expected to be fully repaid before [REDACTED]. Save as disclosed, no loans or guarantees provided by, or granted to, Dr. Gong were outstanding as of the Latest Practicable Date.

Based on the above, our Directors are of the view that they and our senior management are capable of carrying on our business independently of, and do not place undue reliance on Dr. Gong after the [REDACTED].

### NON-COMPETITION UNDERTAKING

Dr. Gong provided a Non-Competition Undertaking in favour of us on [●], pursuant to which he undertook not to, either directly or indirectly, compete with our business, which includes novel drug development for cancer treatment (the “**Restricted Activities**”). Dr. Gong further irrevocably undertaken in the Non-Competition Undertaking that, during the term of the Non-Competition Undertaking, he will not, alone or with a third party, in any form, directly or indirectly, engage in, participate in, support to engage in or participate in any business that competes, or is likely to compete, directly or indirectly, with the Restricted Activities.

### CORPORATE GOVERNANCE

Other than deviation from Code Provision C.2.1 as disclosed in “Directors and Senior Management – Corporate Governance,” our Company will comply with the provisions of the Code, which sets out principles of good corporate governance in relation to, among other matters, directors, the chairman and chief executive officer, board composition, the appointment, re-election and removal of Directors, their responsibilities and remuneration and communications with Shareholders.

Our Directors recognize the importance of good corporate governance to protect the interests of our Shareholders. We would adopt the following corporate governance measures to manage potential conflict of interests between our Group and Dr. Gong:

- (a) where a Shareholders meeting is to be held for considering proposed transactions in which Dr. Gong has a material interest, Dr. Gong shall not vote on the resolutions and shall not be counted in the quorum for the voting;
- (b) the Company has established internal control mechanisms to identify connected transactions. Upon [REDACTED], if the Company enters into connected transactions with Dr. Gong or his associates, the Company will comply with the applicable Listing Rules;

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## RELATIONSHIP WITH OUR SINGLE LARGEST SHAREHOLDER

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- (c) our Board will consist of three non-executive Directors and three independent non-executive Directors to ensure that our Board is able to effectively exercise independent judgment in its decision-making process and provide independent advice to our Shareholders. Our independent non-executive Directors, details of whom are set out in “Directors and Senior Management” individually and together possess the requisite knowledge and experience. All of our independent non-executive Directors are experienced. They will review whether there is any conflict of interests between the Group and Dr. Gong annually and provide impartial and professional advice to protect the interest of our minority Shareholders;
- (d) in the event that the independent non-executive Directors are requested to review any conflicts of interests circumstances between the Group and Dr. Gong, Dr. Gong and/or the Company shall provide the independent non-executive Directors with all necessary information and the Company shall disclose the decisions of the independent non-executive Directors (including why business opportunities referred to it by Dr. Gong were not taken up) either in its annual report or by way of announcements;
- (e) where the advice from independent professional, such as that from financial adviser, is reasonably requested by our Directors (including the independent non-executive Directors), the appointment of such independent professional will be made at our Company’s expenses; and
- (f) we have appointed China Securities (International) Corporate Finance Company Limited as our compliance adviser, which will provide advice and guidance to us in respect of compliance with the applicable laws and the Listing Rules including various requirements relating to corporate governance.

Based on the above, our Directors are satisfied that sufficient corporate governance measures have been put in place to manage conflicts of interest between our Group and Dr. Gong, and to protect minority Shareholders’ rights after the [REDACTED].

## SHARE CAPITAL

### AUTHORIZED AND ISSUED SHARE CAPITAL

The following is a description of the authorized and issued share capital of our Company in issue and to be issued as fully paid prior to and immediately following the completion of the [REDACTED]:

Authorized share capital	Aggregate par value (HK\$)
500,000,000 Shares of par value of HK\$0.001 each as of the Latest Practicable Date	500,000
<i>Issued and to be issued, fully paid or credited as fully paid immediately upon completion of the [REDACTED]</i>	
239,290,252 Shares in issue as of the date of this document (assuming all Preferred Shares are converted into Shares on a 1:1 basis)	239,290.252
[REDACTED] Shares to be issued pursuant to the [REDACTED]	[REDACTED]
[REDACTED] Shares to be issued under the [REDACTED] assuming no exercise of the [REDACTED]	[REDACTED]
<b><u>[REDACTED]</u> Total</b>	<b><u>[REDACTED]</u></b>

### ASSUMPTION

The above table assumes that the [REDACTED] becomes unconditional and the Shares are issued pursuant to the [REDACTED] and the [REDACTED]. The above table does not take into account any Shares which may be allotted and issued pursuant to the exercise of the [REDACTED] or any Shares which may be issued or repurchased by our Company pursuant to the general mandates granted to our Directors to issue or repurchase Shares as described below.

### RANKING

The [REDACTED] are Ordinary Shares in the share capital of our Company and will rank equally in all respects with all Shares then in issue or to be issued as set forth in the above table, and will qualify and rank in full for all dividends or other distributions declared, made or paid after the date of this document.

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## SHARE CAPITAL

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### CIRCUMSTANCES UNDER WHICH GENERAL MEETINGS ARE REQUIRED

Our Company will have only one class of shares upon completion of the [REDACTED], namely Ordinary Shares, and each ranks pari passu with each other. Pursuant to the Cayman Companies Act and the terms of our Memorandum and Articles of Association, our Company may from time to time by ordinary resolution (i) increase its capital; (ii) consolidate and divide its capital into shares of larger amount; (iii) divide its shares into several classes; (iv) subdivide its shares into shares of smaller amount; and (v) cancel any shares which have not been taken. In addition, our Company may subject to the provisions of the Cayman Companies Act reduce its share capital or capital redemption reserve by passing a special resolution. For details, please refer to the section headed “Appendix III – Summary of the Constitution of the Company and Cayman Islands Company Law” in this document.

Pursuant to the terms of our Memorandum and Articles of Association, all or any of the special rights attached to the share or any class of shares may be varied, modified or abrogated either with the consent in writing of the holders of not less than three-fourths in nominal value of the issued shares of that class or with the sanction of a special resolution passed at a separate general meeting of the holders of the shares of that class. For details, please refer to the section headed “Appendix III – Summary of the Constitution of the Company and Cayman Islands Company Law” in this document.

Further, our Company will also hold general meetings from time to time as may be required under our Articles of Association, a summary of which is set out in the section headed “Appendix III – Summary of the Constitution of the Company and Cayman Islands Company Law” in this document.

### GENERAL MANDATE TO ISSUE SHARES

Subject to the [REDACTED] becoming unconditional, our Directors have been granted a general unconditional mandate to allot, issue and deal with Shares and to make or grant offers, agreements or options which might require such Shares to be allotted and issued or dealt with at any time subject to the requirement that the aggregate nominal value of the Shares so allotted and issued or agreed conditionally or unconditionally to be allotted and issued, shall not exceed the sum of:

- (a) 20% of the aggregate nominal value of the share capital of the Company in issue immediately following completion of the [REDACTED]; and
- (b) the nominal amount of our share capital repurchased by the Company (if any) pursuant to the repurchase mandate (as mentioned below).

This mandate does not cover Shares to be allotted, issued, or dealt with under a rights issue or scrip dividend scheme or similar arrangements or a specific authority granted by our Shareholders or upon the exercise of the [REDACTED].

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## SHARE CAPITAL

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This mandate to issue Shares will remain in effect until:

- (i) at the conclusion of our next annual general meeting; or
- (ii) the expiration of the period within which the next annual general meeting of our Company is required to be held under any applicable laws or the Articles of Association; or
- (iii) it is varied or revoked by an ordinary resolution of our Shareholders at a general meeting,

whichever is the earliest.

For further details of this general mandate, please see the section headed “Appendix IV – Statutory and General Information – A. Further Information about Our Group – 5. Resolutions of the Shareholders of the Company Passed on [●].”

### GENERAL MANDATE TO REPURCHASE SHARES

Subject to the [REDACTED] becoming unconditional, our Directors have been granted a general unconditional mandate to exercise all the powers of our Company to repurchase Shares with an aggregate nominal value of not more than 10% of the aggregate nominal value of our share capital in issue immediately following the [REDACTED] (excluding any Shares which may be allotted and issued pursuant to the exercise of the [REDACTED]).

This mandate relates to repurchases made on the Stock Exchange, or on any other stock exchange which the Shares may be listed (and which is recognized by the SFC and the Stock Exchange for this purpose), and made in accordance with all applicable laws and regulations and the requirements of the Listing Rules. A summary of the relevant Listing Rules is set out in the section headed “Appendix IV – Statutory and General Information – A. Further Information about Our Group – 6. Restrictions on Repurchase”.

This general mandate to repurchase Shares will remain in effect until:

- (a) at the conclusion of our next annual general meeting; or
- (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 or the Articles of Association; or
- (c) it is varied or revoked by an ordinary resolution of our Shareholders at a general meeting, whichever is the earliest.

For further details of this general mandate, please see the paragraph headed “A. Further Information about Our Group – 5. Resolutions of the Shareholders of the Company Passed on [●]” in Appendix IV to this document.

## SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and the [REDACTED] and without taking into account any Shares which may be issued pursuant to the exercise of the [REDACTED], the following persons will have an interest or short position in the Shares or the underlying Shares which would fall to be disclosed to 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 issued voting shares of our Company:

Name	Capacity/nature of interest <sup>(1)</sup>	Number of Shares held as of the Latest Practicable Date	Approximate percentage of shareholding in the total issued share capital of our Company as of the Latest Practicable Date	Number of Shares held immediately following completion of the [REDACTED] and the [REDACTED]	Approximate percentage of shareholding in the total issued share capital of our Company immediately following completion of the [REDACTED] and the [REDACTED]
Dr. Gong	Interest of controlled corporation <sup>(2)</sup>	35,992,100	15.04%	[REDACTED]	[REDACTED]%
	Interest held through voting powers entrusted by other persons <sup>(3)</sup>	38,337,760	16.02%	[REDACTED]	[REDACTED]%
Simcere Pharmaceutical Group Limited	Beneficial owner	23,047,300	9.63%	[REDACTED]	[REDACTED]%
Dragon Prosper Holdings Limited	Beneficial owner <sup>(2)</sup>	35,992,100	15.04%	[REDACTED]	[REDACTED]%
Immunal Medixin US Limited	Beneficial owner <sup>(3)</sup>	19,143,220	8.00%	[REDACTED]	[REDACTED]%
KASTLE LIMITED	Trustee <sup>(3)</sup>	19,143,220	8.00%	[REDACTED]	[REDACTED]%
Shanghai Zhenlu Enterprise Management Consulting Partnership (Limited Partnership)	Beneficial owner <sup>(4)</sup>	13,817,280	5.77%	[REDACTED]	[REDACTED]%
Shenzhen Efung	Interest in controlled corporation <sup>(4)</sup>	13,817,280	5.77%	[REDACTED]	[REDACTED]%

## SUBSTANTIAL SHAREHOLDERS

Name	Capacity/nature of interest <sup>(1)</sup>	Number of Shares held as of the Latest Practicable Date	Approximate percentage of shareholding in the total issued share capital of our Company as of the Latest Practicable Date	Number of Shares held immediately following completion of the [REDACTED] and the [REDACTED]	Approximate percentage of shareholding in the total issued share capital of our Company immediately following completion of the [REDACTED] and the [REDACTED]
Shenzhen Efung Investment Management Enterprise (L.P.)	Interest in controlled corporation <sup>(4)</sup>	13,817,280	5.77%	[REDACTED]	[REDACTED]%
Shenzhen Efung Holding	Interest in controlled corporation <sup>(4)</sup>	13,817,280	5.77%	[REDACTED]	[REDACTED]%
Zhu Pai	Interest held through voting powers entrusted by other persons <sup>(4)</sup>	13,817,280	5.77%	[REDACTED]	[REDACTED]%
Zhu Jinqiao	Interest held through voting powers entrusted by other persons <sup>(4)</sup>	13,817,280	5.77%	[REDACTED]	[REDACTED]%

*Notes:*

- (1) All interests stated are long positions.
- (2) Dr. Gong is the sole director and sole shareholder of Dragon Prosper Holdings Limited and is deemed to be interested in the Shares held by Dragon Prosper Holdings Limited.
- (3) Immunal Medixin US Limited and certain other entities are share incentive platforms managed by KASTLE LIMITED as trustee, who, in accordance with the trust deed, acts in accordance with Dr. Gong’s instructions when exercising voting rights attached to the Shares held by itself. Dr. Gong is deemed to be interested in the Shares held by the trustee of the Immunal Medixin US Limited.
- (4) Shenzhen Efung is interested in our Shares through its affiliate, Shanghai Zhenlu Enterprise Management Consulting Partnership (Limited Partnership). Shenzhen Efung’s executive partner is Shenzhen Efung Investment Management Enterprise (L.P.), which is in turn owned as to 51% by Shenzhen Efung Holding. Shenzhen Efung Holding is in turn owned as to 54% and 23% by Mr. Zhu Jinqiao and Mr. Zhu Pai respectively. Mr. Zhu Jinqiao and Mr. Zhu Pai shall act in concert in relation to the exercising of their voting rights in Shenzhen Efung Holding. Accordingly, each of Shenzhen Efung, Shanghai Zhenlu Enterprise Management Consulting Partnership (Limited Partnership), Shenzhen Efung Investment Management Enterprise (L.P.), Shenzhen Efung Holding, Mr. Zhu Pai and Mr. Zhu Jinqiao are deemed to be interested in the Shares held by Shanghai Zhenlu Enterprise Management Consulting Partnership (Limited Partnership).



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## SUBSTANTIAL SHAREHOLDERS

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Except as disclosed above, our Directors are not aware of any other person who will, immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised, and each Preferred Share will be automatically converted to one Share upon the [REDACTED] becoming unconditional), have any interest and/or short positions in the 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, interested in 10% or more of the nominal value of any class of our share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group.

## DIRECTORS AND SENIOR MANAGEMENT

### BOARD OF DIRECTORS

Our Board consists of seven Directors, with one executive Director, three are non-executive Directors and three are independent non-executive Directors. Our Board is responsible for, and has general powers for, the management and conduct of our business.

The table below sets out certain information in respect of the members of the Board.

Name	Position	Age	Date of appointment as Director	Time of joining the Group	Role and responsibility	Relationship with other Directors and senior management
Gong Zhaolong (龔兆龍)	Chairman Executive Director, chief executive officer, Key Founder	58	October 9, 2019	January 30, 2018	Overall strategic planning, business direction and operational management	N/A
Zhu Pai (朱湃)	Non-executive Director	30	June 23, 2021	June 23, 2021	Participating in decision-making in respect of major matters such as corporate and business strategies	N/A
Zhou Feng (周峰)	Non-executive Director	40	October 9, 2019	October 9, 2019	Participating in decision-making in respect of major matters such as corporate and business strategies	N/A

## DIRECTORS AND SENIOR MANAGEMENT

Name	Position	Age	Date of appointment as Director	Time of joining the Group	Role and responsibility	Relationship with other Directors and senior management
Chen Yawen (陳雅雯)	Non-executive Director	31	July 12, 2022	July 12, 2022	Participating in decision-making in respect of major matters such as corporate and business strategies	N/A
Li Jin	Independent Non-executive Director	57	June 25, 2021 (with effect from [REDACTED])	June 25, 2021	Supervising and providing independent judgment to our Board	N/A
Lin Tat Pang (連達鵬)	Independent Non-executive Director	66	June 25, 2021 (with effect from [REDACTED])	June 25, 2021	Supervising and providing independent judgment to our Board	N/A
Liu Xinguang (劉信光)	Independent Non-executive Director	60	June 25, 2021 (with effect from [REDACTED])	June 25, 2021	Supervising and providing independent judgment to our Board	N/A

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## DIRECTORS AND SENIOR MANAGEMENT

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The following sets forth the biographies of our Directors:

### Executive Director

**Gong Zhaolong** (龔兆龍), the Key Founder of our Group, aged 58, has been a Director and chief executive officer since October 9, 2019 and was re-designated as an executive Director on June 25, 2021. Dr. Gong has been our chief executive officer since January 30, 2018, and the chairman of the Board since October 11, 2019. Dr. Gong is primarily responsible for the overall strategic planning, business direction and operational management of our Group. Dr. Gong also holds the following positions in the subsidiaries of our Group:

<u>Name of subsidiary</u>	<u>Position(s)</u>	<u>Period</u>
Full Goal Trading Limited	Director	November 2019 to present
Integral Lane Holdings Limited	Director	November 2019 to present
3DMed Hong Kong	Director	November 2019 to present
3DMed Beijing	Executive director	October 10, 2019 to present
3DMed Sichuan	Executive director and general manager	October 25, 2019 to present
3D Medicines	Executive director and general manager	June 7, 2018 to present
	Chief executive officer	January 30, 2018 to present
3DMed Xuzhou	Executive director and general manager	November 24, 2020 to present
3DMed Shanghai	Executive director	October 10, 2019 to present
3dMed Qingdao	Executive director and general manager	June 11, 2021 to present

Dr. Gong has around 24 years of experience in the pharmaceutical industry. From October 1998 to March 2008, Dr. Gong worked as a new drug reviewer of the Centre for Drug Evaluation and Research in the United States FDA. Dr. Gong then served as a general manager of Beijing Labsay Luxem Pharmaceutical Technology Co., Ltd. (北京萊博賽路森藥物科技有限公司) from March 2012 to April 2013. From May 2013 to July 2014, he was new drug development and regulatory affairs vice president (新藥開發和藥證事務副總裁) of BeiGene (Beijing) Biotechnology Co., Ltd. (百濟神州(北京)生物科技股份有限公司), an indirectly wholly-owned subsidiary of BeiGene, Ltd. (“**BeiGene**”), which was subsequently listed on NASDAQ (stock code: BGNE) and the Stock Exchange (stock code: 6160). From September 2015 to January 2018, Dr. Gong worked at the Predecessor Holdco.

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## DIRECTORS AND SENIOR MANAGEMENT

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From September 2015 to August 2021, Dr. Gong served as an independent director of Shutaishen (Beijing) Biopharmaceutical Co., Ltd. (舒泰神(北京)生物製藥股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 300204). Since July 2017, he has also served as an independent director of Shandong Jincheng Pharmaceutical Group Co., Ltd. (山東金城醫藥集團股份有限公司), a company also listed on the Shenzhen Stock Exchange (stock code: 300233).

Dr. Gong obtained his master’s degree in toxicology from Peking Medical College (北京醫科大學) (currently known as Peking University Health Science Center (北京大學醫學部)) in the PRC in July 1987. He proceeded to obtain his PhD in toxicology from New York University in the United States in September 1996. Dr. Gong is a member of various industry associations, including the China Advisory Committee of the Drug Information Association, the translational medical expert committee (轉化醫學專家委員會) of the Chinese Society of Clinical Oncology, the International Innovative Drug Supervision Professional Committee of the China Pharmaceutical Innovation and Research Development Association (中國醫藥創新促進會國際創新藥物監管專業委員會), an editorial board member of the Chinese Journal of New Drugs (中國新藥雜誌) and Progress in Pharmaceutical Sciences (藥學進展).

### Non-executive Directors

**Zhu Pai (朱湃)**, aged 30, has been a Director since June 23, 2021 and was re-designated as a non-executive Director on June 25, 2021. He participates in decision-making in respect of major matters such as corporate and business strategies.

Mr. Zhu has around 6 years of experience in the asset management sector. From December 2016 to May 2018, he was the project manager of the asset management headquarters of Guosen Securities Co., Ltd (國信證券股份有限公司). From August 2016 to March 2021, Mr. Zhu has been a director of Shenzhen Jinbaihui Investment Management Co., Ltd. (深圳金柏匯投資管理有限公司). Mr. Zhu joined the Efung investment group in May 2018, and has been an authorized representative of the executive partner of Shenzhen Efung Investment Management Enterprise (Limited Partnership) (深圳市倚鋒投資管理企業(有限合伙)) since July 2018, an executive partner of Shenzhen Qiaoyue Entrepreneurship Center Enterprise (Limited Partnership) (深圳市喬悅創業中心企業(有限合伙)) since October 2019, an executive director and general manager of Shenzhen Efung Investment Group Co., Ltd. (深圳市倚鋒投資發展有限公司), and an executive director and general manager of Hainan Efung Junma Fund Management Co., Ltd. (海南倚鋒駿馬私募基金管理有限公司) since December 2020. He was also an executive director and general manager of Shenzhen Yixing Investment Management Co., Ltd. (深圳市倚鋒控股集團有限公司(曾用名:深圳易星投資管理有限公司)) from June 2018 to March 2021 and the supervisor of the foregoing company since March 2021, and a director of Shenzhen Tuwei Anchuang Technology Development Co., Ltd. (深圳市圖微安創科技開發有限公司) since May 2019. Since August 2020, he has been a director of Heyuan Biotechnology (Shanghai) Co., Ltd. (和元生物技術(上海)股份有限公司) a company listed on the Shanghai Stock Exchange STAR Market (stock code: 688238) since March 2022. Since December 2020, he has been a director of Shenzhen Shineng Ketai Energy Technology Co., Ltd. (深圳世能科泰能源技術股份有限公司).

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## DIRECTORS AND SENIOR MANAGEMENT

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Mr. Zhu obtained his bachelor's degree in economics from University of California, San Diego in the United States in March 2016.

Set out below is a limited partnership established in the PRC which was dissolved when Mr. Zhu was its executive director:

<b>Name of the enterprise</b>	<b>Nature of business immediately before dissolution</b>	<b>Date of dissolution</b>	<b>Nature of dissolution</b>
Shenzhen Qiaoyue Entrepreneurship Center Enterprise (Limited Partnership) (深圳市喬悅創業中心企業(有限合夥))	Investment holding	February 9, 2022	Voluntary deregistration

As confirmed by Mr. Zhu, the above deregistered limited partnership was solvent and in compliance with all relevant laws and regulations immediately before its dissolution, that there was no wrongful act on his part leading to the dissolution and he is not aware of any actual or potential claim which has been or will be made against him as a result of the dissolution and de-registration of the above limited partnership.

**Zhou Feng (周峰)**, aged 40, has been a Director since October 9, 2019, and was re-designated as a non-executive Director on June 25, 2021. He participates in decision-making in respect of major matters such as corporate and business strategies.

Mr. Zhou has around 11 years of experience in corporate finance. From June 2011 to August 2013, he was an analyst of China International Capital Corporation Limited (中國國際金融有限公司). From August 2013 to June 2015, he was a senior fund manager at Sinopharm Capital Co., Limited (國藥資本管理有限公司). He was a vice president at Bank of America Merrill Lynch (Asia Pacific) Limited from May 2015 to June 2016 before joining Guoxin Venture Capital Management (Shenzhen) Co., Ltd. (國新風險投資管理(深圳)有限公司) as an executive director in May 2017.

Mr. Zhou obtained his bachelor's degree in accounting from Fudan University (復旦大學) in July 2005.

**Chen Yawen (陳雅雯)**, aged 31, has been a Director since July 12, 2022, and was re-designated as a non-executive Director on the same date. She participates in decision-making in respect of major matters such as corporate and business strategies.

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## DIRECTORS AND SENIOR MANAGEMENT

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Ms. Chen has involved herself in business incubation programmes and venture capital. For instance, from October 2018 to December 2020, she consulted and incubated projects with Xinli001.com (壹心裡), a startup business providing online mental health services and networks for more than 20 million users in China. From 2020 to 2021, Ms. Chen served as an investment advisor at Waveray Capital (潮信投資), a China and US-based venture firm focusing on biomedical technology. Since February 2021, she has been an investment director of Fang Fund Partners (芳晟股權投資基金), primarily focused on sustainability investing.

Ms. Chen obtained her bachelor’s degree in computer science and art history from Carleton College in the United States in June 2015.

### Independent Non-executive Directors

**Li Jin**, aged 57, was appointed as an independent non-executive Director on June 25, 2021 (with effect from [REDACTED]). He is responsible for providing independent advice and judgment to our Board.

Dr. Li has been the chairman of the board and general manager of Beijing Orbiopharm Co., Ltd. (北京歐博方醫藥科技有限公司) since August 2015, chairman of the board and manager of Beijing Yuanbofang Co., Ltd. (北京元博方醫藥科技有限公司) since February 2014, and chairman of the board of Qingdao Orbiopharm Co., Ltd. (青島歐博方醫藥科技有限公司) since November 2013 and Qingdao Pet Love Animal Hospital Management Co., Ltd. (青島寵之愛動物醫院管理有限公司) since August 2018. He has also served as a director in Yaodu (Beijing) Medical Information Consulting Co., Ltd. (藥渡(北京)醫藥信息諮詢有限公司) since July 2017, and Beijing Zhongguancun Shangdi Biotechnology Development Co., Ltd. (北京中關村上地生物科技發展有限公司) since September 2021. Since December 2018, he has served as an independent director at Chengdu Easton Biopharmaceuticals Co., Ltd (成都苑東生物製藥股份有限公司), a company listed on the Shanghai Stock Exchange STAR Market (stock code: 688513).

Dr. Li obtained his Ph.D. in chemistry from the University of Wisconsin-Milwaukee in the United States in May 1999. He has published more than 25 papers and 14 book chapters in the chemistry field, and is the inventor of more than 30 patents. He also obtained the Fund Practicing Qualification Certificate (基金從業資格證) in September 2018 from the Asset Management Association of China (中國證券投資基金業協會), and the independent director certificate issued by the Shanghai Stock Exchange in November 2018.

**Lin Tat Pang (連達鵬)**, aged 66, was appointed as an independent non-executive Director on June 25, 2021 (with effect from [REDACTED]). He is responsible for providing independent advice and judgment to our Board.

Dr. Lin has 42 years of experience in accounting, finance and public offerings. Dr. Lin served as assistant accountant, accounting manager and chief accountant in Sun Hung Kai Securities Limited during 1980 to 1988. He was an executive director at Sun Hung Kai Investment Services Limited and Sun Hung Kai Forex & Bullion Co. Limited from December

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## DIRECTORS AND SENIOR MANAGEMENT

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1989 to December 1992. From November 1990 to November 1992, he was the company secretary of Sun Hung Kai & Co. Limited (stock code: 86), a company listed on the Hong Kong Stock Exchange. Subsequently, he worked for Hong Kong Exchanges and Clearing Limited and the Hong Kong Stock Exchange between December 1992 and March 2013, and his last position was senior consultant to the Listing, Listing & Regulatory Affairs Division of Hong Kong Exchanges and Clearing Limited.

Dr. Lin was an adjunct professor of Huazhong University of Science and Technology Law School (華中科技大學法學院) in the PRC from May 2009 to May 2012, and a visiting professor of the same university from December 2011 to December 2014. He was also a visiting professor of the Southwest University of Political Science and Law (西南政法大學) in the PRC from May 2012 to May 2015. From October 2015 to June 2020, he was a part-time lecturer at the Faculty of Business, the City University of Macau.

Dr. Lin also serves as an independent non-executive director of two companies listed on the Hong Kong Stock Exchange. He has been an independent non-executive director of China Aluminum Cans Holdings Limited (stock code: 6898) since June 2013, and that of Leadway Technology Investment Group Limited (formerly known as HNA Technology Investments Holdings Limited) (stock code: 2086) since December 2017.

Dr. Lin obtained his Doctor of Law, Master of Law and Bachelor of Law from Peking University (北京大學) in the PRC in 2009, 1998 and 1992 respectively. He also completed his Postgraduate Certificate in Hong Kong Law in City University of Hong Kong (previously known as City Polytechnic of Hong Kong) in November 1993. Dr. Lin has been a member of the Hong Kong Institute of Certified Public Accountants since May 1983 and a fellow of the Chartered Association of Certified Accountants, United Kingdom since August 1987. He has been also a member of the Chartered Institute of Arbitrators, United Kingdom since February 2000.

**Liu Xinguang (劉信光)**, aged 60, was appointed as an independent non-executive Director on June 25, 2021 (with effect from [REDACTED]). He is responsible for providing independent advice and judgment to our Board.

From October 1988 to September 1994, he worked as a civil servant in the Guangshan County Committee of the Communist Party in Henan Province. From October 1994 to November 1997, he was a reporter at Henan Economic Daily (河南經濟日報). From December 1997 to December 1999, he was the head of the news department at Henan Business Daily (河南商報), which belongs to Xinhua News Agency.

Mr. Liu has around 21 years of experience in investment banking and stock investments. From October 2001 to August 2003, he was a vice president of Bestar Investment Consultant Co., Ltd. (北京博星證券投資顧問有限公司). Since September 2004, he has been a vice president of Beijing Global Bank Securities Investment Co., Ltd. (北京環球銀證投資有限公司). From July 2014 to August 2020, he served as an independent director of Zhejiang Yinlun Machinery Co., Ltd (浙江銀輪機械股份有限公司), a company listed on the Shenzhen stock



## DIRECTORS AND SENIOR MANAGEMENT

exchange (stock code: 002126). Since April 2019, he has been an independent director of Angel Yeast Co., Ltd. (安琪酵母股份有限公司), a company listed on the Shanghai stock exchange (stock code: 600298). Since October 2018, he has been an expert member of the Independent Board Committee of Association of Listed Companies (中國上市公司協會獨立董事委員會).

Mr. Liu obtained his college diploma in Chinese from Henan University in the PRC in June 1988. He obtained the Fund Practicing Qualification Certificate (基金從業資格證) in 2015 and the Securities Practitioner Qualification Certificate (證券從業資格證) in 2004 from the Asset Management Association of China (中國證券投資基金業協會).

Set out below are companies established in the PRC which were dissolved during the period when Mr. Liu was a legal representative, director and/or management:

Name of the Company	Nature of business immediately before dissolution	Date of dissolution	Nature of dissolution
Shanxi Yutai Baoying International Trade Co., Ltd. (山西裕泰寶盈國際貿易有限公司)	Trade and commerce	July 25, 2018	Voluntary dissolution by shareholders
Beijing Yuda Rongtong Investment Consulting Co., Ltd. (北京裕達融通投資顧問有限公司)	Trade and commerce	October 22, 2009	Revocation of business license due to failure to renew business license
Beijing Zhongjin Yuda Investment Consulting Co., Ltd. (北京中金裕達投資顧問有限公司)	Trade and commerce	October 22, 2008	Revocation of business license due to failure to renew business license
Dandong Haohai Global Trade City Development Co., Ltd. (丹東昊海環球商貿城開發有限公司)	Trade and commerce	September 18, 2016	Voluntary dissolution by shareholders
Beijing China Financial Link Investment Consulting Co., Ltd. (北京中金融通投資顧問有限公司)	Trade and commerce	October 22, 2008	Revocation of business license due to failure to renew business license

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## DIRECTORS AND SENIOR MANAGEMENT

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As confirmed by Mr. Liu, the above companies were solvent and in compliance with all relevant laws and regulations immediately before their dissolutions and as far as he was aware, the dissolutions of the above companies have not resulted in any liability or obligation being imposed against him. As confirmed by Mr. Liu, the above companies whose business licenses had been revoked had no actual business operations at the material time and were at a non-operation status. Mr. Liu was not involved in the actual inspection of these procedures. The failure of these companies to go through the formality of annual inspection were due to the negligence of the then designated staff of these relevant companies, and was not due to any default on the part of Mr. Liu.

### General

Our Directors have confirmed that:

- (1) save as disclosed in the section headed "Statutory and General Information – C. Further Information about our Directors and Substantial Shareholders – 2. Further information about our Directors" in Appendix IV to this document, none of our Directors has any existing or proposed service contract with our Company or any of its subsidiaries other than contracts expiring or determinable by the relevant member of our Group within one year without payment of compensation (other than statutory compensation);
- (2) save as disclosed in the section headed "Statutory and General Information – C. Further Information about our Directors and Substantial Shareholders – 1. Disclosure of interests" in Appendix IV to this document and above, each of our Directors has no interests in the Shares within the meaning of Part XV of the SFO;
- (3) save as disclosed above, each of our Directors has not been a director of any other publicly listed company during the three years prior to the Latest Practicable Date and as of the Latest Practicable Date;
- (4) save as disclosed herein, other than being a Director of our Company, none of our Directors has any relationship with any other Directors, senior management of our Company or substantial shareholders of our Company; and
- (5) none of our Directors completed their respective education programs as disclosed in this section by way of attendance of long distance learning or online courses.

Except as disclosed in this document, to the best of the knowledge, information and belief of our Directors having made all reasonable enquiries:

- (1) there is no other matter with respect to the appointment of our Directors that need to be brought to the attention to the Shareholders as of the Latest Practicable Date; and
- (2) there is no other information relating to our Directors that is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules as of the Latest Practicable Date.

## DIRECTORS AND SENIOR MANAGEMENT

### SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management and operation of our business. The table below sets out certain information in respect of the senior management of the Group.

Name	Position	Age	Date of appointment as senior management of our Group	Time of joining the Group	Role and responsibility	Relationship with other Directors and senior management
Gong Zhaolong (龔兆龍)	Chief executive officer	58	January 30, 2018	January 30, 2018	Overall strategic planning, business direction and operational management	N/A
Zhang Jing (張競)	Chief financial officer	48	August 28, 2020	August 28, 2020	Overall management of financial, fundraising and business development	N/A
Liu Dongfang (劉東方)	Chief medical officer	52	January 11, 2019	January 11, 2019	Directing and overseeing clinical research and development	N/A
Xiao Shen (肖申)	Chief strategy officer	57	March 1, 2021	March 1, 2021	Directing and overseeing company strategies and regulatory affairs	N/A
Lin Yihui (林毅暉)	Head of the translational medical center	41	January 30, 2018	January 30, 2018	Directing and overseeing pre-clinical research and development	N/A
He Yue (何越)	Quality assurance senior director	45	August 1, 2019	January 30, 2018	Overseeing quality assurance of products	N/A

**Gong Zhaolong (龔兆龍)**, please refer to the paragraph headed “– Directors – Executive Director” in this section for details.

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## DIRECTORS AND SENIOR MANAGEMENT

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**Zhang Jing (張競)**, aged 48, has been the chief financial officer of the Company since August 28, 2020, and is responsible for overall management of financial, fundraising and business development. Since August 28, 2020, she has served as the chief financial officer of the Company.

Ms. Zhang had almost 24 years of experience in financial management. After working in public accounting firms in the United States, including KPMG, on taxation and financial assurance from January 1999 to February 2005, Ms. Zhang took on management positions in several MNCs and was responsible for their internal audit and financial planning and analysis functions in the Asia region, as an auditor in the internal audit department of the headquarters and the director of China region at Anthem Inc., a renowned medical, health and insurance company in the U.S. and listed on the New York Stock Exchange (stock code: ANTM), from November 2006 to December 2012. From April 2015 to October 2019, she served multiple roles in United Technologies Corporation, a company listed on the New York Stock Exchange (stock code: UTX), and most recently as the regional chief financial officer in Hong Kong, Macau, Taiwan region and Guam regions. From November 2019 to July 2020, she was the chief financial officer at Miconvey Technologies Co, Ltd., a medical device company.

Ms. Zhang obtained her bachelor’s degree in medical nutrition from Yat-sen University of Medical Sciences (中山醫科大學) in the PRC in July 1995. She then obtained her master’s degree in accounting from the University of South Carolina in the United States in December 1998. She is a certified public accountant with the Washington State Board of Accountancy. She was also a Certified Information Systems Auditor (CISA) of the Information Systems Audit and Control Association from November 2007 to January 2011. Her audit projects were awarded the first prizes in US national competitions.

**Liu Dongfang (劉東方)**, aged 52, has been the chief medical officer of the Company since January 11, 2019, and is responsible for directing and overseeing clinical research and development.

Dr. Liu has almost 21 years of experience in the pharmaceutical industries. From November 2001 to June 2005, he was a scientist at AstraZeneca plc, where he focused on cancer biosciences and in vivo pharmacology. From June 2005 to November 2014, he held various leadership positions, including being a group director leading oncology clinical research at Bristol Myers Squibb, a company listed on the New York Stock Exchange (stock code: BMY). From November 2014 to January 2019, he was an executive director at Celgene Corporation, where he led clinical research and development in lymphoma and chronic lymphocytic leukemia.

Dr. Liu obtained his bachelor’s degree in clinical medicine from Beijing Medical University (北京醫科大學) in July 1993. He then obtained his master’s degree in pharmaceutical sciences from the University of Toledo in the United States in June 1997. He obtained his PhD in bioengineering from the Massachusetts Institute of Technology in the United States in June, 2001.

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## DIRECTORS AND SENIOR MANAGEMENT

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**Xiao Shen** (肖申), aged 57, has been the chief strategy officer of the Company since March 1, 2021, and is responsible for directing and overseeing company strategies and regulatory affairs.

Prior to joining our Group, Dr. Xiao was a doctor of General Hospital of Nanjing Military Region (南京軍區總醫院), chiefly responsible for treating kidney diseases. From September 2002 to March 2021, he was a reviewer in the United States Food and Drug Administration (the “FDA”). During his 19 years at the FDA, he was chiefly responsible for the review and approval of new drug applications.

Dr. Xiao obtained his master’s degree majoring in kidney diseases in September 1989 from the Shanghai Jiao Tong University School of Medicine (上海交大醫學院) in the PRC. He obtained his PhD in kidney physiology and cell biology from West Virginia University in the United States in August 1999.

**Lin Yihui** (林毅暉), aged 41, has been the head of translational medicine center of the Group since January 30, 2018 and the vice president (副總經理) of 3D Medicines since September 10, 2020, and is responsible for directing and overseeing the translational medical centre of the Group.

From May 2011 to January 2013, he was a scientist at GlaxoSmithKline plc, a company listed on the London Stock Exchange and the New York Stock Exchange (stock code: GSK). From February 2013 to January 2018, Dr. Lin worked at the Predecessor Holdco.

Dr. Lin obtained his bachelor’s degree in biology from University of Science and Technology of China (中國科學技術大學) in Anhui, the PRC in July 2002 and his doctorate degree in biology from the Shanghai Institute of Biochemistry, China Academy of Sciences (中國科學院上海生物化學與細胞生物學研究所) Shanghai, the PRC in March 2010.

**He Yue** (何越), aged 45, has been the senior director of the quality management department of the Group since August 1, 2019, and is responsible for building a quality management system for the full life cycle of products and supervising its effective operation.

Mr. He has 13 years of experience in the pharmaceutical industry. From 2009 to 2012, he worked in Ronggang Biotechnology Consulting (Beijing) Co., Ltd. 榮港生技顧問(北京)有限公司. From 2010 to 2013, he served as the medical director of Baitai Biopharmaceutical Co., Ltd (百泰生物藥業有限公司). From 2013 to 2015, he was the clinical associate director of the clinical development department in BeiGene Biotechnology Co., Ltd. (百濟神州生物科技股份有限公司). Mr. He first joined our Group as the clinical operation director and was subsequently appointed as the quality assurance director of our Group in February 2018, and since then he has been in charge of clinical research and quality management of the Group. From July 2016 to January 2018, Mr. He worked at the Predecessor Holdco.

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## DIRECTORS AND SENIOR MANAGEMENT

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Mr. He obtained his bachelor’s degree in clinical medicine from North Sichuan Medical College (川北醫學院) in the PRC in July 2001, his master’s degree in on-the-job clinical medicine from Sichuan University (四川大學) in the PRC in July 2003, and his master’s degree in business administration from the Hong Kong Asia Business College (香港亞洲商學院) in January 2021.

### General

Save as disclosed above, each of our senior management members has confirmed that:

- (1) he/she does not hold and has not held any other positions in our Company and any other members of our Group as of the Latest Practicable Date;
- (2) save as being a member of the Company’s senior management, he/she does not have any other relationship with any Directors, substantial shareholders of our Company, or other members of senior management of our Group as of the Latest Practicable Date;
- (3) save as disclosed above, he/she does not hold and has not held any other directorships in public companies the securities of which are listed on any securities market in Hong Kong or overseas in the three years prior to the Latest Practicable Date and as of the Latest Practicable Date; and
- (4) save as disclosed above, he/she has not completed their respective education programs as disclosed in this section by way of attendance of long distance learning or online courses.

### JOINT COMPANY SECRETARIES

**Xia Fang** (夏芳), aged 41, has been the board secretary since September 1, 2020. She has been appointed as our joint company secretary on June 25, 2021.

Prior to joining our Group, from August 2003 to November 2016, Ms. Xia had worked at Taiji Group Co., Ltd. (太極集團股份有限公司) (“**Taiji Group**”), a company listed on the Shanghai stock exchange (stock code: 600667). Specifically, from January 2008 to November 2016, she was the deputy director of the Beijing product design centre of Taiji Group. She also served as the board secretary of the executive committee of the Tai Chi Anti-Cancer Science Foundation of China Anti-Cancer Association (中國抗癌協會太極抗癌科學基金) from January 2007 to December 2012.

Ms. Xia obtained her bachelor’s degree from Jilin Agricultural University (吉林農業大學) in the PRC in July 2003. She obtained her master’s degree from Peking University Health Science Center (北京大學醫學部) in the PRC in July 2013.

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## DIRECTORS AND SENIOR MANAGEMENT

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**Li Ching Yi (李菁怡)**, has been appointed as our joint company secretary on June 25, 2021. Ms. Li is a manager of the Listing Corporate Services Department of Trident Corporate Services (Asia) Ltd., a global professional services firm. She has around 11 years of professional experience in company secretarial field. She is currently a joint company secretary of Sinco Pharmaceuticals Holdings Ltd. (stock code: 6833) and Pop Mart International Group Limited (stock code: 9992), and the company secretary of China Fortune Financial Group Limited (stock code: 290), all of which are listed on the Hong Kong Stock Exchange.

Ms. Li is an associate member of The Chartered Governance Institute (formerly known as The Institute of Chartered Secretaries and Administrators) in the United Kingdom and The Hong Kong Institute of Chartered Secretaries. She obtained a bachelor’s degree in social sciences in October 2011 from Lingnan University in Hong Kong and a master’s degree in professional accounting and corporate governance in July 2015 from City University of Hong Kong.

### COMPETITION

Each of our executive Director and non-executive Directors confirms that as of the Latest Practicable Date, he 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.

### COMPLIANCE ADVISER

We have appointed China Securities (International) Corporate Finance Company Limited as our compliance adviser pursuant to Rule 3A.19 of the Listing Rules. Pursuant to Rule 3A.23 of the Listing Rules, the compliance adviser will advise us on the following circumstances:

- before the publication of any announcements, circulars or financial reports required by regulatory authorities or applicable laws;
- where a transaction, which might be a notifiable or connected transaction under Chapters 14 and 14A of the Listing Rules is contemplated, including share issues and share repurchases;
- where we propose to use the [REDACTED] of the [REDACTED] in a manner different from that detailed in this document or where our business activities, developments or results deviate from any forecast, estimate or other information in this document; and
- where the Stock Exchange makes an inquiry of us regarding unusual price movement and trading volume or other issues under Rule 13.10 of the Listing Rules.

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## DIRECTORS AND SENIOR MANAGEMENT

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The terms of the appointment shall commence on the [REDACTED] and end on the date which we distribute our annual report of our financial results for first full the financial year commencing after the [REDACTED].

### BOARD COMMITTEES

We have established the following committees on our Board: an audit committee, a remuneration committee and a nomination committee. The committees operate in accordance with the terms of reference established by our Board.

#### Audit Committee

The Company has established an audit committee (effective from the [REDACTED]) with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph C.3 and paragraph A.2 of the Corporate Governance Code as set out in Appendix 14 to the Listing Rules (the “Corporate Governance Code”). The audit committee consists of Dr. Lin Tat Pang, Mr. Zhu Pai and Dr. Li Jin, with Dr. Lin Tat Pang serving as the chairman. Dr. Lin Tat Pang holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules. The primary duties of the audit committee are to assist our Board by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of the Group, overseeing the audit process, and performing other duties and responsibilities as assigned by our Board.

#### Remuneration Committee

The Company has established a remuneration committee (effective from the [REDACTED]) with written terms of reference in compliance with Rule 3.25 of the Listing Rules and paragraph E.1 of the Corporate Governance Code. The remuneration committee consists of Mr. Liu Xinguang, Dr. Gong and Dr. Li Jin, with Mr. Liu Xinguang serving as the chairman. The primary duties of the remuneration committee include, but are not limited to, the following: (i) making recommendations to our Board on our policy and structure for all remuneration of Directors and senior management and on the establishment of a formal and transparent procedure for developing policy on such remuneration; (ii) determining the specific remuneration packages of all Directors and senior management; and (iii) reviewing and approving performance-based remuneration by reference to corporate goals and objectives resolved by our Board from time to time.



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## DIRECTORS AND SENIOR MANAGEMENT

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### Nomination Committee

The Company has established a nomination committee (effective from the [REDACTED]) with written terms of reference in compliance with paragraph B.3 of the Corporate Governance Code. The nomination committee consists of Dr. Gong, Dr. Li Jin and Mr. Liu Xinguang, with Dr. Gong serving as the chairman. The primary functions of the nomination committee include, without limitation, reviewing the structure, size and composition of our Board, assessing the independence of independent non-executive Directors and making recommendations to our Board on matters relating to the appointment of Directors.

### CORPORATE GOVERNANCE

#### Code Provision C.2.1 of the Corporate Governance Code

Under paragraph C.2.1 of the Corporate Governance Code, the roles of the chairman and chief executive officer should be separate and should not be performed by the same individual. Dr. Gong is the chairman of the Board and the chief executive officer of our Company. Therefore, vesting the roles of the chairman and the chief executive officer in Dr. Gong constitutes a deviation from paragraph C.2.1 of the Corporate Governance Code. With extensive experience in the pharmaceutical industry and having served in our Company since its establishment, Dr. Gong is in charge of overall strategic planning, business direction and operational management of our Group. Our Board considers that vesting the roles of chairman and chief executive officer in the same person is beneficial to the management of our Group. The balance of power and authority is ensured by the operation of our Board and our senior management, which comprises experienced and diverse individuals. Our Board currently comprises one executive Director, three non-executive Directors and three independent non-executive Directors, and therefore has a strong independence element in its composition.

Save as disclosed above, our Company intends to comply with all code provisions under the Corporate Governance Code after the [REDACTED].

### Board Diversity

We have adopted a board diversity policy (the “**Board Diversity Policy**”) to enhance the effectiveness of our Board and to maintain a high standard of corporate governance. Pursuant to the Board Diversity Policy, in reviewing and assessing suitable candidates to serve as a Director of the Company, the Nomination Committee will consider a range of diversity perspectives with reference to the Company’s business model and specific needs, including but not limited to gender, age, language, cultural and educational background, professional qualifications, skills, knowledge, industry and regional experience and/or length of service.

Our Directors have a balanced mixed of knowledge and skills, including but not limited to overall business management, finance and accounting, research and development, and investment. They obtained degrees in various majors including public health and toxicology, biotechnology, organic chemistry, economics, law and history of science. Furthermore, our

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## DIRECTORS AND SENIOR MANAGEMENT

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Board has a relatively wide range of ages, ranging from 30 years old to 66 years old and consists of six male members and one female member. We will also continue to take steps to promote gender diversity at all levels of our Company, including but without limitation at our Board and senior management levels. In particular, our chief financial officer who is responsible for supervising the financial management of the Group, is female and a member of our senior management team.

The Nomination Committee is responsible for reviewing the diversity of the Board, reviewing the Board Diversity Policy from time to time, developing and reviewing measurable objectives for implementing the Board Diversity Policy, and monitoring the progress on achieving these measurable objectives in order to ensure that the policy remains effective. The Company will (i) disclose the biographical details of each Director and (ii) report on the implementation of the Board Diversity Policy (including whether we have achieved board diversity) in its annual corporate governance report. However, we will take opportunities to increase the proportion of female members of the Board when selecting and recommending suitable candidates for Board appointments to help enhance gender diversity in accordance with stakeholder expectations and recommended best practices.

We will continue to promote gender diversity when recruiting staff at the mid to senior level so that we will have a pipeline of female senior management and potential successors to the Board. We plan to offer all-round trainings to female employees whom we consider to have the suitable experience, skills and knowledge of our operation and business, including but not limited to, business operation, management, accounting and finance, legal and compliance and research and development. We are of the view that such strategy will offer chances for our Board to identify capable female employees to be nominated as members of the Board in future with an aim to providing our Board with a pipeline of female candidates to achieve gender diversity in our Board in the long run.

### KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into (i) an employment contract and (ii) a confidentiality and non-competition agreement with our senior management members and other key personnel (other than Directors). Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel.

#### **Confidentiality**

- *Confidentiality obligations.* The employee shall, during the course of employment with the Group and thereafter, keep in confidence all technical, operational information or trade secrets belonging to the Company or other third parties to whom the Group owes confidentiality obligations. Without the Group’s prior consent, the employee shall not leak, disclose, publish, announce, issue, teach, transfer or otherwise make available to any third party (including employees who are not privy to such trade secrets) any such trade secrets of the Group or the aforementioned third parties in any manner and shall not utilize such trade secret beyond his or her scope of work.

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## DIRECTORS AND SENIOR MANAGEMENT

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### Ownership of intellectual work products

- *Acknowledgement:* The employee acknowledges and agrees that the Group shall own all intellectual work products he or she produces during the course of employment with the Group for the purposes of undertaking their duties and responsibilities.

### Non-competition

- *Non-competition obligation during employment term.* During the term of his/her employment with our Company, unless with the Group’s prior consent, the employee shall not engage in any business that competes with or are similar to that of the Group’s business.
- *Non-competition obligation following termination of employment relationship.* Within two years after termination of the employment relationship between the employee and the Group, the employee shall not serve in any capacity at any company engaged in a business competing with that of the Group.

### Compensation for breach of covenants

- If the employee breaches the obligations under the confidentiality, intellectual property and non-competition agreement, our Group shall be entitled to recover from the employee any losses incurred and any profits earned by the employee as a result of the breaches.

### SHARE INCENTIVE SCHEME

We have adopted the Share Incentive Scheme. The principal terms of the Share Incentive Schemes are summarized in the paragraph headed “Statutory and General Information – D. Share Incentive Scheme” in Appendix IV to this document.

### COMPENSATION OF DIRECTORS AND MANAGEMENT

Our Directors receive compensation in the form of fees, salaries, bonuses, other allowances and benefits in kind, including the Company’s contribution to the pension scheme on their behalf. We determine the salaries of our Directors based on each Director’s responsibilities, qualification, position and seniority.

The aggregate amount of fees, salaries, allowances and retirement benefit scheme contributions we paid to our Directors in respect of the financial year ended December 31, 2020 and 2021 and the five months ended May 31, 2022 were approximately RMB1,300,000 and RMB2,700,000 and RMB1,125,000, respectively.

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## DIRECTORS AND SENIOR MANAGEMENT

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The aggregate amount of equity-settled share award expenses paid or payable by us to the Directors in respect of the financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022 were approximately nil, RMB76,973,000 and RMB29,556,000, respectively.

It is estimated that remuneration and benefits in kind (excluding any possible payment of discretionary bonus) equivalent to approximately RMB65.54 million in aggregate will be paid and granted to our Directors by us in respect of the financial year ending December 31, 2022 under arrangements in force at the date of this document.

The aggregate amount of fees, salaries, allowances and retirement benefit scheme contributions we paid to our five highest paid individuals (including both employees and Directors) in respect of the financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022 were approximately RMB11,667,000, RMB10,805,000 and RMB9,102,000, respectively.

The aggregate amount of equity-settled share award expenses paid or payable by us to the Directors in respect of the financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022 were approximately RMB239,000, RMB137,694,000 and RMB37,717,000, respectively.

During the Track Record Period, (i) no remuneration was paid to our Directors or the five highest paid individuals as an inducement to join, or upon joining our Group, (ii) no compensation was paid to, or receivable by, our Directors or past Directors or the five highest paid individuals for the loss of office as director of any member of our Group or any other office in connection with the management of the affairs of any member of our Group, and (iii) none of our Directors waived any emoluments.

Our Directors’ remuneration is determined with reference to the relevant Director’s experience and qualifications, level of responsibility, performance and the time devoted to our business, and the prevailing market conditions.

For additional information on Directors’ remuneration during the Track Record Period as well as information on the highest paid individuals, please see Notes 9 and 10 of the Accountants’ Report set out in Appendix I to this document.

Save as disclosed herein, to the best of the knowledge, information and belief of our Directors having made all reasonable enquiries, there was no other matter with respect to the appointment of our Directors that needs to be brought to the attention of the Shareholders and there was no information relating to our Directors that is required to be disclosed pursuant to Rules 13.51(2)(h) to (v) of the Listing Rules as of the Latest Practicable Date.

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## FUTURE PLANS AND USE OF [REDACTED]

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### FUTURE PLANS

For a detailed description of our future plans, please refer to the paragraphs headed “Business – Our Strategies” in this document.

### USE OF [REDACTED]

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

- (a) approximately [REDACTED]%, or HK\$[REDACTED], will be used primarily for the research and development, regulatory filings and commercialization of our product and drug candidates:
  - (i) approximately [REDACTED]%, or HK\$[REDACTED], will be used for our Core Product envafolimab, including:
    - (a) approximately [REDACTED]% or HK\$[REDACTED], will be used for ongoing and planned clinical trials to evaluate envafolimab for the treatment of UC, TMB-H, EC and other solid tumors;
    - (b) approximately [REDACTED]% or HK\$[REDACTED], will be used for ongoing and planned clinical trials to evaluate envafolimab as combinational therapies for the treatment of HCC, RCC, NSCLC, BTC and other solid tumors;
    - (c) approximately [REDACTED]% or HK\$[REDACTED], will be used for marketing business development (including employee salary, employee training, and procurement service), and the maintenance and management of envafolimab as its MAH holder; and
    - (d) approximately [REDACTED]% or HK\$[REDACTED], will be used for expanding our production-lines, including procurement of production equipment, procurement of active pharmaceutical ingredients, procurement of pre-filled syringe, packing materials accessory ingredients, commissioning and production debugging, and setting up of personnel and quality management system.

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## FUTURE PLANS AND USE OF [REDACTED]

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- (ii) approximately [REDACTED]%, or HK\$[REDACTED], will be used for our other drug candidates, including:
  - (a) approximately [REDACTED]%, or HK\$[REDACTED], will be used for ongoing and planned clinical trials and the preparation for registration filings of 3D189. We submitted the IND in China in July 2021 and obtained the IND approval in China in March 2022. We plan to enroll the first patient for the Phase I clinical trial in the second half of 2022 and join the ongoing Phase III clinical trial in AML sponsored by SELLAS Group;
  - (b) approximately [REDACTED]%, or HK\$[REDACTED], will be used for ongoing and planned clinical trials and the preparation for registration filings of 3D229. We completed the Phase I clinical trial in May 2022, and have expanded the Phase III pivotal trial to China;
  - (c) approximately [REDACTED]%, or HK\$[REDACTED], will be used for planned clinical trials for the treatment of advanced malignant solid tumors and the preparation for registration filings of 3D011 in China. We received the IND approval from the NMPA in January 2021 and initiated a Phase I clinical trial in February 2022, and we plan to enroll the first patient for this trial in the third quarter of 2022. The site for this clinical trial was activated in first quarter of 2022;
  - (d) approximately [REDACTED]%, or HK\$[REDACTED], will be used for ongoing and planned clinical trials for the treatment of cholangiocarcinoma, UC and other tumors with FGFR genetic alterations and the preparation for registration filings of 3D185 in China. We completed the Phase I clinical trial in August 2021 and plan to further explore the clinical potential for the treatment of cholangiocarcinoma, UC and other tumors with FGFR genetic alterations. We received the IND approval from the FDA in September 2019 and submitted a protocol to FDA in September 2021 for a Phase II clinical trial, which we withdrew later as we decided to establish a RP2D first before we start the Phase II clinical trial;
  - (e) approximately [REDACTED]%, or HK\$[REDACTED], will be used for ongoing and planned clinical trials for the treatment of post-surgical dental pain and the preparation for registration filings of 3D1001 in China. We obtained the IND approval from the NMPA in February 2019 and are preparing for a potential Phase I/II clinical trial in China. The first subject of this trial is expected to be enrolled in the first half of 2023;

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## FUTURE PLANS AND USE OF [REDACTED]

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- (f) approximately [REDACTED]%, or HK\$[REDACTED], will be used for ongoing and planned clinical trials for the treatment of cancer pain and the preparation for registration filings of 3D1002 in China. We obtained the IND approval in July 2018 and plan to conduct a randomized Phase II clinical trial. The first patient of this trial is expected to be enrolled in fourth quarter of 2022;
  - (g) approximately [REDACTED]%, or HK\$[REDACTED], will be used for pre-clinical discovery and development of 3D197. We obtained the IND approval in China in January 2022 and plan to conduct phase I study in China. The first patient of this trial is expected to be enrolled in the second half of 2022;
  - (h) approximately [REDACTED]%, or HK\$[REDACTED], will be used for pre-clinical discovery and development of 3D057; and
  - (i) approximately [REDACTED]%, or HK\$[REDACTED], will be used for early-stage drug discovery and development, including pre-clinical of our other pipeline assets, discovery and development of new drug candidates.
- (iii) approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund the following:
- (a) approximately [REDACTED]%, or HK\$[REDACTED], will be used for the construction of our in-house production facilities in Xuzhou, Jiangsu province (and for more information, please refer to the paragraphs headed “Business – Production and Quality Control” in this document), including the construction of our infrastructure and decoration of facilities in compliance with cGMP standards, and we expect to complete such construction of infrastructure and decoration by 2023. As of the Latest Practicable Date, our manufacturing facilities in Xuzhou did not have production capacity as we are still in the process of construction. We expect that their total production capacity will reach 6,000 L (3x2,000 L) by 2024;
  - (b) approximately [REDACTED]%, or HK\$[REDACTED], will be used for the procurement of new machineries, instruments and equipment, including approximately HK\$[REDACTED] for API (Active Pharmaceutical Ingredients) production machineries and equipment (e.g. bioreactors, filters, centrifuges, sterilization cabinet and their ancillary equipment), approximately HK\$[REDACTED] for drug production machineries and equipment (e.g. bioreactors, filters and isolators, visual inspection and leak detection systems and packaging systems), and approximately HK\$[REDACTED] for engineering equipment (e.g. water distribution systems, distilled water machines and sewage treatment equipment), and we expect to complete such procurement by 2023; and

**FUTURE PLANS AND USE OF [REDACTED]**

- (c) approximately [REDACTED]%, or HK\$[REDACTED], will be used for the recruitment and training of manufacturing talents and the procurement of professional services. We expect to recruit approximately 200 additional employees by 2024. We expect that the professional service required include preliminary project consulting service, designing service, construction project supervision service and GMP/cGMP verification services, and we expect to procure such professional services by 2024.
- (b) approximately [REDACTED]%, or HK\$[REDACTED], will be used to fund our business development activities, the expansion of our drug pipeline and portfolio, and the potential acquisition of high value and differentiated innovative assets and/or equities, if practicable. In evaluating the potential acquisition targets, we will prudently consider various factors where applicable, including and without limitation to the target’s drug products and pipelines, the strategic position of the target in the industry, the target’s competitive strengths and growth potential, expertise of the target’s management and research and development teams, the target’s financial conditions, and synergies with our existing business. As confirmed by Frost & Sullivan, there are available acquisition targets in the market that satisfy our acquisition criteria; and
- (c) approximately [REDACTED]%, or HK\$[REDACTED], will be used for our general corporate and working capital purposes.

None of the net [REDACTED] will be applied for discharging our payment obligations under the Co-Development Agreements, the 3D Alphamab TRACON Agreement, or the 3D Alphamab Simcere Agreements.

The table below specifies the further breakdown for net [REDACTED] to be allocated to different indications of our Core Product envafolimab for the R&D on the one hand (i.e. approximately [REDACTED]%, or HK\$[REDACTED] will be used for research and development of multiple indications) and commercialization on the other hand (i.e. approximately [REDACTED]%, or HK\$[REDACTED] will be used for marketing business development).

Indications	Net [REDACTED] to Be Allocated			Future Development Plan <sup>(2)</sup> and Expected Timetable
	R&D	Commercialization	Latest Development Stage <sup>(2)</sup>	
EC	[REDACTED]%, or approximately HK\$[REDACTED]		<ul style="list-style-type: none"> <li>• We submitted IND for a Phase II clinical trial in June 2021 and received the IND approval in September 2021</li> </ul>	<ul style="list-style-type: none"> <li>• Q2 2022: Expected FPI</li> <li>• Q4 2023: Expected full enrollment</li> <li>• Q4 2024: Expected NDA submission</li> </ul>



**FUTURE PLANS AND USE OF [REDACTED]**

Indications	R&D	Net [REDACTED] to Be Allocated		Future Development Plan <sup>(2)</sup> and Expected Timetable
		Commercialization	Latest Development Stage <sup>(2)</sup>	
TMB-H advanced solid tumors	[REDACTED]%, or approximately HK\$[REDACTED]		<ul style="list-style-type: none"> <li>We enrolled the first patient for a Phase II clinical trial in August 2021</li> </ul>	<ul style="list-style-type: none"> <li>Q1 2023: Expected full enrollment</li> <li>Q1 2024: Expected NDA submission</li> </ul>
UC	[REDACTED]%, or approximately HK\$[REDACTED]		<ul style="list-style-type: none"> <li>We had communications with CDE in March 2021, and we have completed pre-IND communication with CDE in July 2021.</li> </ul>	<ul style="list-style-type: none"> <li>Q4 2022: Expected IND submission</li> <li>Q2 2023: Expected FPI</li> <li>Q4 2025: Expected NDA submission</li> </ul>
Other solid tumors	[REDACTED]%, or approximately HK\$[REDACTED]	[REDACTED]%, or approximately HK\$[REDACTED] <sup>(1)</sup>	–	–
BTC (combinational therapy)	[REDACTED]%, or approximately HK\$[REDACTED]		<ul style="list-style-type: none"> <li>We enrolled the first patient for a Phase III clinical trial in April 2018</li> </ul>	<ul style="list-style-type: none"> <li>Q4 2022: Expected NDA submission</li> </ul>
NSCLC (combination with chidamide)	[REDACTED]%, or approximately HK\$[REDACTED]		<ul style="list-style-type: none"> <li>We obtained the IND approval for a Phase II clinical trial in July 2021 and enrolled the first patient for this trial in the fourth quarter of 2021.</li> </ul>	<ul style="list-style-type: none"> <li>Q2 2024: Expected NDA submission</li> </ul>
NSCLC (vs. standard of care)			<ul style="list-style-type: none"> <li>We had communications with CDE in January 2021, and are still in the process of communicating with CDE</li> </ul>	<ul style="list-style-type: none"> <li>Q2 2023: Expected FPI</li> <li>Q2 2027: Expected NDA submission</li> </ul>

**FUTURE PLANS AND USE OF [REDACTED]**

Indications	Net [REDACTED] to Be Allocated		Latest Development Stage <sup>(2)</sup>	Future Development Plan <sup>(2)</sup> and Expected Timetable
	R&D	Commercialization		
NSCLC, HCC, RCC (combination with lenvatinib)	[REDACTED]%, or approximately HK\$[REDACTED]	[REDACTED]%, or approximately HK\$[REDACTED]	• We obtained the IND approval for a Phase Ib/II clinical trial in June 2021 and enrolled the first patient for this trial in the fourth quarter of 2021.	• Q4 2026: Expected NDA submission
<b>Total</b>	[REDACTED]%, or approximately HK\$[REDACTED]	[REDACTED]%, or approximately HK\$[REDACTED]		

Abbreviations: EC = endometrial cancer; TMB-H = tumor mutational burden-high; UC = urothelial carcinoma; BTC = biliary tract cancer; NSCLC = non-small cell lung cancer; HCC = hepatocellular carcinoma; RCC = renal cell carcinoma; Q1 = first quarter; Q2 = second quarter; Q3 = third quarter; Q4 = fourth quarter; FPI = first patient-in.

*Note:*

- (1) Represents the net [REDACTED] to be allocated to the commercialization of all indications.
- (2) For more details on the latest development stage and future development plan, please refer to the paragraphs headed “Business – Our Core Product – Envafolimab – Clinical Development Plan.”

If the [REDACTED] is exercised in full, the net [REDACTED] of the [REDACTED] would increase to approximately HK\$[REDACTED] (based on the mid-point [REDACTED] of HK\$[REDACTED] per Share). We intend to apply the additional net [REDACTED] to the above uses in the proportions stated above.

The allocation of the [REDACTED] used for the above will be adjusted in the event that the [REDACTED] is fixed at a higher or lower level compared to the mid-point of the estimated [REDACTED] range. If the [REDACTED] is fixed at HK\$[REDACTED] per Share, being the high end of the stated [REDACTED] range, our net [REDACTED] will (i) assuming the [REDACTED] is not exercised, be increased to approximately HK\$[REDACTED], or (ii) assuming the [REDACTED] is exercised in full, be increased to approximately HK\$[REDACTED]. In such circumstances, we currently intend to use such additional [REDACTED] to increase the net [REDACTED] applied for the same purposes as set out above on a pro rata basis. If the [REDACTED] is fixed at HK\$[REDACTED] per Share, being the low end of the stated [REDACTED] range, our net [REDACTED] will (i) assuming the [REDACTED] is not exercised, be decreased to approximately HK\$[REDACTED], or (ii) assuming the [REDACTED] is exercised in full, be decreased to approximately HK\$[REDACTED]. In such circumstances, we currently intend to reduce the net [REDACTED] applied for the same purposes as set out above on a pro rata basis.

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## FUTURE PLANS AND USE OF [REDACTED]

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To the extent that our net [REDACTED] are not sufficient to fund the purposes set out above, we intend to fund the balance through a variety of means, including but not limited to cash generated from operations, equity and equity-linked instruments, bank loans and other borrowings.

To the extent that the net [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 placed in short-term demand deposits with licensed banks or authorised financial institutions.

**[REDACTED]**

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**[REDACTED]**

**[REDACTED]**

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**[REDACTED]**

**[REDACTED]**

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**[REDACTED]**

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**[REDACTED]**

**[REDACTED]**

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**[REDACTED]**

**[REDACTED]**

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**[REDACTED]**

**STRUCTURE OF THE [REDACTED]**

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[REDACTED]



**STRUCTURE OF THE [REDACTED]**

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[REDACTED]

**STRUCTURE OF THE [REDACTED]**

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[REDACTED]

**STRUCTURE OF THE [REDACTED]**

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[REDACTED]

**STRUCTURE OF THE [REDACTED]**

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[REDACTED]

**STRUCTURE OF THE [REDACTED]**

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[REDACTED]

**STRUCTURE OF THE [REDACTED]**

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[REDACTED]

**STRUCTURE OF THE [REDACTED]**

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[REDACTED]

**STRUCTURE OF THE [REDACTED]**

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[REDACTED]



**STRUCTURE OF THE [REDACTED]**

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[REDACTED]

**STRUCTURE OF THE [REDACTED]**

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[REDACTED]

## HOW TO APPLY FOR [REDACTED]

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[REDACTED]

## HOW TO APPLY FOR [REDACTED]

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[REDACTED]

## HOW TO APPLY FOR [REDACTED]

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[REDACTED]

## HOW TO APPLY FOR [REDACTED]

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[REDACTED]



## HOW TO APPLY FOR [REDACTED]

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[REDACTED]

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## APPENDIX I

## ACCOUNTANTS’ REPORT

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*The following is the text of a report received from the Company’s reporting accountants, Ernst & Young, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this Document.*

*“[To insert the firm’s letterhead]”*

### **ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF 3D MEDICINES INC., CHINA INTERNATIONAL CAPITAL CORPORATION HONG KONG SECURITIES LIMITED AND CHINA SECURITIES (INTERNATIONAL) CORPORATE FINANCE COMPANY LIMITED**

#### **INTRODUCTION**

We report on the historical financial information of 3D Medicines Inc. (the “Company”) and its subsidiaries (together, the “Group”) set out on pages [●] to [●], which comprises the consolidated statements of profit or loss and other comprehensive income, statements of changes in equity and statements of cash flows of the Group for each of the years ended December 31, 2020 and 2021, and the five months ended May 31, 2022 (the “Relevant Periods”), the consolidated statements of financial position of the Group and the statements of financial position of the Company as at December 31, 2020 and 2021 and May 31, 2022 and a summary of significant accounting policies and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages [●] to [●] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [Date] (the “Document”) in connection with the initial [REDACTED] of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

#### **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 presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively, and for such internal control as the directors determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

#### **REPORTING ACCOUNTANTS’ RESPONSIBILITY**

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 *Accountants’ Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

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## APPENDIX I

## ACCOUNTANTS’ REPORT

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Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively, 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 accountants’ report, a true and fair view of the financial position of the Group and the Company as at December 31, 2020 and 2021 and May 31, 2022 and of the financial performance and cash flows of the Group for each of the Relevant Periods in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively.

### REVIEW OF INTERIM COMPARATIVE FINANCIAL INFORMATION

We have reviewed the interim comparative financial information of the Group which comprises the consolidated statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows of the Group for the five months ended May 31, 2021 and other explanatory information (the “Interim Comparative Financial Information”).

The directors of the Company are responsible for the preparation and presentation of the Interim Comparative Financial Information in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively. Our responsibility is to express a conclusion on the Interim Comparative Financial Information based on our review. We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the HKICPA. A review consists of making 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 Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that causes us to believe that the Interim Comparative Financial Information, for the purposes of the accountants’ report, is not prepared, in all material respects, in accordance with the basis of presentation and the basis of preparation set out in notes 2.1 and 2.2 to the Historical Financial Information, respectively.

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**APPENDIX I**

**ACCOUNTANTS’ REPORT**

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**REPORT ON MATTERS UNDER THE RULES GOVERNING THE LISTING OF SECURITIES ON THE STOCK EXCHANGE AND THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

**Adjustments**

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page [●] have been made.

**Dividends**

We refer to note 12 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

**No historical financial statements for the Company**

As at the date of this report, no statutory financial statements have been prepared for the Company since its date of incorporation.

*Certified Public Accountants*

Hong Kong

[●], 2022

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**APPENDIX I**

**ACCOUNTANTS’ REPORT**

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**I. HISTORICAL FINANCIAL INFORMATION**

**Preparation of the Historical Financial Information**

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by Ernst & Young in accordance with Hong Kong Standards on Auditing issued by the HKICPA (the “Underlying Financial Statements”).

The Historical Financial Information is presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME**

		Year ended		Five months ended	
		December 31,		May 31,	
	Notes	2020	2021	2021	2022
		RMB'000	RMB'000	RMB'000	RMB'000
				<i>(unaudited)</i>	
Revenue	5	–	60,260	–	161,062
Cost of sales	8	–	(4,277)	–	(11,458)
		<u>–</u>	<u>(4,277)</u>	<u>–</u>	<u>(11,458)</u>
Gross profit		–	55,983	–	149,604
Other income and gains	5	2,337	19,637	1,494	21,480
Research and development expenses		(263,970)	(371,162)	(129,940)	(138,259)
Administrative expenses		(40,528)	(150,956)	(26,757)	(46,631)
Selling and marketing expenses		–	(42,834)	–	(103,567)
Royalty expenses	8	–	(7,153)	–	(17,364)
Other expenses	6	(5,929)	(8,940)	(1,371)	(14,224)
Finance costs	7	(8,058)	(1,528)	(365)	(740)
Fair value losses on preferred shares	26	(319,232)	(954,742)	(647,031)	(143,642)
Impairment losses on financial assets, net	18	–	(130)	–	(74)
		<u>–</u>	<u>(130)</u>	<u>–</u>	<u>(74)</u>
LOSS BEFORE TAX	8	(635,380)	(1,461,825)	(803,970)	(293,417)
Income tax expense	11	–	–	–	–
		<u>–</u>	<u>–</u>	<u>–</u>	<u>–</u>
LOSS FOR THE YEAR/PERIOD		<u>(635,380)</u>	<u>(1,461,825)</u>	<u>(803,970)</u>	<u>(293,417)</u>
LOSS AND TOTAL COMPREHENSIVE LOSS FOR THE YEAR/PERIOD		<u>(635,380)</u>	<u>(1,461,825)</u>	<u>(803,970)</u>	<u>(293,417)</u>
Attributable to:					
Owners of the parent		(635,380)	(1,434,092)	(803,970)	(280,379)
Non-controlling interests		–	(27,733)	–	(13,038)
		<u>–</u>	<u>(27,733)</u>	<u>–</u>	<u>(13,038)</u>
		<u>(635,380)</u>	<u>(1,461,825)</u>	<u>(803,970)</u>	<u>(293,417)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT					
Basic and diluted (RMB)	13	(13.93)	(36.72)	(17.63)	(7.65)
		<u>(13.93)</u>	<u>(36.72)</u>	<u>(17.63)</u>	<u>(7.65)</u>

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

	<i>Notes</i>	<b>As at December 31,</b>		<b>As at May 31,</b>
		<b>2020</b>	<b>2021</b>	<b>2022</b>
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
<b>NON-CURRENT ASSETS</b>				
Property, plant and equipment	14	10,864	52,246	97,401
Intangible assets	15	–	929	887
Right-of-use assets	16	15,937	66,293	62,333
Other non-current assets	17	7,660	18,384	10,878
Amounts due from related parties	34	–	3,214	3,254
		<u>34,461</u>	<u>141,066</u>	<u>174,753</u>
<b>TOTAL non-current assets</b>				
<b>CURRENT ASSETS</b>				
Trade receivables	18	–	65,004	101,889
Prepayments, other receivables and other assets	19	41,122	29,654	29,510
Amounts due from related parties	34	372	–	–
Financial assets at fair value through profit or loss (“FVTPL”)	20	–	50,178	50,021
Pledged deposits	21	6,000	–	–
Restricted bank balances	21	–	72	72
Cash and bank balances	21	414,261	774,306	660,231
Inventories		–	13	1,545
		<u>461,755</u>	<u>919,227</u>	<u>843,268</u>
<b>TOTAL current assets</b>				
<b>CURRENT LIABILITIES</b>				
Trade payables	22	2,416	3,742	2,650
Other payables and accruals	23	88,340	137,431	193,404
Interest-bearing bank borrowings	24	3,522	–	–
Amounts due to a related party	34	1,702	150	150
Preferred shares	26	215,237	3,093,968	3,233,922
Lease liabilities	16	3,791	12,754	13,701
		<u>315,008</u>	<u>3,248,045</u>	<u>3,443,827</u>
<b>TOTAL current liabilities</b>				
<b>NET CURRENT ASSETS/(LIABILITIES)</b>		<u>146,747</u>	<u>(2,328,818)</u>	<u>(2,600,559)</u>
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<u>181,208</u>	<u>(2,187,752)</u>	<u>(2,425,806)</u>
<b>NON-CURRENT LIABILITIES</b>				
Deferred income	25	7,579	–	–
Lease liabilities	16	13,061	45,987	41,512
Preferred shares	26	1,430,383	38,823	42,511
		<u>1,451,023</u>	<u>84,810</u>	<u>84,023</u>
<b>TOTAL non-current liabilities</b>				
<b>NET LIABILITIES</b>		<u>(1,269,815)</u>	<u>(2,272,562)</u>	<u>(2,509,829)</u>
<b>EQUITY</b>				
Equity attributable to owners of the parent				
Share capital	27	37	57	57
Treasury shares	27	–	(27)	(27)
Deficits	28	(1,269,852)	(2,238,041)	(2,467,519)
		<u>(1,269,815)</u>	<u>(2,238,011)</u>	<u>(2,467,489)</u>
<b>Non-controlling interests</b>				
	29	–	(34,551)	(42,340)
<b>Total deficits</b>		<u>(1,269,815)</u>	<u>(2,272,562)</u>	<u>(2,509,829)</u>

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

**Year ended December 31, 2020**

	<b>Share capital</b>	<b>Other reserve</b>	<b>Accumulated losses</b>	<b>Total</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
	<i>(note 27)</i>	<i>(note 28)</i>		
At January 1, 2020	37	(92,635)	(542,253)	(634,851)
Total comprehensive loss for the year	–	–	(635,380)	(635,380)
Recognition of equity-settled share-based payments <i>(note 30)</i>	–	416	–	416
At December 31, 2020	<u>37</u>	<u>(92,219)*</u>	<u>(1,177,633)*</u>	<u>(1,269,815)</u>



**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**Year ended December 31, 2021**

	Attributable to owners of the parent					Total	Non-controlling interests	Total deficits
	Share capital	Treasury Shares	Share premium	Other reserve	Accumulated losses			
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
	(note 27)	(note 27)	(note 28)	(note 28)				
At January 1, 2021	37	-	-	(92,219)	(1,177,633)	(1,269,815)	-	(1,269,815)
Total comprehensive loss for the year	-	-	-	-	(1,434,092)	(1,434,092)	(27,733)	(1,461,825)
Shares issued for share incentive scheme (note 27)	32	(32)	-	-	-	-	-	-
Repurchase of shares (note 27)	(16)	-	-	(32,714)	-	(32,730)	-	(32,730)
Capital contribution from a non-controlling shareholder of a subsidiary	-	-	-	344,466	-	344,466	(23,333)	321,133
Recognition of equity-settled share-based payments (note 30)	4	-	59,240	88,904	-	148,148	16,515	164,663
Exercise of restricted share units (note 30)	-	5	75,424	(69,417)	-	6,012	-	6,012
At December 31, 2021	<u>57</u>	<u>(27)</u>	<u>134,664*</u>	<u>239,020*</u>	<u>(2,611,725)*</u>	<u>(2,238,011)</u>	<u>(34,551)</u>	<u>(2,272,562)</u>

**Five months ended May 31, 2022**

	Attributable to owners of the parent					Total	Non-controlling interests	Total deficits
	Share capital	Treasury shares	Share premium	Other reserve	Accumulated losses			
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
	(note 27)	(note 27)	(note 28)	(note 28)				
At January 1, 2022	57	(27)	134,664	239,020	(2,611,725)	(2,238,011)	(34,551)	(2,272,562)
Total comprehensive loss for the period	-	-	-	-	(280,379)	(280,379)	(13,038)	(293,417)
Recognition of equity-settled share-based payments (note 30)	-	-	-	50,186	-	50,186	5,249	55,435
Exercise of restricted share units (note 30)	-	-	5,138	(4,423)	-	715	-	715
At May 31, 2022	<u>57</u>	<u>(27)</u>	<u>139,802*</u>	<u>284,783*</u>	<u>(2,892,104)*</u>	<u>(2,467,489)</u>	<u>(42,340)</u>	<u>(2,509,829)</u>

\* The reserve accounts comprised the consolidated deficits of RMB1,269,852,000, RMB2,238,041,000 and RMB2,467,519,000 in the consolidated statement of financial position as at December 31, 2020, and 2021 and May 31, 2022, respectively.

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**Five months ended May 31, 2021 (unaudited)**

	<u>Attributable to owners of the parent</u>				<u>Non- controlling interests</u>	<u>Total deficits</u>
	<u>Share capital</u>	<u>Other reserve</u>	<u>Accumulated losses</u>	<u>Total</u>		
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
	<i>(note 27)</i>	<i>(note 28)</i>				
At January 1, 2021	37	(92,219)	(1,177,633)	(1,269,815)	–	(1,269,815)
Total comprehensive loss for the period	–	–	(803,970)	(803,970)	–	(803,970)
Capital contribution from a non-controlling shareholder of a subsidiary**	–	344,466	–	344,466	(23,333)	321,133
Recognition of equity-settled share-based payments <i>(note 30)</i>	–	94	–	94	–	94
At May 31, 2021	<u>37</u>	<u>252,341</u>	<u>(1,981,603)</u>	<u>(1,729,225)</u>	<u>(23,333)</u>	<u>(1,752,558)</u>

\*\* It represented capital contribution received from a non-controlling shareholder of a subsidiary, which was recorded as restricted bank balances as at May 31,2021 and become unrestricted in September 2021.

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Notes	Year ended December 31,		Five months ended May 31,	
		2020 RMB'000	2021 RMB'000	2021 RMB'000 (unaudited)	2022 RMB'000
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>					
Loss before tax		(635,380)	(1,461,825)	(803,970)	(293,417)
Adjustments for:					
Finance costs	7	8,058	1,528	365	740
Interest income	5	(1,610)	(5,502)	(1,164)	(2,311)
Depreciation of property, plant and equipment	14	1,153	3,750	1,144	3,331
Amortisation of intangible assets	15	–	84	25	42
Depreciation of right-of-use assets	16	2,218	8,757	2,132	5,442
Loss on disposal of property, plant and equipment	6	2	959	–	–
Investment income on other investments classified as financial assets at FVTPL	5	(156)	(424)	–	(593)
Fair value gains on other investments classified as financial assets at FVTPL	5	–	(178)	–	(21)
Fair value losses on preferred shares	26	319,232	954,742	647,031	143,642
Impairment losses on financial assets, net	18	–	130	–	74
Foreign exchange losses/(gain), net	6	5,927	3,699	1,371	(17,809)
Government grant recognised from deferred income		–	(7,579)	–	–
Equity-settled share-based payments	30	416	164,659	94	55,435
		<u>335,240</u>	<u>1,124,625</u>	<u>650,998</u>	<u>187,972</u>
Increase in inventories		–	(13)	–	(1,532)
Increase in restricted bank balances		–	(72)	–	–
Increase in trade receivables		–	(65,134)	–	(36,959)
Decrease/(increase) in other non-current assets		9,266	(5,020)	(1,557)	6,930
(Increase)/decrease in amounts due from related parties		(297)	372	172	–
Decrease/(increase) in prepayments and other receivables		17,243	(3,919)	(2,329)	1,828
(Decrease)/increase in trade payables		(13,261)	1,326	847	(1,092)
Decrease in amounts due to related parties		(13)	(1,552)	–	–
Increase in other payables and accruals		8,873	34,133	27,846	23,374
		<u>8,873</u>	<u>34,133</u>	<u>27,846</u>	<u>23,374</u>
Net cash flows used in operating activities		<u>(278,329)</u>	<u>(377,079)</u>	<u>(127,993)</u>	<u>(112,896)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>					
Purchases of items of property, plant and equipment		(11,147)	(43,872)	(5,617)	(16,248)
Payment for acquisition of a land use right	16	–	(11,492)	(11,492)	–
Purchase of intangible assets	15	–	(1,013)	(766)	–
Payment for acquisition of subsidiaries in the Restructuring		(11,118)	–	–	–
Proceeds from disposal of property, plant and equipment		4	–	–	–
Loans provided to a third party*		(10,000)	–	–	–
Loans provided to related parties		–	(3,200)	–	–
Loan provided to an employee		–	(1,200)	–	–
Repayment of loans to a third party*		10,000	–	–	–
Purchase of financial assets at FVTPL		–	(100,000)	–	(100,000)
Interest received		1,610	5,482	1,164	2,311
(Increase)/decrease in pledged bank deposits		(6,000)	6,000	–	–
Proceeds from disposal of financial assets at FVTPL		6,171	50,424	–	100,771
		<u>6,171</u>	<u>50,424</u>	<u>–</u>	<u>100,771</u>
Net cash flows used in investing activities		<u>(20,480)</u>	<u>(98,871)</u>	<u>(16,711)</u>	<u>(13,166)</u>

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	Notes	Year ended		Five months ended	
		December 31, 2020 RMB’000	2021 RMB’000	May 31, 2021 RMB’000 (unaudited)	2022 RMB’000
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>					
Payments for share repurchase		–	(32,730)	–	–
Proceeds from issue of preferred shares		783,818	1,614,410	1,114,744	–
Payments for repurchase of onshore investments		–	(843,030)	(843,030)	–
Payments for offshore preferred shares repurchase		(29,885)	(204,151)	(157,996)	–
Proceeds from equity-settled share-based payments		–	4	–	–
[REDACTED] expenses paid		(959)	(7,001)	(1,184)	(1,069)
New bank borrowings		3,522	–	–	–
Interest paid		(17,533)	(1,528)	(365)	(740)
Payments for rental deposit		–	(3,783)	(1,672)	(231)
Principal portion of lease payments		(1,217)	(5,732)	(2,595)	(5,010)
Repayment of loans to related parties		(11,948)	–	–	–
Repayment of bank loans and other borrowings		(124,956)	(3,522)	(3,522)	–
Advances from issue of preferred shares		6,545	–	–	–
Proceeds from exercise of restricted share units		–	6,012	–	715
Commissions paid in relation to capital contribution		–	(11,647)	–	–
Capital contribution from a shareholder of a subsidiary		–	332,780	–	–
		<u>607,387</u>	<u>840,082</u>	<u>104,380</u>	<u>(6,335)</u>
<b>NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS</b>					
		308,578	364,132	(40,324)	(132,397)
Cash and cash equivalents at beginning of year/period		112,156	414,261	414,261	774,306
Effect of foreign exchange rate changes, net		(6,473)	(4,087)	(1,370)	18,322
		<u>414,261</u>	<u>774,306</u>	<u>372,567</u>	<u>660,231</u>
<b>CASH AND CASH EQUIVALENTS AT END OF YEAR/PERIOD</b>					
		<u>414,261</u>	<u>774,306</u>	<u>372,567</u>	<u>660,231</u>
<b>ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS</b>					
Cash and bank balances as stated in the consolidated statements of financial position	21	<u>414,261</u>	<u>774,306</u>	<u>372,567</u>	<u>660,231</u>

\* On November 30, 2020, the Company entered into a loan agreement with Rui Xia Investment Holding Limited (“Rui Xia”), one of the 2019 Investors as defined in the section headed “Definitions” of the [REDACTED]. The loan was provided to Rui Xia to facilitate its overseas direct investment registration with the local regulator. The loan was interest free, unsecured and has a term of three business days. The Company provided the loan to Rui Xia on December 3, 2020 and collected on December 7, 2020.

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**STATEMENTS OF FINANCIAL POSITION OF THE COMPANY**

	<i>Notes</i>	<b>As at December 31,</b>		<b>As at May 31,</b>
		<b>2020</b>	<b>2021</b>	<b>2022</b>
		<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
<b>NON-CURRENT ASSETS</b>				
Investments in subsidiaries		228,033	1,770,227	1,845,947
Total non-current assets		228,033	1,770,227	1,845,947
<b>CURRENT ASSETS</b>				
Amounts due from subsidiaries	34	161,870	34,868	35,583
Prepayments, other receivables and other assets	19	25,876	10,143	11,864
Cash and bank balances	21	118,200	15,830	16,573
Total current assets		305,946	60,841	64,020
<b>CURRENT LIABILITIES</b>				
Other payables and accruals	23	18,024	20,762	24,039
Amounts due to subsidiaries	34	185,800	34,414	34,414
Preferred shares	26	215,237	3,093,968	3,233,922
Total current liabilities		419,061	3,149,144	3,292,375
<b>NET CURRENT LIABILITIES</b>		<b>(113,115)</b>	<b>(3,088,303)</b>	<b>(3,228,355)</b>
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<b>114,918</b>	<b>(1,318,076)</b>	<b>(1,382,408)</b>
<b>NON-CURRENT LIABILITIES</b>				
Preferred shares	26	549,006	38,823	42,511
Total non-current liabilities		549,006	38,823	42,511
<b>NET LIABILITIES</b>		<b>(434,088)</b>	<b>(1,356,899)</b>	<b>(1,424,919)</b>
<b>EQUITY</b>				
Share capital	27	37	57	57
Treasury shares	27	–	(27)	(27)
Deficits	28	(434,125)	(1,356,929)	(1,424,949)
Total deficits		(434,088)	(1,356,899)	(1,424,919)

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II NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE INFORMATION

3D Medicines Inc. (the “Company”) is a limited liability company incorporated in the Cayman Islands on January 30, 2018. The registered office address of the Company is Cricket Square, Hutchins Drive, P.O. Box 2681, Grand Cayman KY1-1111, Cayman Islands.

The Company is an investing holding company. The Company and its subsidiaries now comprising the Group underwent the restructuring as set out in the paragraph headed “Corporate Development” in the section headed “History, Development and Corporate Structure” in the Document (the “Restructuring”).

During the Relevant Periods, the Group was involved in the research, development and commercialisation of pharmaceutical products.

As at the date of this report, the Company had direct and indirect interests in its subsidiaries, all of which are private limited liability companies (or, if incorporated outside Hong Kong, have substantially similar characteristics to a private company incorporated in Hong Kong), the particulars of which are set out below:

Name	Place and date of incorporation/ registration and place of operations	Issued ordinary/ registered share capital	Percentage of equity attributable to the Company		Principal activities
			Direct	Indirect	
Full Goal Trading Limited (“Full Goal”) <i>(note (a))</i>	British Islands Islands (“BVI”) January 30, 2018	US\$50,000	100%	–	Investment holding
3D Medicines USA, Inc. (“3DMed USA”) <i>(note (b))</i>	United States of America (“USA”) October 12, 2018	US\$1,500	100%	–	Research and development
3D Medicines (Hong Kong) Co., Limited (思路迪醫藥科技(香港)有限公司) (“3DMed HK”) <i>(note (b))</i>	Hong Kong February 8, 2018	HK\$10,000	–	100%	Investment holding
Integral Lane Holding Limited <i>(note (a))</i>	BVI April 17, 2018	US\$50,000	–	100%	Investment holding
3D Medicines (Shanghai) Co., Limited* (思路迪生物醫藥(上海)有限公司) (“3D Medicines”) <i>(note (c), (d), (g) and (i))</i>	Mainland China September 10, 2015	US\$119,735,390	–	89.46%	Research and development
3D Medicines (Beijing) Science & Technology Co., Limited* (思路迪(北京)醫藥科技有限公司) (“3DMed Beijing”) <i>(note (c), (d) and (f))</i>	Mainland China December 22, 2014	RMB200,000,000	–	89.46%	Research and development

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Name	Place and date of incorporation/ registration and place of operations	Issued ordinary/ registered share capital	Percentage of equity attributable to the Company		Principal activities
			Direct	Indirect	
3D Medicines (Shanghai) Science & Technology Co., Limited* (思路迪(上海)醫藥科技有限公司) (“3DMed Shanghai”) (note (c) and (d))	Mainland China April 13, 2017	RMB50,000,000	–	89.46%	Research and development
Sichuan 3DMed-Alphamab Co., Ltd.* (四川思路康瑞藥業有限公司) (“3DMed Sichuan”) (note (c), (d) and (h))	Mainland China March 16, 2016	RMB50,000,000	–	89.46%	Research and development
Xuzhou 3D Medicines Pharmaceutical Co., Ltd* (徐州思路迪藥業有限公司) (“3DMed Xuzhou”) (note (e))	Mainland China November 26, 2020	US\$150,000,000	–	100%	Manufacturing and trading
Longteng Pharmaceutical (Jiangsu) Co., Limited* (龍騰藥業(江蘇)有限公司) (note (d))	Mainland China March 30, 2021	RMB50,000,000	–	100%	Manufacturing and trading
3D Medicines (Qingdao) Co., Ltd.* (思路迪醫藥(青島)有限公司) (“3DMed Qingdao”) (note (d))	Mainland China June 18, 2021	US\$50,000,000	–	100%	Research and development

Notes:

- (a) No audited financial statements have been prepared, as the entities were not subject to any statutory audit requirements under the relevant rules and regulations in their jurisdiction of incorporation.
- (b) As at the date of this report, no audited financial statements have been prepared for these entities, as they had limited level of business operations.
- (c) The statutory financial statements of these entities for the year ended December 31, 2020 prepared in accordance with accepted accounting principles and financial regulations in the People’s Republic of China (“PRC”) were audited by EPA CPA Partnership (上海至臻聯合會計師事務所(特殊普通合夥)), certified public accountants registered in the PRC.
- (d) The statutory financial statements of these entities for the year ended December 31, 2021 prepared in accordance with accepted accounting principles and financial regulations in the PRC were audited by Shanghai Ding Mai Baychine Certified Public Accountants Co., Ltd. (上海鼎邁北勤會計師事務所有限公司), certified public accountants registered in the PRC.
- (e) The statutory financial statements of this entity for the years ended December 31, 2020 and 2021 prepared in accordance with accepted accounting principles and financial regulations in the PRC were audited by Shanghai Ding Mai Baychine Certified Public Accountants Co., Ltd. (上海鼎邁北勤會計師事務所有限公司), certified public accountants registered in the PRC.

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- (f) Pursuant to a share pledge contract between 3D Medicines and Simcere Pharmaceutical Co., Ltd. (先聲藥業有限公司) (“Simcere Pharmaceutical”) entered into on December 23, 2019, 100% of 3DMed Beijing’s registered share capital held by 3D Medicines was pledged to secure the then investments amounted to RMB210,345,000 in 3D Medicines held by Simcere pharmaceutical. The pledge was discharged on June 29, 2021.
  - (g) Pursuant to a cooperation agreement between 3D Medicines, 3DMed HK and Simcere Pharmaceutical on September 9, 2019 and a share pledge contract between 3DMed HK and Simcere Pharmaceutical on September 18, 2019, 8.5714% of 3D Medicines’ registered share capital held by 3DMed HK was pledged to secure the loan amounted to RMB60,000,000 borrowed from Simcere Pharmaceutical, which was settled in 2019 and the pledge was discharged on August 24, 2020.
  - (h) Pursuant to an equity transfer agreement on April 29, 2021, 3D Medicines transferred 49% equity interest in 3DMed Sichuan to the Jiangsu Alphamab Biopharmaceuticals Co., Ltd. at a nominal consideration. Upon completion of the aforementioned equity transfer on May 6, 2021 and pursuant to the articles of association currently in effect of 3DMed Sichuan, 3D Medicines retains 100% voting right at shareholders’ meetings and is entitled to 100% economic interests and nomination right of the director(s), supervisor(s) and senior management, and retains 100% voting rights of 3DMed Sichuan. Accordingly, 3DMed Sichuan remains an indirect subsidiary of the Company.
  - (i) Pursuant to a capital increase agreement on May 24, 2021, Qingdao Hainuo Investment Development Co., Ltd. (青島海諾投資發展有限公司), an independent third party, subscribed for an increased registered capital of 3D Medicines of US\$12,616,807, representing 10.54% equity interest in 3D Medicines at a consideration of RMB332,780,000.
- \* The English names of these companies represent the best effort made by the directors of the Company (the “Directors”) to translate the Chinese names as these companies have not been registered with any official English names.

### 2.1 BASIS OF PRESENTATION

Pursuant to the Restructuring, as more fully explained in the paragraph headed “Corporate Development” in the section headed “History, Development and Corporate Structure” in the Document, the Company became the holding company of the companies now comprising the Group on August 7, 2018.

As the Restructuring mainly involved inserting new holding companies and has not resulted in any change of the respective voting, economic substance and beneficial interests, the Historical Financial Information for the Relevant Periods has been presented by applying the principles of pooling of interests as if the Restructuring had been completed at the beginning of the Relevant Periods.

Accordingly, the consolidated statements of profit or loss and other comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows of the Group for the Relevant Periods and the five months ended May 31, 2021 include the results and cash flows of all companies now comprising the Group from the earliest date presented or since the date of incorporation of the subsidiaries, where there is a shorter period. The consolidated statements of financial position of the Group as at December 31, 2020 and 2021 and May 31, 2022 have been prepared to present the assets and liabilities of the subsidiaries using the existing book values. No adjustments are made to reflect fair values or recognise any new assets or liabilities as a result of the Restructuring.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Company and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group transactions and balances have been eliminated on consolidation.



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### 2.2 BASIS OF PREPARATION

Notwithstanding that the Group recorded net liabilities of RMB2,509,829,000 and net current liabilities of RMB2,600,559,000 which mainly included preferred shares of RMB3,233,922,000 being classified as current liabilities as at May 31, 2022 and continually incurred recurring losses from operations, the Historical Financial Information has been prepared on a going concern basis based on the following:

- the directors of the Company do not expect that the preferred shares would be redeemed within the next twelve months from May 31, 2022 as the redemption right associated in the Memorandum and Articles of Association of the Company was postponed upon the Company’s submission of the first Application Proof in June 2021; and
- the directors of the Company have considered the additional financial resources available to the Group, the internally generated funds from operations and the ability in adjusting the pace of the research and development projects and capital investments at management’s discretion and are of the opinion that the Group will have sufficient working capital to meet its financial liabilities and obligations as and when they fall due and to sustain its operations for the next twelve months from May 31, 2022.

The Historical Financial Information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board (“IASB”). All IFRSs effective for the accounting period commencing from January 1, 2022, together with the relevant transitional provisions, have been adopted by the Group in the preparation of the Historical Financial Information throughout the Relevant Periods and the five months ended May 31, 2021.

The Historical Financial Information has been prepared under the historical cost convention except for certain financial instruments which have been measured at fair value at the end of each of the Relevant Periods.

### 2.3 ISSUED BUT NOT YET EFFECTIVE IFRSs

The Group has not applied the following new and revised IFRSs that have been issued but are not yet effective, in the Historical Financial Information.

Amendments to IAS 28 and IFRS 10	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> <sup>2</sup>
IFRS 17	<i>Insurance Contracts</i> <sup>1</sup>
Amendments to IFRS 17	<i>Insurance Contracts</i> <sup>1,3</sup>
Amendments to IFRS 17	<i>Initial Application of IFRS17 and IFRS9 Comparative Information</i> <sup>1</sup>
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current</i> <sup>1,4</sup>
Amendments to IAS 1 and IFRS Practice Statement 2	<i>Disclosure of Accounting Policies</i> <sup>1</sup>
Amendments to IAS 8	<i>Definition of Accounting Estimates</i> <sup>1</sup>
Amendments to IAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction</i> <sup>1</sup>

- 1 Effective for annual periods beginning on or after January 1, 2023
- 2 No mandatory effective date yet determined but available for adoption
- 3 As a consequence of the amendments to IFRS 17 issued in June 2020, the effective date of IFRS 17 was deferred to annual period beginning on or after January 1, 2023, and IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before January 1, 2023
- 4 In July 2021, the effective date of the amendments to IAS 1 was tentatively decided to be deferred to annual period beginning on or after January 1, 2024

The Group is in the process of making an assessment of the impact of these new and revised IFRSs upon initial application. So far, the Group considers that these new and revised IFRSs may result in changes in accounting policies and are unlikely to have a significant impact on the Group’s results of operations and financial position.

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### 2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### Subsidiaries

A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e. existing rights that give the Group the current ability to direct the relevant activities of the investee).

When the Company has, directly or indirectly, less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group’s voting rights and potential voting rights.

The financial statements of the subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction. The results of subsidiaries are included in the Company’s profit or loss to the extent of dividends received and receivable. The Company’s investments in subsidiaries are stated at cost less any impairment losses.

#### Business combinations of entities under common control

Business combinations of entities under common control are accounted for using the pooling of interests method with restatement of financial information in the consolidated financial statements for periods prior to the completion of the combination under common control, to reflect the combination as if it had occurred from the beginning of the earliest period presented, regardless of the actual date of the combination. Under the pooling of interests method, the assets and liabilities of the combining entities are reflected at their existing carrying amounts at the date of combination with no new goodwill recognised. Difference between the consideration transferred and acquired net assets at the date of the combination is recorded in equity.

#### Fair value measurement

The Group measures its certain financial instruments at fair value at the end of each of the Relevant Periods. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

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All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly
- Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognised in the Historical Financial Information on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Relevant Periods.

### Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than financial assets), the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of the asset's or cash-generating unit's value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each of the Relevant Periods as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to profit or loss in the period in which it arises.

### Related parties

A party is considered to be related to the Group if:

- (a) the party is a person or a close member of that person's family and that person:
  - (i) has control or joint control over the Group;
  - (ii) has significant influence over the Group; or
  - (iii) is a member of the key management personnel of the Group or of a parent of the Group;
- or
- (b) the party is an entity where any of the following conditions applies:
  - (i) the entity and the Group are members of the same group;
  - (ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);

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- (iii) the entity and the Group are joint ventures of the same third party;
- (iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;
- (v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;
- (vi) the entity is controlled or jointly controlled by a person identified in (a);
- (vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and
- (viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

### Property, plant and equipment and depreciation

Property, plant and equipment are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used for this purpose are as follows:

Leasehold improvements	Shorter of remaining lease terms and estimated useful lives
Office equipment	19% to 32%
Laboratory equipment	19% to 32%
Transportation equipment	24%

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at the end of each of the Relevant Periods.

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress represents a building under construction, which is stated at cost less any impairment losses, and is not depreciated. Cost comprises the direct costs of construction during the period of construction. Construction in progress is reclassified to the appropriate category of plant and equipment when completed and ready for use.

### Intangible assets (other than goodwill)

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at the end of each of the Relevant Periods.

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Intangible assets are amortized on the straight-line basis over the following useful economic lives:

Software	10 years
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### *Research and development costs*

All research costs are charged to profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

### **Leases**

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

### *The Group as a lessee*

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

#### *(a) Right-of-use assets*

Right-of-use assets are recognised at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and any impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Where applicable, the cost of a right-of-use asset also includes an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Office and laboratory	2 to 5 years
Leasehold land	40 years

If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

#### *(b) Lease liabilities*

Lease liabilities are recognised at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate the lease. The variable lease payments that do not depend on an index or a rate are recognised as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

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### *(c) Short-term leases and leases of low-value assets*

The Group applies the short-term lease recognition exemption to its short-term leases of office (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the recognition exemption for leases of low-value assets to leases of office equipment that are considered to be of low value. Lease payments on short-term leases and leases of low-value assets are recognised as an expense on a straight-line basis over the lease term.

### **Investments and other financial assets**

#### *Initial recognition and measurement*

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost, and FVTPL.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Group’s business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15.

In order for a financial asset to be classified and measured at amortized cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest (“SPPI”) on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group’s business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortised cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

All regular way purchases and sales of financial assets are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace.

#### *Subsequent measurement*

The subsequent measurement of financial assets depends on their classification as follows:

##### *Financial assets at amortised cost (debt instruments)*

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised in profit or loss when the asset is derecognised, modified or impaired.

##### *Financial assets at FVTPL*

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognised in profit or loss.

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### **Derecognition of financial assets**

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group’s consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a “pass-through” arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset, nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of its continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

### **Impairment of financial assets**

The Group recognises an allowance for expected credit losses (“ECLs”) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

#### ***General approach***

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information.

The Group considers a financial asset in default when contractual payments are 45-70 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

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Financial assets at amortised cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables and contract assets which apply the simplified approach as detailed below.

- Stage 1 – Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs
- Stage 2 – Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs
- Stage 3 – Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

### *Simplified approach*

For trade receivables that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

### **Financial liabilities**

#### *Initial recognition and measurement*

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, or payables, as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group’s financial liabilities include trade payables, other payables and accruals, interest-bearing bank borrowings, amounts due to a related party and preferred shares.

#### *Subsequent measurement*

The subsequent measurement of financial liabilities depends on their classification as follows:

##### *Financial liabilities at amortised cost (loans and borrowings)*

After initial recognition, trade payables, other payables and accruals, interest-bearing bank borrowings and amounts due to a related party, are subsequently measured at amortised cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in statement of profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in the statement of profit or loss and other comprehensive income.

##### *Financial liabilities at FVTPL*

Financial liabilities measured at FVTPL include preferred shares which are designated upon initial recognition as at fair value through profit or loss.



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Financial liabilities designated upon initial recognition as at fair value through profit or loss are designated at the initial date of recognition, and only if the criteria in IFRS 9 are satisfied. Gains or losses on liabilities designated at fair value through profit or loss are recognised in profit or loss, except for the gains or losses arising from the Group’s own credit risk which are presented in other comprehensive income with no subsequent reclassification to the statement of profit or loss.

### **Derecognition of financial liabilities**

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in profit or loss and other comprehensive income.

### **Offsetting of financial instruments**

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position if there is a currently enforceable legal right to offset the recognised amounts and there is an intention to settle on a net basis, or to realise the assets and settle the liabilities simultaneously.

### **Treasury shares**

Own equity instruments which are reacquired and held by the Company or the Group (treasury shares) are recognised directly in equity at cost. No gain or loss is recognised in the statement of profit or loss on the purchase, sale, issue or cancellation of the Group’s own equity instruments.

### **Inventories**

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the weighted average method and, in the case of work in progress and finished goods, comprises direct materials, direct labour and an appropriate proportion of overheads. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

### **Cash and cash equivalents**

For the purpose of the consolidated statement of cash flows, cash and cash equivalents comprise cash and bank balances, which are subject to an insignificant risk of changes in value, less bank overdrafts which are repayable on demand and form an integral part of the Group’s cash management.

For the purpose of the consolidated statement of financial position, cash and cash equivalents comprise cash on hand and at banks, including term deposits, and assets similar in nature to cash, which are not restricted as to use.

### **Provisions**

A provision is recognised when a present obligation (legal or constructive) has arisen as a result of a past event and it is probable that a future outflow of resources will be required to settle the obligation, provided that a reliable estimate can be made of the amount of the obligation.

When the effect of discounting is material, the amount recognised for a provision is the present value at the end of each of the Relevant Periods of the future expenditures expected to be required to settle the obligation. The increase in the discounted present value amount arising from the passage of time is included in finance costs in profit or loss and other comprehensive income.

### **Income tax**

Income tax comprises current and deferred tax. Income tax relating to items recognised outside profit or loss is recognised outside profit or loss, either in other comprehensive income or directly in equity.

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Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the Relevant Periods, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of each of the Relevant Periods between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of taxable temporary differences associated with investments in subsidiaries, associates and joint ventures, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognised for all deductible temporary differences, and the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of deductible temporary differences associated with investments in subsidiaries, associates and joint ventures, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of each of the Relevant Periods and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of each of the Relevant Periods and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the Relevant Periods.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

### **Government grants**

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed. When the grant relates to expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future costs and obligations, it is recognised in profit or loss in the period in which it becomes receivable.

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Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to profit or loss over the expected useful life of the relevant asset by equal annual instalments or deducted from the carrying amount of the asset and released to profit or loss by way of a reduced depreciation charge.

### Revenue recognition

#### *Revenue from contracts with customers*

Revenue from contracts with customers is recognised 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.

##### *(a) Sales of products*

Revenue from the sale of products is recognised at the point in time when control of the product is transferred to the customer, generally when the products are delivered and accepted by the customers.

During the year ended December 31, 2021 and the five months ended May 31, 2022, 100% and 99% of the sales of products were made through Jiangsu Simcere Pharmaceutical Co., Ltd. (“Jiangsu Simcere”) to pharmacy stores and distributors which are the Group’s customers. Jiangsu Simcere acted as a service provider of the Group and the service fees retained by Jiangsu Simcere are recognised as selling expenses.

#### *Other income*

Interest income is recognised on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Research service income is recognised at the point in time when the research report is delivered and accepted by the customers.

### Share-based payments

3D Medicines and its immediate holding company before the Restructuring (“Predecessor Holdco”), operated share award schemes for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. The share award schemes of 3D Medicines and the Predecessor Holdco were terminated in June 2021 and the Company adopted a share incentive scheme on June 22, 2021. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (“equity-settled transactions”).

The cost of equity-settled transactions with employees is measured by reference to the fair value at the date on which they are granted. The fair value of share award is determined using the back-solve method or binomial model. Further details are included in note 30 to the Historical Financial Information.

The cost of equity-settled transactions is recognised in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognised for equity-settled transactions at the end of each of the Relevant Periods until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of equity instruments that will ultimately vest. The charge or credit to profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group’s best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

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For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. This includes any award where non-vesting conditions within the control of either the Group or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

When the equity-settled award are exercised, the amount previously recognised in equity-settled share-based reserve will be transferred to share premium. When the equity-settled award are forfeited after the vesting date or are still not exercised at the expiry date, the amount previously recognised in equity-settled share-based reserve will be transferred to retained earnings.

### **Other employee benefits**

#### *Pension scheme*

The employees of the Group’s subsidiaries which operate in Mainland China are required to participate in a central pension scheme operated by the local municipal government. The subsidiaries are required to contribute a certain percentage of their payroll costs to the central pension scheme. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme.

The subsidiary in the USA maintains multiple qualified contributory savings plans as allowed under Section 401(k) of the Internal Revenue Code in the USA. These plans are defined contribution plans covering substantially all its qualifying employees and provide for voluntary contributions by employees, subject to certain limits. The contributions are made by both the employees and the employer. The employees’ contributions are primarily based on specified dollar amounts or percentages of employee compensation. The only obligation of the subsidiary in the USA with respect to the retirement benefits plans is to make the specified contributions under the plans.

### **Borrowing costs**

All borrowing costs are expensed in the period in which they are incurred. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

### **Foreign currencies**

The Historical Financial Information is presented in RMB, which is the Company’s functional currency. Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of each of the Relevant Periods. Differences arising on settlement or translation of monetary items are recognised in profit or loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognised in other comprehensive income or profit or loss is also recognised in other comprehensive income or profit or loss, respectively).

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In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of initial transaction is the date on which the Group initially recognises the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of the advance consideration.

### 3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group's Historical Financial Information requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

#### **Judgements**

In the process of applying the Group's accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognised in the Historical Financial Information:

#### *Research and development expenses*

All research costs are charged to the statement of profit or loss as incurred. Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred. Determining the amounts of development costs to be capitalised requires the use of judgements and estimation.

#### **Estimation uncertainty**

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of each of the Relevant Periods, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

#### *Provision for expected credit losses on trade receivables*

The Group uses a provision matrix to calculate ECLs for trade receivables. The provision rates are based on internal credit ratings as groupings of debtors that have similar loss patterns.

The provision matrix is initially based on the credit loss rate of similar companies in the market as the Group has not had sufficient credit loss data. The Group will calibrate to adjust the expected loss rate with forward-looking information. The expected loss rate will be back-tested against observed default rates in the future and changes in the forward-looking estimates will be analysed.

The assessment of the correction among credit loss rates of comparable companies, forecast economic conditions and ECLs is a significant estimate. The amount of ECLs is sensitive to changes in circumstances and forecast economic conditions. The Group's expected credit loss rate and forecast of economic conditions may also not be representative of a customer's actual default in the future. The information about the ECLs on the Group's trade receivables is disclosed in note 18 to the Historical Financial Information.

#### *Recognition of income taxes and deferred tax assets*

Determining income tax provision involves judgement on the future tax treatment of certain transactions and when certain matters relating to the income taxes have not been confirmed by the local tax bureau. Management evaluates tax implications of transactions and tax provisions are set up accordingly. The tax treatments of such transactions are reconsidered periodically to take into account all changes in tax legislation.

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Deferred tax assets are recognised for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilised. Significant management judgement is required to determine the amount of deferred tax assets that can be recognised, based upon the likely timing and level of future taxable profits together with future tax planning strategies.

### *Fair value of preferred shares measured at FVTPL*

The fair value of the preferred shares measured at FVTPL is determined using valuation techniques, including the discounted cash flow method, the back-solve method and the equity allocation model. Such valuation requires key assumptions include the risk-free interest rate, discounts for lack of marketability (“DLOM”) and volatility, which are subject to uncertainty. Improper application of such parameters might result in material differences from the actual results.

The fair values of preferred shares at December 31, 2020 and 2021 and May 31, 2022 were RMB1,645,620,000, RMB3,132,791,000 and RMB3,276,433,000, respectively. Further details are included in note 26 to the Historical Financial Information.

### *Fair value of share-based payment transactions*

Estimating the fair value of share-based payment transactions requires the determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. This estimate also requires the determination of the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them.

For the measurement of the fair value of share-based payment transactions with employees at the grant date, the Group uses a binomial model. The assumptions and models used for estimating fair value for share-based payments transactions are disclosed in note 30 to the Historical Financial Information.

### *Leases – Estimating the incremental borrowing rate*

The Group cannot readily determine the interest rate implicit in a lease, and therefore, it uses an incremental borrowing rate (“IBR”) to measure lease liabilities. The IBR is the rate of interest that the Group would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what the Group “would have to pay”, which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when it needs to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary’s functional currency). The Group estimates the IBR using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates (such as the subsidiary’s stand-alone credit rating).

### *Impairment of non-financial assets (other than goodwill)*

The Group assesses whether there are any indicators of impairment for all non-financial assets (including right-of-use assets) at the end of each of the Relevant Periods. The non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm’s length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

## **4. OPERATING SEGMENT INFORMATION**

### **Operating segment information**

The Group is engaged in biopharmaceutical research, development and commercialisation, which is regarded as a single reportable segment in a manner consistent with the way in which information is reported internally to the Group’s senior management for purposes of resource allocation and performance assessment. Therefore, no further operating segment analysis thereof is presented.

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**Geographical information**

During the Relevant Periods and the five months ended May 31, 2021, all of the Group’s revenue was derived from customers located in Mainland China and almost all of the Group’s non-current assets were located in Mainland China, and therefore no geographical segment information is presented in accordance with IFRS 8 *Operating Segments*.

**Information about major customers**

Revenue from each major customer, including revenue to a group of entities which are known to be under common control with that customer, which accounted for 10% or more of the Group’s revenue during the Relevant Periods and the five months ended May 31, 2021 is set out below:

	Year ended December 31,		Five months ended May 31,	
	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000	RMB’000
			(unaudited)	
Customer A	–	21,789	–	72,103
Customer B	–	8,399	–	21,946
	<u>–</u>	<u>30,188</u>	<u>–</u>	<u>94,049</u>

**5. REVENUE, OTHER INCOME AND GAINS**

An analysis of revenue is as follows:

	Year ended December 31,		Five months ended May 31,	
	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000	RMB’000
			(unaudited)	
Revenue from contracts with customers				
Sales of products	–	60,260	–	161,062
	<u>–</u>	<u>60,260</u>	<u>–</u>	<u>161,062</u>

Revenue from contracts with customers

**(a) Disaggregated revenue information**

	Year ended December 31,		Five months ended May 31,	
	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000	RMB’000
			(unaudited)	
<b>Geographical market</b>				
Mainland China	–	60,260	–	161,062
	<u>–</u>	<u>60,260</u>	<u>–</u>	<u>161,062</u>
<b>Timing of revenue recognition</b>				
Goods transferred at a point in time	–	60,260	–	161,062
	<u>–</u>	<u>60,260</u>	<u>–</u>	<u>161,062</u>

There was no revenue recognised during the Relevant Periods and the five months ended May 31, 2021 that was included in the contract liabilities at the beginning of each of the Relevant Periods and the five months ended May 31, 2021 and recognised from performance obligations satisfied in previous periods.

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**(b) Performance obligations**

Information about the Group’s performance obligations is summarised below:

*Sales of products*

The performance obligation is satisfied upon delivery of the products and acceptance by the customers. The credit term granted to the distributors is usually 45-70 days upon acceptance. During the year ended December 31, 2021 and the five months ended May 31, 2022, Jiangsu Simcere reconciles and settles the payments received from the majority customers of the Group on a monthly basis.

An analysis of other income and gains is as follows:

	<b>Year ended December 31,</b>		<b>Five months ended May 31,</b>	
	<b>2020</b>	<b>2021</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(unaudited)</i>	
Other income				
Government grants income*	571	8,423	330	746
Investment income on other investments classified as financial assets at FVTPL	156	424	–	593
Interest income	1,610	5,502	1,164	2,311
Research service income	–	5,110	–	–
	<u>2,337</u>	<u>19,459</u>	<u>1,494</u>	<u>3,650</u>
Other gains				
Foreign exchange gain, net	–	–	–	17,809
Fair value gains on other investments classified as financial assets at FVTPL	–	178	–	21
	<u>2,337</u>	<u>19,637</u>	<u>1,494</u>	<u>21,480</u>

\* The government grants mainly represent subsidies received from the local governments for the purpose of compensation of expenses spent on research and clinical trial activities, allowances for new drug development. There were no unfulfilled conditions or contingencies relating to the grants.



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**6. OTHER EXPENSES**

An analysis of other expenses is as follows:

	Year ended December 31,		Five months ended May 31,	
	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000
			(unaudited)	
Foreign exchange losses, net	5,927	3,699	1,371	–
Research service cost	–	2,538	–	–
Loss on disposal of property, plant and equipment	2	959	–	–
Donations*	–	1,424	–	14,224
Others	–	320	–	–
	<u>5,929</u>	<u>8,940</u>	<u>1,371</u>	<u>14,224</u>

\* Donations represented the expenditures incurred in relation to a drug donation program hosted by a charity organization.

**7. FINANCE COSTS**

	Year ended December 31,		Five months ended May 31,	
	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000
			(unaudited)	
Interest on loans from a related party (note 34 (b))	641	–	–	–
Interest on bank loans and other borrowings	7,107	46	46	–
Interest on lease liabilities (note 16 (c))	310	1,482	319	740
	<u>8,058</u>	<u>1,528</u>	<u>365</u>	<u>740</u>

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8. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging/(crediting):

	Notes	Year ended December 31,		Five months ended May 31,	
		2020 RMB’000	2021 RMB’000	2021 RMB’000	2022 RMB’000
Cost of inventories sold		–	4,277	–	11,458
Depreciation of property, plant and equipment	14	1,153	3,750	1,144	3,331
Depreciation of right-of-use assets	16	2,218	8,757	2,132	5,442
Amortisation of intangible assets	15	–	84	25	42
[REDACTED] expenses		4,187	25,565	8,799	3,541
Loss on disposal of property, plant and equipment	6	2	959	–	–
Foreign exchange losses/(gains), net	5/6	5,927	3,699	1,371	(17,809)
Donations	6	–	1,424	–	14,224
Fair value losses on preferred shares	26	319,232	954,742	647,031	143,642
Lease payments in respect of short-term leases	16(c)	137	1,263	143	189
Impairment losses on trade receivables	18	–	130	–	74
Royalty expenses*		–	7,153	–	17,364
Marketing service fees**		–	38,281	–	94,077
Auditor’s remuneration		22	23	9	14
Employee benefit expenses (excluding directors’ and chief executive’s remuneration (note 9))					
– Wages and salaries		55,261	103,682	36,506	77,096
– Pension scheme contributions***		460	7,153	2,489	4,060
– Staff welfare expenses		1,696	2,272	780	739
– Share-based payments expenses		416	87,686	94	25,879
		<u>57,833</u>	<u>200,793</u>	<u>39,869</u>	<u>107,774</u>

\* Pursuant to the co-development agreement with Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (“Jiangsu Alphamab”), the Group needs to pay Jiangsu Alphamab royalty fees on a profit-sharing basis as part of the consideration for the exclusive rights acquired from Jiangsu Alphamab to conduct clinical trials and commercialise Envafolelimab worldwide. The royalty expenses are recognised at the time when the Group is obligated to pay and the amount is determinable.

\*\* Pursuant to the marketing and promotion agreement with Jiangsu Simcere, the Group needs to pay Jiangsu Simcere marketing service fees for the marketing and promotion services performed by Jiangsu Simcere for the Group’s sales of Envafolelimab. The marketing service fees are recognised in selling and marketing expenses at the time when the Group is obligated to pay and the amount is determinable.

\*\*\* There are no forfeited contributions that may be used by the Group as the employer to reduce the existing level of contributions.

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**9. DIRECTORS’ AND CHIEF EXECUTIVE’S REMUNERATION**

Directors’ and chief executive’s remuneration as recorded during the Relevant Periods and the five months ended May 31, 2021, disclosed pursuant to the Rules Governing the Listing of Securities on the Hong Kong Stock Exchange (the “Listing Rules”), section 383(1)(a), (b), (c) and (f) of the Hong Kong Companies Ordinance and Part 2 of the Companies (Disclosure of Information about Benefits of Directors) Regulation, is set out below:

	Year ended December 31,		Five months ended May 31,	
	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000	RMB’000
			(unaudited)	
Fees	—	—	—	—
Other emoluments:				
Salaries, bonuses, allowances and benefits in kind	1,300	2,700	1,125	1,125
Share-based payment expenses	—	76,973	—	29,556
	<u>1,300</u>	<u>79,673</u>	<u>1,125</u>	<u>30,681</u>

**(a) Independent non-executive directors**

In June 2021, Mr. Liu Xinguang, Mr. Lin Tat Pang, Mr. Li Jin and Mr. Yan Shi were appointed as independent non-executive directors of the Company. Mr. Yan Shi was resigned as an independent non-executive director of the Company with effective from December 2021. There were no fees and other emoluments paid for the independent non-executive directors during the Relevant Periods and the five months ended May 31, 2021.

**(b) Directors and the chief executive**

**Year ended December 31, 2020**

	Fees	Salaries, bonuses, allowances and benefits in kind	Pension scheme contributions	Share-based payment expenses	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Executive director and chief executive:					
Dr. Gong Zhaolong (note (i))	—	1,300	—	—	1,300
Non-executive directors:					
Dr. Xiong Lei (note (ii))	—	—	—	—	—
Mr. Chen Lei (note (iii))	—	—	—	—	—
Mr. Xiong Minghua (note (iiii))	—	—	—	—	—
Mr. Zhou Feng (note (iv))	—	—	—	—	—
Mr. He Ming (note (v))	—	—	—	—	—
Mr. Zhang Liang (note (v))	—	—	—	—	—
Mr. Wang Feng (note (vi))	—	—	—	—	—
Mr. Tang Renhong (note (vii))	—	—	—	—	—
	<u>—</u>	<u>1,300</u>	<u>—</u>	<u>—</u>	<u>1,300</u>

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(b) **Directors and the chief executive (continued)**

**Year ended December 31, 2021**

	Fees <i>RMB'000</i>	Salaries, bonuses, allowances and benefits in kind <i>RMB'000</i>	Pension scheme contributions <i>RMB'000</i>	Share-based payment expenses <i>RMB'000</i>	Total <i>RMB'000</i>
Executive director and chief executive:					
Dr. Gong Zhaolong	–	2,700	–	76,973	79,673
Non-executive directors:					
Dr. Xiong Lei	–	–	–	–	–
Mr. Chen Lei	–	–	–	–	–
Mr. Xiong Minghua	–	–	–	–	–
Mr. Zhou Feng	–	–	–	–	–
Mr. Wang Feng	–	–	–	–	–
Mr. Tang Renhong	–	–	–	–	–
Mr. Zhu Pai ( <i>note (viii)</i> )	–	–	–	–	–
Mr. Wu Gang ( <i>note (ix)</i> )	–	–	–	–	–
	–	2,700	–	76,973	79,673

**Five months ended May 31, 2022**

	Fees <i>RMB'000</i>	Salaries, bonuses, allowances and benefits in kind <i>RMB'000</i>	Pension scheme contributions <i>RMB'000</i>	Share-based payment expenses <i>RMB'000</i>	Total <i>RMB'000</i>
Executive director and chief executive:					
Dr. Gong Zhaolong	–	1,125	–	29,556	30,681
Non-executive directors:					
Mr. Zhou Feng	–	–	–	–	–
Mr. Zhu Pai	–	–	–	–	–
Mr. Wu Gang	–	–	–	–	–
	–	1,125	–	29,556	30,681

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**Five months ended May 31, 2021 (unaudited)**

	Fees <i>RMB'000</i>	Salaries, bonuses, allowances and benefits in kind <i>RMB'000</i>	Pension scheme contributions <i>RMB'000</i>	Share-based payment expenses <i>RMB'000</i>	Total <i>RMB'000</i>
Executive director and chief executive:					
Dr. Gong Zhaolong	–	1,125	–	–	1,125
Non-executive directors:					
Dr. Xiong Lei	–	–	–	–	–
Mr. Chen Lei	–	–	–	–	–
Mr. Xiong Minghua	–	–	–	–	–
Mr. Zhou Feng	–	–	–	–	–
Mr. Wang Feng	–	–	–	–	–
Mr. Tang Renhong	–	–	–	–	–
	–	1,125	–	–	1,125

During the Relevant Periods, shares were granted to Dr. Gong Zhaolong through his holding vehicle in respect of his services to the Group and restricted share units were granted to him through trustee entities, further details of which are included in the disclosures in note 30 to the Historical Financial Information. The fair value of such awarded shares, which has been recognised in profit or loss, was determined as at the date of grant and the amount included in the Historical Financial Information for the Relevant Periods is included in the above directors’ remuneration disclosures.

There was no arrangement under which a director or the chief executive waived or agreed to waive any remuneration during the Relevant Periods and the five months ended May 31, 2021.

*Notes:*

- (i) Dr. Gong Zhaolong was appointed as a director and the chief executive officer of the Company and the chairman of the Board with effect from October 2019.
- (ii) Dr. Xiong Lei was appointed as a director of the Company with effect from March 2018 and resigned as a director of the Company with effect from June 2021.
- (iii) Mr. Chen Lei and Mr. Xiong Minghua were appointed as directors of the Company with effect from October 2019 and resigned as directors of the Company with effect from June 2021.
- (iv) Mr. Zhou Feng was appointed as a director of the Company with effect from October 2019.
- (v) Mr. He Ming and Mr. Zhang Liang were appointed as directors of the Company with effect from October 2019 and resigned as directors of the Company with effect from June 2020.
- (vi) Mr. Wang Feng was appointed as a director of the Company with effect from June 2020 and resigned as a director of the Company with effect from June 2021.
- (vii) Mr. Tang Renhong was appointed a director of the Company with effect from June 2020 and resigned as a director of the Company with effect from December 2021.
- (viii) Mr. Zhu Pai was appointed as a director of the Company with effect from June 2021.
- (ix) Mr. Wu Gang was appointed as a director of the Company with effect from June 2021 and resigned as a director of the Company with effect from July 2022.
- (x) Ms. Chen Yawen was appointed as a director of the Company with effect from July 2022.

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### 10. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees during the Relevant Periods and the five months ended May 31, 2021 included one director, details of whose remuneration are set out in note 9 above. Details of the remuneration for the remaining four highest paid employees who are neither a director nor chief executive of the Company during the Relevant Periods and the five months ended May 31, 2021 are as follows:

	Year ended December 31,		Five months ended May 31,	
	2020	2021	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(unaudited)</i>	
Salaries, bonuses, allowances and benefits in kind	10,166	7,811	4,810	7,809
Pension scheme contributions	201	294	107	168
Share-based payment expenses	239	60,721	74	8,161
	<u>10,606</u>	<u>68,826</u>	<u>4,991</u>	<u>16,138</u>

The number of non-director and non-chief executive highest paid employees whose remuneration fell within the following bands is as follows:

	Year ended December 31,		Five months ended May 31,	
	2020	2021	2021	2022
	<i>Numbers of employees</i>		<i>Numbers of employees</i>	
			<i>(unaudited)</i>	
Nil to HK\$1,000,000	–	–	2	–
HK\$1,000,001 to HK\$1,500,000	1	–	1	–
HK\$1,500,001 to HK\$2,000,000	1	–	–	1
HK\$3,000,001 to HK\$3,500,000	1	–	–	2
HK\$5,000,001 to HK\$5,500,000	–	–	1	–
HK\$6,500,001 to HK\$7,000,000	1	–	–	–
HK\$10,500,001 to HK\$11,000,000	–	–	–	1
HK\$12,500,001 to HK\$13,000,000	–	1	–	–
HK\$14,000,001 to HK\$14,500,000	–	1	–	–
HK\$17,500,001 to HK\$18,000,000	–	1	–	–
HK\$39,000,001 to HK\$39,500,000	–	1	–	–
	<u>4</u>	<u>4</u>	<u>4</u>	<u>4</u>

During the Relevant Periods and the five months ended May 31, 2021, restricted share units were granted to a non-director and non-chief executive highest paid employee in respect of his services to the Group, further details of which are included in the disclosures in note 30 to the Historical Financial Information. The fair value of such options, which has been recognised in the statement of profit or loss over the vesting period, was determined as at the date of grant and the amount included in the Historical Financial Information is included in the above non-director and non-chief executive highest paid employees’ remuneration disclosures.

### 11. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

#### Cayman Islands/BVI

Pursuant to the rules and regulations of the Cayman Islands and the BVI, the Company and the subsidiaries of the Group incorporated therein are not subject to any income tax in the Cayman Islands and the BVI.

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### USA

The subsidiary incorporated in Delaware, USA, is subject to statutory United States federal corporate income tax at a rate of 21%. It is also subject to the state income tax in Delaware at a rate of 8.7% during the Relevant Periods and the five months ended May 31, 2021.

### Hong Kong

The subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the rate of 16.5% on any estimated assessable profits arising in Hong Kong during the Relevant Periods. No provision for Hong Kong profits tax has been made as the Group has no assessable profits derived from or earned in Hong Kong during the Relevant Periods and the five months ended May 31, 2021.

### Mainland China

The provision for corporate income tax in Mainland China is based on the statutory rate of 25% of the taxable profits determined in accordance with the PRC Corporate Income Tax Law which was approved and became effective on January 1, 2008, except for 3DMed Beijing, which was qualified as a High and New Technology Enterprise to enjoy a preferential income tax rate of 15% from 2019 to 2021. This qualification is subject to review by the relevant tax authority in the PRC for every three years. The renewal of such qualification for 2022 to 2024 is in process and expected to be obtained in October 2022.

A reconciliation of the tax expense applicable to loss before tax using the statutory rate for the jurisdictions in which the Company and the majority of its subsidiaries are domiciled to the tax expense at the effective tax rate is as follows:

	Year ended December 31,		Five months ended May 31,	
	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000
			(unaudited)	
Loss before tax	(635,380)	(1,461,825)	(803,970)	(293,417)
Tax charge at the statutory tax rate of 25%	(158,845)	(365,456)	(200,993)	(73,354)
Effect of different tax rates enacted by local authorities	71,919	276,132	182,759	35,942
Additional deductible allowance for qualified research and development expenses	(8,382)	(12,579)	(2,647)	(11,979)
Deductible temporary difference and tax losses not recognised	89,627	77,145	20,831	36,625
Expenses not deductible for tax	5,681	24,758	50	12,766
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Tax charge at the Group's effective rate	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

The Group has accumulated tax losses in Mainland China of RMB897,916,000, RMB1,288,673,000 and RMB1,441,374,000 in aggregate as at December 31, 2020 and 2021 and May 31, 2022, respectively, which will expire in one to ten years for 3DMed Beijing and one to five years for the rest of entities within the Group in Mainland China, to offset against future taxable profits of the companies in which losses were incurred.

The Group also has accumulated tax losses in the USA and Hong Kong of RMB20,456,000, RMB39,186,000 and RMB47,031,000 in aggregate as at December 31, 2020 and 2021 and May 31, 2022, respectively, that can be carried forward indefinitely to offset against future taxable profits of the companies in which losses were incurred.

Deferred tax assets have not been recognised in respect of these tax losses as they have been incurred in subsidiaries that were loss-making in the past and it is not probable that they will generate sufficient taxable income in the foreseeable future to utilise such tax losses.

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**12. DIVIDENDS**

No dividend was paid or declared by the Company during the Relevant Periods and the five months ended May 31, 2021.

**13. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT**

The calculation of the basic loss per share amount is based on the loss attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares in issue (excluding shares reserved for share incentive scheme) during the Relevant Periods and the five months ended May 31, 2021. The weighted average number of ordinary shares has been retrospectively adjusted for the effect of the implemented share subdivision (note 27).

No adjustment has been made to the basic loss per share amounts presented for the Relevant Periods and the five months ended May 31, 2021 in respect of a dilution as the impact of the preferred shares and restricted share units had an anti-dilutive effect on the basic loss per share amounts presented.

The calculations of basic and diluted loss per share are based on:

	<b>Year ended December 31,</b>		<b>Five months ended May 31,</b>	
	<b>2020</b>	<b>2021</b>	<b>2021</b>	<b>2022</b>
			<i>(unaudited)</i>	
<b>Loss</b>				
Loss attributable to ordinary equity holders of the parent, used in the basic earnings per share calculation (RMB'000)	<u>(635,380)</u>	<u>(1,434,092)</u>	<u>(803,970)</u>	<u>(280,379)</u>
<b>Shares</b>				
Weighted average number of ordinary shares in issue during the year/period, used in the basic loss per share calculation ('000)	<u>45,599</u>	<u>39,051</u>	<u>45,599</u>	<u>36,669</u>
Loss per share (basic and diluted) RMB per share	<u>(13.93)</u>	<u>(36.72)</u>	<u>(17.63)</u>	<u>(7.65)</u>



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**14. PROPERTY, PLANT AND EQUIPMENT**

**The Group**

	Leasehold improvements <i>RMB'000</i>	Office equipment <i>RMB'000</i>	Laboratory equipment <i>RMB'000</i>	Transportation equipment <i>RMB'000</i>	Construction in progress <i>RMB'000</i>	Total <i>RMB'000</i>
<b>As at December 31, 2020</b>						
At January 1, 2020:						
Cost	805	249	1,929	–	–	2,983
Accumulated depreciation	(299)	(131)	(1,056)	–	–	(1,486)
Net carrying amount	<u>506</u>	<u>118</u>	<u>873</u>	<u>–</u>	<u>–</u>	<u>1,497</u>
At January 1, 2020, net of accumulated depreciation						
Cost	506	118	873	–	–	1,497
Additions	–	520	138	575	9,293	10,526
Transfers	9,293	–	–	–	(9,293)	–
Depreciation provided during the year	(699)	(100)	(318)	(36)	–	(1,153)
Disposals	–	(6)	–	–	–	(6)
At December 31, 2020, net of accumulated depreciation	<u>9,100</u>	<u>532</u>	<u>693</u>	<u>539</u>	<u>–</u>	<u>10,864</u>
At December 31, 2020:						
Cost	10,098	769	2,067	575	–	13,509
Accumulated depreciation	(998)	(237)	(1,374)	(36)	–	(2,645)
Net carrying amount	<u>9,100</u>	<u>532</u>	<u>693</u>	<u>539</u>	<u>–</u>	<u>10,864</u>
<b>As at December 31, 2021</b>						
At January 1, 2021:						
Cost	10,098	769	2,067	575	–	13,509
Accumulated depreciation	(998)	(237)	(1,374)	(36)	–	(2,645)
Net carrying amount	<u>9,100</u>	<u>532</u>	<u>693</u>	<u>539</u>	<u>–</u>	<u>10,864</u>
At January 1, 2021, net of accumulated depreciation						
Cost	9,100	532	693	539	–	10,864
Additions	–	1,839	1,532	273	42,447	46,091
Transfers	13,332	–	–	–	(13,332)	–
Depreciation provided during the year	(2,817)	(355)	(384)	(194)	–	(3,750)
Disposals	–	–	–	–	(959)	(959)
At December 31, 2021, net of accumulated depreciation	<u>19,615</u>	<u>2,016</u>	<u>1,841</u>	<u>618</u>	<u>28,156</u>	<u>52,246</u>
At December 31, 2021:						
Cost	23,430	2,608	3,600	848	28,156	58,642
Accumulated depreciation	(3,815)	(592)	(1,759)	(230)	–	(6,396)
Net carrying amount	<u>19,615</u>	<u>2,016</u>	<u>1,841</u>	<u>618</u>	<u>28,156</u>	<u>52,246</u>

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	Leasehold improvements <i>RMB'000</i>	Office equipment <i>RMB'000</i>	Laboratory equipment <i>RMB'000</i>	Transportation equipment <i>RMB'000</i>	Construction in progress <i>RMB'000</i>	Total <i>RMB'000</i>
<b>As at May 31, 2022</b>						
At January 1, 2022:						
Cost	23,430	2,608	3,600	848	28,156	58,642
Accumulated depreciation	(3,815)	(592)	(1,759)	(230)	–	(6,396)
Net carrying amount	<u>19,615</u>	<u>2,016</u>	<u>1,841</u>	<u>618</u>	<u>28,156</u>	<u>52,246</u>
At January 1, 2022, net of accumulated depreciation						
Additions	–	458	374	–	47,654	48,486
Transfers	8,392	–	–	–	(8,392)	–
Depreciation provided during the period	(2,699)	(342)	(206)	(84)	–	(3,331)
At May 31, 2022, net of accumulated depreciation	<u>25,308</u>	<u>2,132</u>	<u>2,009</u>	<u>534</u>	<u>67,418</u>	<u>97,401</u>
At May 31, 2022:						
Cost	31,822	3,066	3,974	848	68,377	108,087
Accumulated depreciation	(6,514)	(934)	(1,965)	(314)	(959)	(10,686)
Net carrying amount	<u>25,308</u>	<u>2,132</u>	<u>2,009</u>	<u>534</u>	<u>67,418</u>	<u>97,401</u>

**15. INTANGIBLE ASSETS**

**The Group**

	<b>Software</b> <i>RMB'000</i>
At January 1, 2020 and 2021	
Cost	–
Accumulated amortisation	–
Net carrying amount	<u>–</u>
At January 1, 2021, net of accumulated amortisation	
Additions	1,013
Amortisation provided during the year	(84)
At December 31, 2021, net of accumulated amortisation	<u>929</u>
At December 31, 2021	
Cost	1,013
Accumulated amortisation	(84)
Net carrying amount	<u>929</u>

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	<b>Software</b> <i>RMB’000</i>
At January 1, 2022	
Cost	1,013
Accumulated amortisation	(84)
	<u>929</u>
Net carrying amount	<u>929</u>
At January 1, 2022, net of accumulated amortisation	929
Amortisation provided during the period	(42)
	<u>887</u>
At May 31, 2022, net of accumulated amortisation	<u>887</u>
At May 31, 2022	
Cost	1,013
Accumulated amortisation	(126)
	<u>887</u>
Net carrying amount	<u>887</u>

**16. LEASES**

**The Group as a lessee**

The Group has lease contracts for various items including leasehold land and several buildings used as its office and laboratory. Lump sum payments were made upfront to acquire the leased land from the owners with lease periods of 40 years, and no ongoing payments will be made under the terms of these land leases. Leases of office and laboratory premises generally have lease terms between 2 and 5 years. Generally, the Group is restricted from assigning and subleasing the leased assets outside the Group.

**(a) Right-of-use assets**

The carrying amounts of right-of-use assets and the movements during the Relevant Periods are as follows:

	<b>Office and laboratory</b> <i>RMB’000</i>	<b>Leasehold land</b> <i>RMB’000</i>	<b>Total</b> <i>RMB’000</i>
As at January 1, 2020	1,203	–	1,203
Additions	16,952	–	16,952
Depreciation charge	(2,218)	–	(2,218)
	<u>15,937</u>	<u>–</u>	<u>15,937</u>
As at December 31, 2020	<u>15,937</u>	<u>–</u>	<u>15,937</u>
As at January 1, 2021	15,937	–	15,937
Additions	47,621	11,492	59,113
Depreciation charge	(8,470)	(287)	(8,757)
	<u>55,088</u>	<u>11,205</u>	<u>66,293</u>
As at December 31, 2021	<u>55,088</u>	<u>11,205</u>	<u>66,293</u>
As at January 1, 2022	55,088	11,205	66,293
Additions	2,238	–	2,238
Lease modification	(756)	–	(756)
Depreciation charge	(5,322)	(120)	(5,442)
	<u>51,248</u>	<u>11,085</u>	<u>62,333</u>
As at May 31, 2022	<u>51,248</u>	<u>11,085</u>	<u>62,333</u>

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**(b) Lease liabilities**

The carrying amount of lease liabilities and the movements during the Relevant Periods are as follows:

	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Carrying amount at January 1	1,117	16,852	58,741
Additions	16,952	47,621	2,238
Lease modification	–	–	(756)
Accretion of interest recognised during the period	310	1,482	740
Lease payment	(1,527)	(7,214)	(5,750)
	<u>16,852</u>	<u>58,741</u>	<u>55,213</u>
Carrying amount at December 31/May 31	<u>16,852</u>	<u>58,741</u>	<u>55,213</u>
Analysed into:			
Current portion	3,791	12,754	13,701
Non-current portion	13,061	45,987	41,512
	<u>16,852</u>	<u>58,741</u>	<u>55,213</u>

**(c) The amounts recognised in profit or loss in relation to leases are follows:**

	<b>Year ended December 31,</b>		<b>Five months ended May 31,</b>	
	<b>2020</b>	<b>2021</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(unaudited)</i>	
Lease payments in respect of short-term leases	137	1,263	143	189
Interest on lease liabilities	310	1,482	319	740
Depreciation charge of right-of-use assets	2,218	8,757	2,132	5,442
	<u>2,665</u>	<u>11,502</u>	<u>2,594</u>	<u>6,371</u>
Total amount recognised in profit or loss	<u>2,665</u>	<u>11,502</u>	<u>2,594</u>	<u>6,371</u>

**17. OTHER NON-CURRENT ASSETS**

**The Group**

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Value-added tax recoverable	7,605	12,425	5,495
Deposits	55	3,690	3,959
Prepayments for property, plant and equipment	–	1,063	203
Loan to an employee*	–	1,206	1,221
	<u>7,660</u>	<u>18,384</u>	<u>10,878</u>

\* Loan to an employee is unsecured, with an annual interest rate of 3% and period of 24 months.

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**18. TRADE RECEIVABLES**

**The Group**

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade receivables	–	65,134	102,093
Impairment	–	(130)	(204)
	<u>–</u>	<u>65,004</u>	<u>101,889</u>

The Group’s trade terms with Jiangsu Simcere and the distributors are payment on credit. The credit period is generally 70 days for Jiangsu Simcere and 45-60 days for the distributors. The Group seeks to maintain strict control over its outstanding receivables and has a credit control department to minimise credit risk. Overdue balances are reviewed regularly by senior management. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing. The Group has a concentration of credit risk as 100% and 99% of trade receivable was due from Jiangsu Simcere, a service provider of the Group, as at December 31, 2021 and May 31, 2022 respectively.

An ageing analysis of the trade receivables as at the end of each of the Relevant Period, based on the invoice date and net of loss allowance, is as follows:

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Within 3 months	<u>–</u>	<u>65,004</u>	<u>101,889</u>

The movements in the loss allowance for impairment of trade receivables are as follows:

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
At beginning of year	–	–	130
Impairment losses	–	130	74
At end of year	<u>–</u>	<u>130</u>	<u>204</u>

The Group performed an impairment analysis as at December 31, 2021 and May 31, 2022 by considering the probability of default of the debtors or comparable companies with published credit ratings. Set out below is the information about the credit risk exposure on the Group’s trade receivables using a provision matrix:

	<b>As at December 31, 2021</b>	<b>As at May 31, 2022</b>
	Current	Current
Expected credit loss rate	0.2%	0.2%
Gross carrying amount (RMB’000)	65,134	102,903
Expected credit losses (RMB’000)	<u>130</u>	<u>204</u>

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**19. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS**

**The Group**

	As at December 31,		As at May 31,
	2020	2021	2022
	RMB’000	RMB’000	RMB’000
Value-added tax recoverable	9,100	5,993	–
Deferred [REDACTED] expenses	1,396	10,141	11,864
Prepayments*	29,500	12,226	16,385
Other receivables	1,126	1,294	1,261
	<u>41,122</u>	<u>29,654</u>	<u>29,510</u>

\* Included in the prepayment balances as at December 31, 2020, an amount of RMB24,480,000 represented the payments made by the Group for the repurchase of preferred shares, which were unsecured, interest-free and settled in 2021.

**The Company**

	As at December 31,		As at May 31,
	2020	2021	2022
	RMB’000	RMB’000	RMB’000
Prepayments	–	2	–
Prepayments in relation to preferred share repurchase	24,480	–	–
Deferred [REDACTED] expenses	1,396	10,141	11,864
	<u>25,876</u>	<u>10,143</u>	<u>11,864</u>

The Group seeks to maintain strict control over its outstanding receivables to minimise credit risk. Long ageing balances are reviewed regularly by senior management. The Group does not hold any collateral or other credit enhancements over its prepayments and other receivable balances.

Other receivables had no historical default. The financial assets included in the above balances relating to receivables were categorised in stage 1 at the end of each of the Relevant Periods. In calculating the expected credit loss rate, the Group considers the historical loss rate and adjusts for forward-looking macroeconomic data. During the Relevant Periods, the Group estimated that the expected credit loss rate for other receivables is minimal.

**20. FINANCIAL ASSETS AT FVTPL**

**The Group**

	As at December 31,		As at May 31,
	2020	2021	2022
	RMB’000	RMB’000	RMB’000
Wealth management products	<u>–</u>	<u>50,178</u>	<u>50,021</u>

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The financial assets measured at FVTPL are wealth management products, denominated in RMB, with expected yield rates ranging from 1.48% to 3.49% per annum. The principals and yields on all of these wealth management products are not guaranteed, and hence their contractual cash flows do not qualify for solely payments of principal and interest.

The fair values are based on cash flows discounted using the expected yield rate and are within Level 2 of the fair value hierarchy.

The movements in the carrying value of the wealth management products classified as financial assets as at FVTPL are as follows:

	<i>RMB’000</i>
At January 1, 2020	6,015
Investment income	156
Disposal	(6,171)
	<u>                    </u>
At December 31, 2020 and January 1, 2021	<u>                    </u> –
Acquisition	100,000
Investment income	424
Disposal	(50,424)
Gain on fair value change	178
	<u>                    </u>
At December 31, 2021	<u>                    </u> 50,178
Acquisition	100,000
Investment income	593
Disposal	(100,771)
Gain on fair value change	21
	<u>                    </u>
At May 31, 2022	<u>                    </u> 50,021

**21. CASH AND BANK BALANCES, PLEDGED DEPOSITS AND RESTRICTED BANK BALANCES**

**The Group**

	<b>As at December 31,</b>	<b>As at May 31,</b>
	<b>2020</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>
Cash and bank balances	<u>414,261</u>	<u>660,231</u>
Pledged deposits*	<u>6,000</u>	<u>–</u>
Restricted bank balances	<u>–</u>	<u>72</u>
Denominated in		
RMB	293,751	222,133
US\$	126,506	437,966
HK\$	4	204
	<u>420,261</u>	<u>660,303</u>

\* It represents pledged deposits to secure certain bank loans of the Group (note 24). None of these deposits are past due or impaired.

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The RMB is not freely convertible into other currencies, however, under Mainland China’s Foreign Exchange Control Regulations and Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

Cash and bank balances earn interest at floating rates based on daily bank deposit rates. The bank balances, pledged deposits and restricted bank balances are deposited with creditworthy banks with no recent history of default.

**The Company**

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Cash and bank balances	118,200	15,830	16,573
Denominated in			
RMB	90,165	2,873	15,204
US\$	28,035	12,138	1,218
HK\$	–	819	151
	<u>118,200</u>	<u>15,830</u>	<u>16,573</u>

**22. TRADE PAYABLES**

**The Group**

An ageing analysis of the trade payables as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Within 3 months	1,948	3,732	2,086
3 to 6 months	468	–	562
6 months to 1 year	–	10	2
	<u>2,416</u>	<u>3,742</u>	<u>2,650</u>

The trade payables are non-interest-bearing and are normally settled on terms of 1 to 3 months.



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**23. OTHER PAYABLES AND ACCRUALS**

**The Group**

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Accrued research and development expenses	60,498	43,087	47,245
Accrued marketing service fees	–	38,281	60,922
Accrued royalty expenses	–	7,153	6,826
Payroll payable	12,093	21,944	15,250
Accrued [REDACTED] expenses	1,746	7,360	9,974
Other tax payables	638	1,425	3,047
Payables for property, plant and equipment	1,141	4,423	35,801
Payables for financing services	8,949	710	741
Payables to precedent investors*	1,143	12,692	13,260
Other payables	2,132	356	338
	<u>88,340</u>	<u>137,431</u>	<u>193,404</u>

**The Company**

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Accrued research and development expenses	13,050	–	–
Accrued [REDACTED] expenses	1,746	7,360	9,974
Payables for financing services	2,085	710	741
Payables to precedent investors*	1,143	12,692	13,260
Other payables	–	–	64
	<u>18,024</u>	<u>20,762</u>	<u>24,039</u>

Other payables are non-interest-bearing and repayable on demand.

\* It represented the amount withheld by the Group which will be returned to the precedent investors when they confirm the completion of tax filing.

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**24. INTEREST-BEARING BANK BORROWINGS**

	As at December 31, 2020			As at December 31, 2021			As at May 31, 2022		
	Effective interest rate (%)	Maturity	RMB’000	Effective interest rate (%)	Maturity	RMB’000	Effective interest rate (%)	Maturity	RMB’000
Secured bank loan*	One-year LPR + 5bp	2021	2,322	-	-	-	-	-	-
Unsecured bank loan	One-year LPR + 65bp	2021	1,200	-	-	-	-	-	-
			3,522			-			-

Analysed into:	As at December 31,		As at May 31,
	2020	2021	2022
	RMB’000	RMB’000	RMB’000
Bank loans repayable within one year	3,522	-	-
	3,522	-	-

\* The bank loan is secured by the Group’s deposits of RMB6,000,000 as at December 31, 2020 (note 21).

**25. DEFERRED INCOME**

	As at December 31,		As at May 31,
	2020	2021	2022
	RMB’000	RMB’000	RMB’000
Government grant*	7,579	-	-
Analysed for reporting purposes as:			
Current liabilities	-	-	-
Non-current liabilities	7,579	-	-
	7,579	-	-

\* Government grant related to the subsidies received from the local government to support the Group’s research and development activities with conditions to fulfill, which was recognised in profit or loss upon the fulfillment of conditions in November 2021 (note 5).

**26. PREFERRED SHARES**

The Company issued totally 6,027,459 preferred shares to the then existing preferred shareholders of the Predecessor Holdco when the Company was incorporated as the holding company of the Group, which included 267,906 Series Seed Preferred Shares, 322,632 Series A Preferred Shares, 688,719 Series A+ Preferred Shares, 2,059,132 Series B Preferred Shares, 937,254 Series B+ Preferred Shares and 1,751,816 Series C Preferred Shares.

In 2020, the Company issued totally 1,403,565 Series D Preferred Shares with a par value of HK\$0.01 at a total consideration of approximately US\$26,125,000.

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In June 2021, the Company sub-divided each issued and unissued share with a par value of HK\$0.01 each into 10 shares with a par value of HK\$0.001 each with immediate effect, after that, the Company issued totally 18,921,712 Series E Preferred Shares with a par value of HK\$0.001 at a total consideration of approximately US\$60,181,000.

From 2019 to 2020, 3D Medicines entered into capital increase agreements with several Series D onshore investors who subscribed for an increased registered capital of 3D Medicines of approximately US\$60,310,000 at a total consideration of approximately US\$119,129,000. Pursuant to a series of share redemption agreements entered into between Series D onshore investors and 3D Medicines, and share purchase agreements entered into between Series D onshore investors and the Company in 2021, the capital investments from Series D onshore investors into 3D Medicines would be returned to Series D onshore investors and injected into the Company, in exchange for the allotment of a total of 6,555,290 preferred shares of one of offshore entities controlled by the Group. The transaction was settled with 6,555,290 Series D Preferred Shares issued by the Company in 2021.

In 2020, 3D Medicines entered into capital increase agreements with several Series D+ onshore investors who subscribed for an increased registered capital of 3D Medicines of approximately US\$9,822,000 at a total consideration of approximately US\$24,507,000. Pursuant to a series of share redemption agreements entered into between Series D+ onshore investors and 3D Medicines, and share purchase agreements entered into between Series D+ onshore investors and the Company in 2021, the capital investments from Series D+ onshore investors into 3D Medicines would be returned to Series D+ onshore investors and injected into the Company, in exchange for the allotment of a total of 1,136,305 preferred shares of one of offshore entities controlled by the Group. The transaction was settled with 1,136,305 Series D+ Preferred Shares issued by the Company in 2021.

For illustration purposes, the holders of Series Seed Preferred Shares, Series A Preferred Shares, Series A+ Preferred Shares, Series B Preferred Shares, Series B+ Preferred Shares and Series C Preferred Shares, Series D Preferred Shares, Series D+ Preferred Shares and Series E Preferred Shares of the Company are referred to as Series Seed Holders, Series A Holders, Series A+ Holders, Series B Holders, Series B+ Holders, Series C Holders, Series D Holders, Series D+ Holders and Series E Holders, respectively.

For illustration purposes, Series Seed Preferred Shares, Series A Preferred Shares, Series A+ Preferred Shares, Series B Preferred Shares, Series B+ Preferred Shares, Series C Preferred Shares, Series D Preferred Shares, Series D+ Preferred Shares and Series E Preferred Shares are collectively referred to as “Preferred Shares”.

According to the amended and restated Memorandum and Articles of Association of the Company (“MOA”), the key terms of the Preferred Shares are as follows:

### **Conversion rights (applicable for Preferred Shares)**

Any fully-paid and non-assessable Preferred Share may, at the option of the holder thereof, be converted at any time after the date of issuance of such shares, without the payment of any additional consideration, into fully-paid and non-assessable ordinary shares of the Company (“Ordinary Shares”) based on the then-effective conversion price (“Conversion Price”). The initial Conversion Price for the Preferred Shares will be the applicable Preferred Share issue price (i.e., a 1-to-1 initial conversion ratio), which will be subject to adjustments to reflect share dividends, share splits, share combinations, reorganisations, mergers, consolidations, reclassifications, exchanges and substitutions, and adjustment upon issuance of new securities for a consideration per share less than the Conversion Price.

Each Preferred Share shall automatically be converted based on the then-effective Conversion Price, without the payment of any additional consideration, into fully-paid and non-assessable Ordinary Shares upon the closing of Qualified [REDACTED] (see definition below) or at such time prior to the Qualified [REDACTED] as may be required to give effect to such Qualified [REDACTED] pursuant to applicable securities laws or listing rules of the applicable stock exchange.

Qualified [REDACTED] means a [REDACTED] of the Ordinary Shares of the Company (or depositary receipts or depositary shares therefor) in another jurisdiction which results in the Ordinary Shares trading publicly on a recognised international securities exchange including, without limitations the Shanghai Stock Exchange, the Shenzhen Stock Exchange, the New York Stock Exchange, the Hong Kong Stock Exchange or Nasdaq.

### **Redemption rights (applicable for Preferred Shares except for Series Seed Preferred Shares)**

At the request of any preferred shareholders (except for series seed preferred shareholders), the Company shall redeem all or a portion of the outstanding Preferred Shares (except for Series Seed Preferred Shares) at any time and from time to time on or after the earliest date of the occurrence of any trigger event.

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Trigger event mainly means any of the following:

- (1) the Qualified [REDACTED] has not occurred before October 31, 2022 (applicable for Series A Preferred Shares, Series A+ Preferred Shares, Series B Preferred Shares, Series B+ Preferred Shares, Series D Preferred Shares, Series D+ Preferred Shares and Series E Preferred Shares);
- (2) the Qualified [REDACTED] has not been achieved before October 31, 2021 (or October 31, 2022 in the event that the Company has entered the formal process of [REDACTED] including, without limitation, submission of [REDACTED], public release of [REDACTED] or [REDACTED]) (applicable for Series C Preferred Shares);
- (3) any material breach of the transaction documents by the Company or Dr. Gong Zhaolong, which results in material losses to all preferred shareholders (applicable for Series B Preferred Shares, Series B+ Preferred Shares, Series C Preferred Shares, Series D Preferred Shares, Series D+ Preferred Shares and Series E Preferred Shares);
- (4) any material breach of the preferred share purchase agreements by the Company or Dr. Gong Zhaolong, which results in material losses to all preferred shareholders (applicable for Series D Preferred Shares, Series D+ Preferred Shares and Series E Preferred Shares);
- (5) any material breach of the loyal and fiduciary duty by the Company or Dr. Gong Zhaolong, including but not limited to the existence of invisible sale income not accounted in the Company’s financial books and records (applicable for Series C Preferred Shares);
- (6) the phase II clinical trials of drug named “重組人源化PD-L1單域抗體Fc融合蛋白注射液” conducted in the PRC and the USA have not been completed prior to December 31, 2019 (applicable for Series C Preferred Shares till cancelled in June 2021);
- (7) holder of any equity securities of the Company has requested a redemption of their shares (applicable for Series C Preferred Shares); and
- (8) any fraud or misappropriation by Dr. Gong Zhaolong including material changes to the use of [REDACTED] from the sale of Series D Preferred Shares to Simcere Pharmaceutical Group Limited and intentionally causing dysfunction of the internal control system of the Group (applicable for Series D Preferred Shares).

The redemption price for each Series A Preferred Share and Series A+ Preferred Share shall be an amount equal to applicable Issue Price (“Issue Price” refers to the consideration actually paid to the Company) with a simple rate of eight percent (8%) per annum return calculating from the corresponding issue date to the date of applicable redemption notice.

The redemption price for each Series B Preferred Share and Series B+ Preferred Share shall be the greater of (i) applicable Issue Price with a simple rate of eight percent (8%) per annum return calculating from the corresponding issue date to the date of applicable redemption notice plus all declared but unpaid dividends, and (ii) the fair market value of each redeeming corresponding preferred share, the valuation of which shall be determined by an independent appraiser selected by the members holding two thirds (2/3) of voting powers of outstanding shares.

The redemption price for each Series C Preferred Share shall be an amount equal to applicable Issue Price with a simple rate of twelve percent (12%) per annum return calculating from the corresponding issue date to the date of applicable redemption notice, plus all declared but unpaid dividends thereon.

The redemption price for each Series D Preferred Share shall be an amount equal to applicable Issue Price with a simple rate of twelve percent (12%) per annum return calculating from the corresponding issue date to the date of applicable redemption notice, plus all declared but unpaid dividends thereon.

The redemption price for each Series D+ Preferred Share shall be an amount equal to applicable Issue Price with a simple rate of eight percent (8%) per annum return calculating from the corresponding issue date to the date of applicable redemption notice, plus all declared but unpaid dividends thereon.

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The redemption price for each Series E Preferred Share other than certain shareholders shall be an amount equal to applicable Series E Issue Price with a simple rate of six percent (6%) per annum return calculating from the corresponding issue date to the date of applicable redemption notice, plus all declared but unpaid dividends thereon. The redemption price for certain shareholders shall be an amount equal to applicable Series E Issue Price with a simple rate of eight percent (8%) per annum return calculating from the corresponding issue date to the date of applicable redemption notice, plus all declared but unpaid dividends thereon.

If the Company does not have sufficient cash or funds legally available to redeem all of the preferred shares required to be redeemed, those assets or funds which are legally available shall be used to redeem the preferred shares, following the order, firstly to Series E Holders, secondly to Series D+ Holders, thirdly to Series D Holders, fourthly to Series C Holders, fifthly to Series B+ Holders, sixthly to Series B Holders, seventhly to Series A+ Holders, and lastly to Series A Holders.

### Liquidation preferences (applicable for Preferred Shares)

In the event of any liquidation, dissolution or winding up of the Company, all assets and funds of the Company legally available for distribution (after satisfaction of all creditors’ claims and claims that may be preferred by law) shall be distributed to the holders of the Preferred Shares in the sequence as follows:

- (1) Firstly, Series E Preferred Shares held by certain shareholders, with the amount equal to the applicable Series E Issue Price, adjusted for any share splits, share dividends, recapitalisation and events with similar effect, plus all accrued or declared but unpaid dividends, adjusted for any share splits, share dividends, recapitalisation and events with similar effect, plus a simple rate of eight percent (8%) per annum return of the Series E Issue Price from the Series E Issue Date and all accrued or declared but unpaid dividends; for other Series E Preferred Shares, the amount equal to the applicable Series E Issue Price, adjusted for any share splits, share dividends, recapitalisation and events with similar effect, plus all accrued or declared but unpaid dividends, adjusted for any share splits, share dividends, recapitalisation and events with similar effect, and all accrued or declared but unpaid dividends (the “Series E Preference Amount”);
- (2) Secondly, Series D+ Preferred Shares with the amount equal to the applicable Series D+ Issue Price, adjusted for any share splits, share dividends, recapitalisation and events with similar effect, plus all accrued or declared but unpaid dividends (the “Series D+ Preference Amount”) and Series D Preferred Shares with the amount equal to the applicable Series D Issue Price, adjusted for any share splits, share dividends, recapitalisation and events with similar effect, plus a simple rate of eight percent (8%) per annum return of the Series D Issue Price from the Series D Issue Date and all accrued or declared but unpaid dividends (the “Series D Preference Amount”);
- (3) Thirdly, Series C Preferred Shares held by certain shareholder with the amount equal to the applicable Series C Issue Price, adjusted for any share splits, share dividends, recapitalisation and events with similar effect, plus a simple rate of eight percent (8%) per annum return of the Series C Issue Price from the Series C Issue Date and all accrued or declared but unpaid dividends and Series C Preferred Shares held by other members other than certain shareholder with the amount equal to the applicable Series C Issue Price, adjusted for any share splits, share dividends, recapitalisation and events with similar effect, plus all accrued or declared but unpaid dividends (the “Series C Preference Amount”);
- (4) Fourthly, Series B+ Preferred Shares with the amount equal to the applicable Series B+ Issue Price, adjusted for any share splits, share dividends, recapitalisation and events with similar effect, plus all accrued or declared but unpaid dividends (the “Series B+ Preference Amount”);
- (5) Fifthly, Series B Preferred Shares with the amount equal to the applicable Series B Issue Price, adjusted for any share splits, share dividends, recapitalisation and events with similar effect, plus all accrued or declared but unpaid dividends (the “Series B Preference Amount”);
- (6) Sixthly, Series A+ Preferred Shares with the amount equal to the applicable Series A+ Issue Price, adjusted for any share splits, share dividends, recapitalisation and events with similar effect, plus all accrued or declared but unpaid dividends (the “Series A+ Preference Amount”);
- (7) Seventhly, Series A Preferred Shares with the amount equal to the applicable Series A Issue Price, adjusted for any share splits, share dividends, recapitalisation and events with similar effect, plus all accrued or declared but unpaid dividends (the “Series A Preference Amount”); and

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- (8) Finally, the remaining assets and funds of the Company available for distribution shall be distributed ratably among all members according to the relative number of Shares held by such member.

Deemed Liquidation Event means any of the following events:

- (a) means a transaction in which a person, or a group of related persons, acquires any equity securities of the Company such that, immediately after such transaction, such person or group of related persons hold equity securities of the Company representing more than fifty percent (50%) of the outstanding voting power of the Company;
- (b) a sale, transfer, lease, exclusive licensing or other disposition of all or substantially all of the assets of the Company, and the Company proposes to stop substantial business operation.

A Deemed Liquidation Event shall be deemed to be a liquidation, dissolution or winding up of the Company, and any proceeds, whether in cash or properties, resulting from a Deemed Liquidation Event shall be distributed in accordance with the liquidation preference terms, unless waived in writing by the majority preferred holders or in such Deemed Liquidation Event each holder of the Preferred Shares shall be entitled to receive no less than fifty percent (50%) return on the applicable preferred Issue Price for each share of the Preferred Shares on a fully diluted and as-converted basis.

**Dividend Rights (applicable for Preferred Shares)**

The Company and its subsidiaries shall not take, permit to occur, approve, authorise, or agree or commit to the declaration or payment of a dividend on any shares of the Company, unless with the affirmative vote or consent of the majority of Series E, Series D+ and D Holders (holders of at least fifty percent (50%) of the voting power of the then outstanding Series E, Series D+ and Series D Preferred Shares), certain leading Series B investors and the majority of Series C Holders (holders of at least fifty percent (50%) of the voting power of the then outstanding Series C Preferred Shares). All the dividends shall be distributed *pari passu* on a pro rata basis among the holders of the Preferred Shares and the Ordinary Shares.

**Voting Rights (applicable for Preferred Shares)**

Each Preferred Share shall carry a number of votes equal to the number of ordinary shares then issuable upon its conversion into ordinary shares at the record date for determination of the Company’s shareholders entitled to vote, or, if no such record date is established, at the date such vote is taken or any written resolution or consent of the Company’s shareholders is solicited. The holders of the Preferred Shares and Ordinary Shares shall vote together as a single class, unless otherwise required by the MOA.

**Presentation and classification**

**The Group**

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Preferred shares	1,645,620	3,132,791	3,276,433
Analysed for reporting purposes as:			
Current liabilities*	215,237	3,093,968	3,233,922
Non-current liabilities	1,430,383	38,823	42,511
	1,645,620	3,132,791	3,276,433

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**The Company**

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Preferred shares	764,243	3,132,791	3,276,433
Analysed for reporting purposes as:			
Current liabilities*	215,237	3,093,968	3,233,922
Non-current liabilities	549,006	38,823	42,511
	<u>764,243</u>	<u>3,132,791</u>	<u>3,276,433</u>

\* As the sixth trigger event in Redemption Rights occurred at December 31, 2019, Series C Preferred Shares were classified as current liabilities as at December 31, 2020.

Due to the first and second trigger events in the Redemption Rights, all Preferred Shares (except for Series Seed Preferred Shares) were classified as current liabilities as at December 31, 2021 and May 31, 2022.

The movements of the Preferred Shares are set out below:

**The Group**

	<b>Preferred shares</b>
	<i>RMB’000</i>
As at December 31, 2019 and January 1, 2020	<u>542,570</u>
New issue	783,818
Changes in fair value	<u>319,232</u>
As at December 31, 2020 and January 1, 2021	<u>1,645,620</u>
Repurchase	(1,081,981)
New issue	1,614,410
Changes in fair value	<u>954,742</u>
As at December 31, 2021 and January 1, 2022	<u>3,132,791</u>
Changes in fair value	<u>143,642</u>
As at May 31, 2022	<u>3,276,433</u>

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**The Company**

	<b>Preferred shares</b> <i>RMB’000</i>
As at December 31, 2019 and January 1, 2020	333,284
New issue	179,283
Changes in fair value	251,676
As at December 31, 2020 and January 1, 2021	764,243
Repurchase	(267,095)
New issue	1,614,410
Changes in fair value	1,021,233
As at December 31, 2021 and January 1, 2022	3,132,791
Changes in fair value	143,642
As at May 31, 2022	3,276,433

The Group has used the back-solve method to determine the underlying equity value of the Group and adopted the equity allocation model to determine the fair value of the Preferred Shares as at December 31, 2020.

The Group used the discounted cash flow method to determine the underlying equity value of the Group and adopted an equity allocation model to determine the fair value of the Preferred Shares as at December 31, 2021 and May 31, 2022.

Key assumptions are set out below:

	<b>As at December 31,</b> <b>2020</b>	<b>2021</b>	<b>As at May 31,</b> <b>2022</b>
Risk-free interest rate	0.12%	0.19%	1.40%
DLOM	12.00%	7.00%	8.00%
Volatility	43.72%	46.23%	56.53%
Discount rate	N/A	13.00%	13.00%

The Group estimated the risk-free interest rate based on the yield of the US Government Bond with maturity close to the expected exit timing as of the valuation date. The DLOM was estimated based on the option-pricing method. Under the option-pricing method, the cost of put option, which can hedge the price change before the privately held share can be sold, was considered as a basis to determine the lack of marketability discount. Volatility was estimated based on recognised standard deviation of daily stock price return of comparable companies for a period from the valuation date and with a similar span as time to expiration.

Set out below is a summary of significant unobservable inputs to the valuation of financial liabilities recognised within Level 3 of the fair value hierarchy, together with a quantitative sensitivity analysis as at the end of each of the Relevant Periods.

<b>Significant unobservable inputs</b>	<b>Increase/</b> <b>(decrease) in</b> <b>the inputs</b>	<b>(Decrease)/increase in the fair value</b>		
		<b>As at December 31,</b>		<b>As at May 31,</b>
		<b>2020</b>	<b>2021</b>	<b>2022</b>
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
DLOM	1%/(1%)	(18,644)/18,644	(33,526)/33,526	(35,420)/35,420
Volatility	1%/(1%)	(1,942)/2,455	365/(1,248)	565/(580)



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**27. SHARE CAPITAL AND TREASURY SHARES**

**Authorised:**

	<b>As at December 31, 2020</b>
	<i>Number of shares</i>
Ordinary shares of HK\$0.01 each	22,559,096
Preferred shares of HK\$0.01 each	27,440,904
	<u>50,000,000</u>

On June 25, 2021, the Company sub-divided each issued and unissued share with a par value of HK\$0.01 each into 10 shares with a par value of HK\$0.001 each with immediate effect.

	<b>As at December 31, 2021</b>	<b>As at May 31, 2022</b>
	<i>Number of shares</i>	<i>Number of shares</i>
Ordinary shares of HK\$0.001 each	225,590,960	225,590,960
Preferred shares of HK\$0.001 each	274,409,040	274,409,040
	<u>500,000,000</u>	<u>500,000,000</u>

**Issued and fully paid:**

	<b>As at December 31, 2020</b>		
	<b>Number of shares in issue</b>	<b>Share capital</b>	
		<i>HK\$'000</i>	<i>RMB'000</i>
Ordinary shares of HK\$0.01 each	<u>4,559,895</u>	<u>46</u>	<u>37</u>
	<b>As at December 31, 2021</b>		
	<b>Number of shares in issue</b>	<b>Share capital</b>	
		<i>HK\$'000</i>	<i>RMB'000</i>
Ordinary shares of HK\$0.001 each*	<u>69,142,320</u>	<u>69</u>	<u>57</u>
	<b>As at May 31, 2022</b>		
	<b>Number of shares in issue</b>	<b>Share capital</b>	
		<i>HK\$'000</i>	<i>RMB'000</i>
Ordinary shares of HK\$0.001 each*	<u>69,142,320</u>	<u>69</u>	<u>57</u>

\* As at December 31, 2021 and May 31, 2022, the total number of issued ordinary shares included 32,693,837 and 32,314,990 shares held for share incentive scheme, with par values of RMB27,000 and RMB27,000, respectively.

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A summary of movements in the share capital is as follows:

	Number of shares in issue	Share capital	
		HK\$'000	RMB'000
As at January 1, 2020 and 2021	4,559,895	46	37
New issue of ordinary shares of HK\$0.01 each ( <i>note 30</i> )	440,015	4	4
Subdivision	44,999,190	–	–
Repurchase of ordinary shares of HK\$0.001 each*	(19,194,540)	(19)	(16)
New issue of ordinary shares of HK\$0.001 each**	38,337,760	38	32
As at December 31, 2021	<u>69,142,320</u>	<u>69</u>	<u>57</u>
As at May 31, 2022	<u>69,142,320</u>	<u>69</u>	<u>57</u>

\* Pursuant to the share transfer agreements entered into in June 2021 between the Company and Grown Champion Engineering Limited, Gain Champion Development Limited, Dragon Time Development Limited, Charm Point Enterprises Limited, Hopeway Development Limited, respectively, the Company repurchased 4,518,280 ordinary shares owned by employees of the Group under the Share Awards at par value as a result of the termination of the scheme (*note 30*). 14,676,260 ordinary shares owned by non-employees of the Group were repurchased by the Group at a consideration of RMB32,730,000.

\*\* In order to facilitate the administration of share incentives granted to the employees and for future grant, on June 24, 2021, the Company established three trusts by entering into trust deeds with Kastle Limited (the “Trustee”). Pursuant to the board resolution on June 25, 2021, 38,337,760 ordinary shares were allotted and issued to three BVI entities wholly-owned by the Trustee, namely Immunal Medixin US Limited, Immunal Medixin Cino L. Limited and Immunal Medixin Cino Limited, among which 5,643,923 and 378,847 shares were exercised during the year ended December 31, 2021 and the five months ended May 31, 2022, respectively. Such three trustee entities were considered as an extension of the Company and shares, other than those exercised, held for share incentive scheme were presented as treasury shares in both consolidated and separate financial statements of the Company.

**28. DEFICITS**

**The Group**

The amounts of the Group’s deficits and the movements therein for the Relevant Periods and the five months ended May 31, 2021 are presented in the consolidated statements of changes in equity.

**Share Premium**

The share premium of the Group represents (1) the difference between the par value of the shares issued and the consideration received and (2) the amount transferred from equity-settled share-based reserve due to the exercise of restricted share units.

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**Other reserve**

It represented the reserves arising from the following:

- (1) Restructuring reserve.

When the Company issued preferred shares to the then existing preferred shareholders of the Predecessor Holdco at par value in the Restructuring, the difference between fair value and par value of the preferred shares on the issuance date was debited to other reserve.

When the Company repurchased ordinary shares from Grown Champion Engineering Limited, Gain Champion Development Limited, Dragon Time Development Limited, Charm Point Enterprises Limited, Hopeway Development Limited, the excess of consideration paid by the Group over the par value of the shares repurchased was debited to other reserve.

- (2) Equity-settled share-based reserve. It represents the share-based compensation reserve due to equity-settled share award, details of which were set out in note 30 to the Historical Financial Information.
- (3) Reserve arising from equity transactions with non-controlling interests.

**The Company**

The amounts of the Company’s deficits and the movements therein for the Relevant Periods are presented as follows:

**Year ended December 31, 2020**

	<b>Other reserve</b> <i>RMB'000</i>	<b>Accumulated losses</b> <i>RMB'000</i>	<b>Total</b> <i>RMB'000</i>
At January 1, 2020	(145,878)	(22,550)	(168,428)
Total comprehensive loss for the year	—	(265,697)	(265,697)
At December 31, 2020	<u>(145,878)</u>	<u>(288,247)</u>	<u>(434,125)</u>

**Year ended December 31, 2021**

	<b>Share premium</b> <i>RMB'000</i>	<b>Other reserve</b> <i>RMB'000</i>	<b>Accumulated losses</b> <i>RMB'000</i>	<b>Total</b> <i>RMB'000</i>
At January 1, 2021	—	(145,878)	(288,247)	(434,125)
Total comprehensive loss for the year	—	—	(1,060,411)	(1,060,411)
Repurchase of shares	—	(32,714)	—	(32,714)
Recognition of equity-settled share-based payments ( <i>note 30</i> )	59,240	105,074	—	164,314
Exercise of restricted share units	75,424	(69,417)	—	6,007
At December 31, 2021	<u>134,664</u>	<u>(142,935)</u>	<u>(1,348,658)</u>	<u>(1,356,929)</u>

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**Five months ended May 31, 2022**

	<b>Share premium</b> <i>RMB’000</i>	<b>Other reserve</b> <i>RMB’000</i>	<b>Accumulated losses</b> <i>RMB’000</i>	<b>Total</b> <i>RMB’000</i>
At January 1, 2022	134,664	(142,935)	(1,348,658)	(1,356,929)
Total comprehensive loss for the period	–	–	(124,170)	(124,170)
Recognition of equity-settled share-based payments ( <i>note 30</i> )	–	55,435	–	55,435
Exercise of restricted share units	5,138	(4,423)	–	715
At May 31, 2022	<u>139,802</u>	<u>(91,923)</u>	<u>(1,472,828)</u>	<u>(1,424,949)</u>

**29. PARTLY-OWNED SUBSIDIARIES WITH MATERIAL NON-CONTROLLING INTERESTS**

Details of the Group’s subsidiaries that have material non-controlling interests are set out below:

	<b>As at December 31, 2021</b>	<b>As at May 31, 2022</b>
Percentage of equity interest held by non-controlling interests		
3D Medicines and its subsidiaries	<u>10.54%</u>	<u>10.54%</u>
	<b>Year ended December 31, 2021</b>	<b>Five months ended May 31, 2022</b>
Loss for the year/period allocated to non-controlling interests:		
3D Medicines and its subsidiaries	<u>(27,733)</u>	<u>(13,038)</u>
	<b>As at December 31, 2021</b>	<b>As at May 31, 2022</b>
Accumulated balances of non-controlling interests:		
3D Medicines and its subsidiaries	<u>(34,551)</u>	<u>(42,340)</u>

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The following tables illustrate the summarised consolidated financial information of the above subsidiaries:

	<b>Year ended December 31, 2021</b>	<b>Five months ended May 31, 2022</b>
Total expense	(371,337)	(275,781)
Total comprehensive loss for the year/period	<u>(299,343)</u>	<u>(123,735)</u>
	<b>As at December 31, 2021</b>	<b>As at May 31, 2022</b>
Current assets	369,395	305,030
Non-current assets	99,460	84,296
Current liabilities	(751,607)	(749,628)
Non-current liabilities	<u>(45,141)</u>	<u>(41,512)</u>
	<b>Year ended December 31, 2021</b>	<b>Five months ended May 31, 2022</b>
Net cash flows used in operating activities	(383,687)	(97,026)
Net cash flows used in investing activities	(61,510)	(828)
Net cash flows from/(used in) financing activities	<u>440,354</u>	<u>(6,002)</u>
Net decrease in cash and cash bank balances	<u><u>(4,843)</u></u>	<u><u>(103,856)</u></u>

### 30. SHARE-BASED PAYMENTS

#### (a) Shares issuance

Pursuant to the board resolution on June 22, 2021, the Company issued 440,015 ordinary shares with par value of HK\$0.01 to Dr. Gong Zhaolong through his holding vehicle, Dragon Prosper Holding Limited, with par value consideration for the contribution of Dr. Gong Zhaolong devoted to the Group in the past.

The aforesaid transactions have been accounted for as share-based payment transactions. Accordingly, the Group measured the fair value of the issued shares on the issue date and recognised the compensation expenses of nil, RMB59,240,000, nil and nil in the years ended December 31, 2020 and 2021 and the five months ended May 31, 2021 and 2022, respectively.

The Group applied the back-solve method to determine the fair value of the shares issued at the date of issuance. Key assumptions are set out below:

	<b>As at June 22, 2021</b>
Risk-free interest rate (%)	0.05
DLOM (%)	5.82
Volatility (%)	48.75

#### (b) Pre-restructuring employee stock incentive

Before the completion of the Restructuring, certain employees (the “Granted Employees”) of the Group were granted with restricted shares of the Predecessor Holdco, the immediate holding company of 3D Medicines before the Restructuring, as an incentive to retain and reward the Granted Employees.

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On September 1, 2016 and December 31, 2017, a total of 451,828 restricted shares were granted to such Granted Employees. Each restricted share is converted into agreed registered capital of the Predecessor Holdco on exercise.

### (c) Onshore employee stock incentive

From October 2018 to April 2019, 3D Medicines granted a total of 111,232 stock options and 95,239 restricted share units to certain Granted Employees.

Employee stock incentive mentioned in (b) and (c) are collectively referred as Share Awards.

The aforesaid transactions have been accounted for as share-based payments transactions as the Grant Employees were providing services to the Group during the vesting periods and hence the Group enjoyed the benefits. Accordingly, the fair value of services received in return for restricted shares and stock options granted is measured by reference to the fair value of the award granted and should be recognised by the Group.

In June 2021, such Share Awards were terminated and the ordinary shares owned by the Granted Employees were repurchased by the Company at par value. The total Share Awards share-based payments expenses recognised in the consolidated statement of profit or loss and other comprehensive income are approximately RMB416,000, RMB345,000, RMB94,000 and nil for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2021 and 2022, respectively.

### (d) 2021 share incentive scheme

Pursuant to the share incentive scheme of the Company approved and adopted on June 22, 2021, 26,068,462 restricted share units had been granted to certain employees of Group on September 30, 2021. 5,643,923 and 378,847 restricted share units have been exercised during the year ended December 31, 2021 and the five months ended May 31, 2022, respectively.

The following restricted share units were outstanding under the scheme during the Relevant Periods:

	<b>Weighted average exercise price <i>HK\$ per share</i></b>	<b>Number of units</b>
At January 1, 2021	–	–
Granted during the year	1.24	26,068,462
Exercised during the year	1.29	<u>(5,643,923)</u>
At December 31, 2021	1.22	<u>20,424,539</u>
Exercised during the period	2.21	(378,847)
Forfeited during the period	2.21	<u>(115,000)</u>
At May 31, 2022	1.20	<u>19,930,692</u>

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The exercise prices and vesting periods of the restricted share units outstanding as at December 31, 2021 and May 31, 2022 are as follows:

**As at December 31, 2021**

<b>Batch</b>	<b>Number of restricted share units</b>	<b>Exercise price per share</b>	<b>Vesting periods</b>
1	8,463,681	HK\$0.001	4 years
2	635,240	HK\$0.001	2 years
3	378,847	HK\$2.2078	Immediately*
4	5,966,531	HK\$2.2078	4 years
5	4,345,000	HK\$2.2078	4 years
6	635,240	HK\$2.2078	2 years
	20,424,539		

\* Batch 3 of 378,847 restricted share units vested immediately were exercised in February 2022.

**As at May 31, 2022**

<b>Batch</b>	<b>Number of restricted share units</b>	<b>Exercise price per share</b>	<b>Vesting periods</b>
1	8,463,681	HK\$0.001	4 years
2	635,240	HK\$0.001	2 years
3	5,966,531	HK\$2.2078	4 years
4	4,230,000	HK\$2.2078	4 years
5	635,240	HK\$2.2078	2 years
	19,930,692		

The Group’s employees have the option to acquire the granted restricted share units at exercise price when all the vesting conditions are fulfilled, and therefore, the fair values of the restricted share units granted were estimated as at the grant date using binomial method, taking into account the terms and conditions upon which the restricted share units were granted. The following table lists the inputs to the model used to determine the fair value of the restricted share units granted in 2021:

	<b>As at September 30, 2021</b>
Expected volatility (%)	44.4
Risk-free interest rate (%)	1.29
Exercise Multiple	2.2-2.8

The expected volatility reflects the assumption that the historical volatility is indicative of future trends, which may also not necessarily be the actual outcome.

The Group recognised the total expense of RMB105,074,000, nil and RMB55,435,000 for the year ended December 31, 2021 and the five months ended May 31, 2021 and 2022, respectively, in relation to 2021 share incentive scheme of the Company.

**31. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(a) Major non-cash transactions**

During the Relevant Periods and the five months ended May 31, 2021, the Group had non-cash additions to right-of-use assets and lease liabilities of RMB16,952,000, RMB47,621,000, RMB2,238,000 and RMB17,047,000 respectively, in respect of lease arrangements for office and laboratory premises.

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(b) Changes in liabilities arising from financing activities

The table below details changes in the Group’s liabilities arising from financing activities, including both cash and non-cash changes. Liabilities arising from financing activities are those for which cash flows were, or future cash flows will be, classified in the Group’s consolidated statement of cash flows as cash flows from financing activities.

	Preferred shares RMB’000	Payables to precedent investors RMB’000	Loan from a related party RMB’000	Interest bearing bank and other borrowings RMB’000	Interest payable RMB’000	Lease liabilities RMB’000	Accrued [REDACTED] expense RMB’000	Total RMB’000
At January 1, 2020	542,570	–	11,853	124,956	10,116	1,117	–	690,612
Changes from financing cash flow	783,818	1,143	(11,948)	(121,434)	(17,223)	(1,527)	(959)	631,870
Changes from non-financing cash flow	–	–	–	–	–	–	(2,878)	(2,878)
Increase in [REDACTED] expenses	–	–	–	–	–	–	4,187	4,187
Increase in deferred [REDACTED] expenses	–	–	–	–	–	–	1,396	1,396
Foreign exchange gains	–	–	(546)	–	–	–	–	(546)
Changes in fair value	319,232	–	–	–	–	–	–	319,232
New lease arrangements	–	–	–	–	–	16,952	–	16,952
Accretion of interest	–	–	641	–	7,107	310	–	8,058
At December 31, 2020 and January 1, 2021	1,645,620	1,143	–	3,522	–	16,852	1,746	1,668,883
	Preferred shares RMB’000	Payables to precedent investors RMB’000	Interest bearing bank and other borrowings RMB’000	Interest payable RMB’000	Lease liabilities RMB’000	Accrued [REDACTED] expense RMB’000	Total RMB’000	
At December 31, 2020 and January 1, 2021	1,645,620	1,143	3,522	–	16,852	1,746	1,668,883	
Changes from financing cash flow	567,229	–	(3,522)	(46)	(7,214)	(7,001)	549,446	
Changes from non-financing cash flow	–	(11,727)	–	–	–	(21,695)	(33,422)	
Changes from non-cash transactions	(34,800)	23,224	–	–	–	–	(11,576)	
Increase in [REDACTED] expenses	–	–	–	–	–	25,565	25,565	
Increase in deferred [REDACTED] expenses	–	–	–	–	–	8,745	8,745	
Foreign exchange losses	–	52	–	–	–	–	52	
Changes in fair value	954,742	–	–	–	–	–	954,742	
New lease arrangements	–	–	–	–	47,621	–	47,621	
Accretion of interest	–	–	–	46	1,482	–	1,528	
At December 31, 2021	3,132,791	12,692	–	–	58,741	7,360	3,211,584	



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	Preferred shares RMB'000	Payables to precedent investors RMB'000	Lease liabilities RMB'000	Accrued [REDACTED] expense RMB'000	Total RMB'000
At December 31, 2021 and January 1, 2022	3,132,791	12,692	58,741	7,360	3,211,584
Changes from financing cash flow	-	-	(5,750)	(1,069)	(6,819)
Changes from non-financing cash flow	-	-	-	(1,581)	(1,581)
Changes from non-cash transactions	-	-	(756)	-	(756)
Increase in [REDACTED] expenses	-	-	-	3,541	3,541
Increase in deferred [REDACTED] expenses	-	-	-	1,723	1,723
Foreign exchange losses	-	567	-	-	567
Changes in fair value	143,642	-	-	-	143,642
New lease arrangements	-	-	2,238	-	2,238
Accretion of interest	-	-	740	-	740
At May 31, 2022	<u>3,276,433</u>	<u>13,259</u>	<u>55,213</u>	<u>9,974</u>	<u>3,354,879</u>

	Preferred shares RMB'000	Payables to precedent investors RMB'000	Interest bearing bank and other borrowings RMB'000	Interest payable RMB'000	Lease liabilities RMB'000	Accrued [REDACTED] expense RMB'000	Total RMB'000
At December 31, 2020 and January 1, 2021	1,645,620	1,143	3,522	-	16,852	1,746	1,668,883
Changes from financing cash flow	79,270	-	(3,522)	(46)	(2,914)	(1,184)	71,604
Changes from non-financing cash flow	-	-	-	-	-	(3,554)	(3,554)
Changes from non-cash transactions	-	23,224	-	-	-	-	23,224
Increase in [REDACTED] expenses	-	-	-	-	-	8,799	8,799
Increase in deferred [REDACTED] expenses	-	-	-	-	-	2,930	2,930
Foreign exchange gains	-	(27)	-	-	-	-	(27)
Changes in fair value	647,031	-	-	-	-	-	647,031
New lease arrangements	-	-	-	-	17,047	-	17,047
Accretion of interest	-	-	-	46	319	-	365
At May 31, 2021 (unaudited)	<u>2,371,921</u>	<u>24,340</u>	<u>-</u>	<u>-</u>	<u>31,304</u>	<u>8,737</u>	<u>2,436,302</u>

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(c) **Total cash outflow of leases**

The total cash outflow for leases included in the statement of cash flows is as follows:

	Year ended December 31,		Five months ended May 31,	
	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000	RMB’000
Within operating activities	137	1,263	143	189
Within investing activities	–	11,492	11,492	–
Within financing activities	1,527	10,997	4,586	5,981
	<u>1,664</u>	<u>23,752</u>	<u>16,221</u>	<u>6,170</u>

**32. PLEDGE OF ASSETS**

Details of the Group’s assets pledged for the Group’s bank loans are included in note 24 to the Historical Financial Information.

**33. COMMITMENTS**

The Group had the following capital commitments at the end of each of the Relevant Periods.

	As at December 31,		As at May 31,
	2020	2021	2022
	RMB’000	RMB’000	RMB’000
Contracted, but not provided for:			
Purchase of items of property, plant and equipment	–	126,260	109,628

**34. RELATED PARTY TRANSACTIONS**

The Directors are of the view that the following companies are related parties that have material transactions or balances with the Group during the Relevant Periods and the five months ended May 31, 2021.

(a) Name and relationships of the related parties

Name	Relationship
Simcere Pharmaceutical*	Controlled by a preferred shareholder of the Company
Jiangsu Simcere*	Controlled by Simcere Pharmaceutical
Simcere (Shanghai) Pharmaceutical Co., Ltd. (先聲(上海)醫藥有限公司) (“Simcere Shanghai”)*	Controlled by Simcere Pharmaceutical
Aves Capital, LLC	Controlled by a director
Dragon Prosper Holdings Limited	Controlled by an Executive Director
Dr. Gong Zhaolong	Chairman and Executive Director
Dr. Xiong Lei**	Non-executive Director
Dr. Lin Yihui	Key management personnel
Ms. Zhang Jing	Key management personnel

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\* Simcere Pharmaceutical is formerly known as Nanjing Simcere Dongyuan Pharmaceutical Co., Ltd. (南京先聲東元製藥有限公司).

As at December 31, 2021 and May 31, 2022, Simcere Pharmaceutical, Jiangsu Simcere and Simcere Shanghai are no longer related parties of the Group, as Mr. Tang Renhong assigned by the ultimate parent company of these entities resigned as a director of the Company with effect from December 2021 (note 9). Therefore, the outstanding balances with these entities as at December 31, 2021 and May 31, 2022 were not disclosed as balances with related parties in note (c) below and the transaction amounts with these entities for the year ended December 31, 2021 and five months ended May 31, 2021 disclosed in note (b) only covered the periods when these entities were related parties.

\*\* Since June 2021, Dr. Xiong Lei is no longer a related party of the Group (note 9).

(b) In addition to the transactions detailed elsewhere in the Historical Financial Information, the Group had the following transactions with related parties during the Relevant Periods and the five months ended May 31, 2021:

	Year ended December 31,		Five months ended	
	2020	2021	2021	2022
	RMB'000	RMB'000	RMB'000	RMB'000
			<i>(unaudited)</i>	
<i>Repayment of loans from a related party:</i>				
Aves Capital, LLC	11,948	–	–	–
<i>Preferred share issuance:</i>				
Dragon Prosper Holdings Limited*	–	165,920	66,178	–
<i>Expenses for utilities:</i>				
Simcere Shanghai	–	693	269	–
<i>Expenses for research and development:</i>				
Jiangsu Simcere	–	3,660	–	–
<i>Interest income on loans to related parties:</i>				
Key management personnel	–	14	–	40
<i>Interest expenses on loans from a related party:</i>				
Aves Capital, LLC	641	–	–	–

\* In January and June 2021, the Company issued 1,363,420 preferred shares with a par value of HK\$0.01 each to Dragon Prosper Holdings Limited at total consideration of approximately RMB165,920,000.

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(c) Outstanding balances with related parties:

**The Group**

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
<i>Amounts due from related parties:</i>			
Dr. Lin Yihui – <i>non-trade</i>	–	2,010	2,035
Ms. Zhang Jing – <i>non-trade</i>	–	1,204	1,219
Simcere Shanghai – <i>trade</i>	200	–	–
Dr. Gong Zhaolong – <i>non-trade</i>	172	–	–
	<u>372</u>	<u>3,214</u>	<u>3,254</u>
<i>Amounts due to a related party:</i>			
Dr. Gong Zhaolong – <i>non-trade</i>	<u>1,702</u>	<u>150</u>	<u>150</u>
<i>Lease liabilities arising from rent from a related party:</i>			
Simcere Shanghai	<u>16,198</u>	<u>–</u>	<u>–</u>

Amounts due from/to Dr. Gong Zhaolong are unsecured, interest-free and repayable on demand. Amounts due from Simcere Shanghai are unsecured, interest-free, and receivable when lease period ends.

Amounts due from Dr. Lin Yihui and Ms. Zhang Jing are unsecured loan, with an annual interest rate of 3% and with period of 36 and 24 months, respectively.

The Group has assessed the expected loss rate for amounts due from related parties by considering the financial position and credit history of these related parties and assessed that the expected credit loss is minimal.

**The Company**

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
<i>Amounts due from subsidiaries:</i>			
3D Medicines	63,796	6,012	6,727
3DMed USA	19,418	28,855	28,855
3DMed Xuzhou	78,656	–	–
Full Goal	–	1	1
	<u>161,870</u>	<u>34,868</u>	<u>35,583</u>
<i>Amounts due to subsidiaries:</i>			
3DMed HK	185,000	33	33
3D Medicines	800	34,381	34,381
	<u>185,800</u>	<u>34,414</u>	<u>34,414</u>

Amounts due from/to subsidiaries are unsecured, interest free and repayable on demand.

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(d) Compensation of key management personnel of the Group:

	Year ended December 31,		Five months ended May 31,	
	2020	2021	2021	2022
	RMB’000	RMB’000	RMB’000	RMB’000
			(unaudited)	
Salaries, bonuses, allowances and benefits in kind	9,018	14,763	7,766	9,917
Pension scheme contributions	150	281	110	130
Equity-settled share-based payment expenses	244	108,338	61	38,142
	<u>9,412</u>	<u>123,382</u>	<u>7,937</u>	<u>48,189</u>

Further details of directors’ and the chief executive’s remuneration are included in note 9 to the Historical Financial Information.

**35. FINANCIAL INSTRUMENTS BY CATEGORY**

The carrying amounts of each of the categories of financial instruments as at the end of each of the Relevant Periods were as follows:

**The Group**

	As at December 31,		As at May 31,
	2020	2021	2022
	RMB’000	RMB’000	RMB’000
<b>Financial assets</b>			
Financial assets at FVTPL:			
Wealth management products	<u>–</u>	<u>50,178</u>	<u>50,021</u>
Financial assets at amortised cost:			
Trade receivables	–	65,004	101,889
Amounts due from related parties	372	3,214	3,254
Financial assets included in prepayments, other receivables and other assets	1,126	1,294	1,261
Financial assets included in other non-current assets	55	4,896	5,180
Pledged deposits	6,000	–	–
Restricted bank balances	–	72	72
Cash and bank balances	<u>414,261</u>	<u>774,306</u>	<u>660,231</u>
	<u>421,814</u>	<u>848,786</u>	<u>771,887</u>
<b>Financial liabilities</b>			
Financial liabilities at FVTPL:			
Preferred shares	<u>1,645,620</u>	<u>3,132,791</u>	<u>3,276,433</u>

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	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Financial liabilities at amortised cost:			
Trade payables	2,416	3,742	2,650
Financial liabilities included in other payables and accruals	75,609	114,062	175,107
Interest-bearing bank and other borrowings	3,522	–	–
Amounts due to a related party	1,702	150	150
	<u>83,249</u>	<u>117,954</u>	<u>177,907</u>

**The Company**

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
<b>Financial assets</b>			
Financial assets at amortised cost:			
Amounts due from subsidiaries	161,870	34,868	35,583
Cash and bank balances	118,200	15,830	16,573
	<u>280,070</u>	<u>50,698</u>	<u>52,156</u>
<b>Financial liabilities</b>			
Financial liabilities at FVTPL:			
Preferred shares	764,243	3,132,791	3,276,433
Financial liabilities at amortised cost:			
Financial liabilities included in other payables and accruals	18,024	20,762	24,039
Amounts due to subsidiaries	185,800	34,414	34,414
	<u>203,824</u>	<u>55,176</u>	<u>58,453</u>

Management has assessed that the fair values of cash and cash balances, pledged deposits, restricted bank balances, financial assets included in prepayments and other receivables, amounts due from related parties, trade payables, interest-bearing bank and other borrowings, loan from a related party, amounts due to related parties, financial liabilities included in other payables and accruals approximate to their carrying amounts largely due to the short-term maturities of these instruments.

The Group’s finance department is responsible for determining the policies and procedures for the fair value measurement of financial instruments. At the end of each of the Relevant Periods, the finance department analysed the movements in the values of financial instruments and determined the major inputs applied in the valuation. The valuation is reviewed and approved by the finance manager. The valuation process and results are discussed with the directors of the Company once a year for annual financial reporting.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

The fair values of the financial assets at FVTPL have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities.

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**36. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS**

Fair value hierarchy

*Financial assets at FVTPL:*

As at December 31, 2021

	Quoted prices in active markets (Level 1) <i>RMB’000</i>	Fair value measurement using Significant observable inputs (Level 2) <i>RMB’000</i>	Fair value measurement using Significant unobservable inputs (Level 3) <i>RMB’000</i>	Total <i>RMB’000</i>
Wealth management products	–	50,178	–	50,178

As at May 31, 2022

	Quoted prices in active markets (Level 1) <i>RMB’000</i>	Fair value measurement using Significant observable inputs (Level 2) <i>RMB’000</i>	Fair value measurement using Significant unobservable inputs (Level 3) <i>RMB’000</i>	Total <i>RMB’000</i>
Wealth management products	–	50,021	–	50,021

*Financial liabilities at FVTPL:*

As at December 31, 2020

	Quoted prices in active markets (Level 1) <i>RMB’000</i>	Fair value measurement using Significant observable inputs (Level 2) <i>RMB’000</i>	Fair value measurement using Significant unobservable inputs (Level 3) <i>RMB’000</i>	Total <i>RMB’000</i>
Preferred shares	–	–	1,645,620	1,645,620

As at December 31, 2021

	Quoted prices in active markets (Level 1) <i>RMB’000</i>	Fair value measurement using Significant observable inputs (Level 2) <i>RMB’000</i>	Fair value measurement using Significant unobservable inputs (Level 3) <i>RMB’000</i>	Total <i>RMB’000</i>
Preferred shares	–	–	3,132,791	3,132,791

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As at May 31, 2022

	Quoted prices in active markets (Level 1) RMB’000	Fair value measurement using		Total RMB’000
		Significant observable inputs (Level 2) RMB’000	Significant unobservable inputs (Level 3) RMB’000	
Preferred shares	–	–	3,276,433	3,276,433

Assets for which fair values are disclosed

As at December 31, 2020

	Quoted prices in active markets (Level 1) RMB’000	Fair value measurement using		Total RMB’000
		Significant observable inputs (Level 2) RMB’000	Significant unobservable inputs (Level 3) RMB’000	
Long-term deposits	–	55	–	55

As at December 31, 2021

	Quoted prices in active markets (Level 1) RMB’000	Fair value measurement using		Total RMB’000
		Significant observable inputs (Level 2) RMB’000	Significant unobservable inputs (Level 3) RMB’000	
Amounts due from related parties	–	3,214	–	3,214
Amounts due from an employee	–	1,206	–	1,206
Long-term deposits	–	3,690	–	3,690
	–	8,110	–	8,110

As at May 31, 2022

	Quoted prices in active markets (Level 1) RMB’000	Fair value measurement using		Total RMB’000
		Significant observable inputs (Level 2) RMB’000	Significant unobservable inputs (Level 3) RMB’000	
Amounts due from related parties	–	3,254	–	3,254
Amounts due from an employee	–	1,221	–	1,221
Long-term deposits	–	3,959	–	3,959
	–	8,434	–	8,434



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*Financial instruments in Level 3*

Further details of preferred shares are included in note 26 to the Historical Financial Information.

During the Relevant Periods, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

**37. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES**

The Group’s principal financial instruments mainly comprise cash and cash equivalents, interest-bearing bank borrowings and preferred shares. The main purpose of these financial instruments is to raise finance for the Group’s operations. The Group has various other financial assets and liabilities such as trade receivables and trade payables, which arise directly from its operations.

The main risks arising from the Group’s financial instruments are foreign currency risk, credit risk and liquidity risk. The Board of Directors reviews and agrees policies for managing each of these risks and they are summarised below.

**Foreign currency risk**

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between RMB and other currencies in which the Group conducts business may affect the Group’s financial condition and results of operations.

The following table demonstrates the sensitivity at the end of each of the Relevant Periods to a reasonably possible change in foreign currency exchange rates, with all other variables held constant, of the Group’s loss before tax (due to changes in the fair value of monetary assets and liabilities) and the Group’s equity.

	<b>Increase/ (decrease) in rate of foreign exchange %</b>	<b>Increase/ (decrease) in loss before tax RMB’000</b>	<b>(Decrease)/ increase in equity RMB’000</b>
<b>December 31, 2020</b>			
If RMB weakens against the US\$	5	76,013	(76,013)
If RMB strengthens against the US\$	(5)	(76,013)	76,013
<b>December 31, 2021</b>			
If RMB weakens against the US\$	5	133,753	(133,753)
If RMB strengthens against the US\$	(5)	(133,753)	133,753
<b>May 31, 2022</b>			
If RMB weakens against the US\$	5	141,923	(141,923)
If RMB strengthens against the US\$	(5)	(141,923)	141,923
<b>May 31, 2021 (unaudited)</b>			
If RMB weakens against the US\$	5	111,919	(111,919)
If RMB strengthens against the US\$	(5)	(111,919)	111,919

**Credit risk**

The Group trades only with recognised and creditworthy parties. It is the Group’s policy that all customers who wish to trade on credit terms are subject to credit verification procedures. Receivable balances are monitored on an ongoing basis and the Group’s exposure to bad debts is not significant. The credit risk of the Group’s other financial assets, which comprise cash and cash equivalents and financial assets included in prepayments, other receivables and other assets, arises from default of the counterparty, with a maximum exposure equal to the carrying amounts of these instruments.

For other receivables and other assets, management makes periodic collective assessment as well as individual assessment on the recoverability of other receivables based on historical settlement records and past experience. The Directors believe that there is no material credit risk inherent in the Group’s outstanding balance of other receivables.

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*Maximum exposure and year-end staging*

The tables below show the credit quality and the maximum exposure to credit risk based on the Group’s credit policy, which is mainly based on past due information unless other information is available without undue cost or effort, and year-end staging classification as at the end of each of the Relevant Periods.

The amounts presented are gross carrying amounts for financial assets.

**As at December 31, 2020**

	12 Month ECLs		Lifetime ECLs		Simplified approach	Total
	Stage 1	Stage 2	Stage 3			
	RMB’000	RMB’000	RMB’000		RMB’000	RMB’000
Amounts due from related parties	372	–	–	–	–	372
Financial assets included in prepayments, other receivables and other assets*	1,126	–	–	–	–	1,126
Financial assets included in other non-current assets	55	–	–	–	–	55
Pledged deposits	6,000	–	–	–	–	6,000
Cash and cash equivalents	414,261	–	–	–	–	414,261
<b>Total</b>	<b>421,814</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>421,814</b>

**As at December 31, 2021**

	12 Month ECLs		Lifetime ECLs		Simplified approach	Total
	Stage 1	Stage 2	Stage 3			
	RMB’000	RMB’000	RMB’000		RMB’000	RMB’000
Trade receivables**	–	–	–	–	65,134	65,134
Amounts due from related parties	3,214	–	–	–	–	3,214
Financial assets included in prepayments, other receivables and other assets*	1,294	–	–	–	–	1,294
Financial assets included in other non-current assets	4,896	–	–	–	–	4,896
Restricted bank balances	72	–	–	–	–	72
Cash and bank balances	774,306	–	–	–	–	774,306
<b>Total</b>	<b>783,782</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>65,134</b>	<b>848,916</b>

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As at May 31, 2022

	12 Month ECLs		Lifetime ECLs		Simplified approach RMB’000	Total RMB’000
	Stage 1 RMB’000	Stage 2 RMB’000	Stage 3 RMB’000			
Trade receivables**	–	–	–	102,093	102,093	
Amounts due from related parties	3,254	–	–	–	3,254	
Financial assets included in prepayments, other receivables and other assets*	1,261	–	–	–	1,261	
Financial assets included in other non-current assets	5,180	–	–	–	5,180	
Restricted bank balances	72	–	–	–	72	
Cash and bank balances	660,231	–	–	–	660,231	
<b>Total</b>	<b>669,998</b>	<b>–</b>	<b>–</b>	<b>102,093</b>	<b>772,091</b>	

\* The credit quality of the financial assets included in prepayments, other receivables and other assets is considered to be “normal” when they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition.

\*\* For trade receivables as at December 31, 2021 and May 31, 2022, the Group applies the simplified approach for impairment, information based on the provision matrix is disclosed in note 18 to the Historical Financial Information.

At the end of each of the Relevant Periods, the Group had certain concentrations of credit risk with respect to trade receivables, which are disclosed in note 18 to the Historical Financial Information.

**Liquidity risk**

The Group monitors and maintains a level of cash and cash equivalents deemed adequate by the management of the Group to finance the operations and mitigate the effects of fluctuations in cash flows.

The maturity profile of the Group’s financial liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

As at December 31, 2020

	Less than 12 months or on demand RMB’000	1 to 5 years RMB’000	Total RMB’000
Trade payables	2,416	–	2,416
Financial liabilities included in other payables and accruals	75,609	–	75,609
Lease liabilities	3,791	15,439	19,230
Amounts due to a related party	1,702	–	1,702
Preferred shares	283,112	1,309,146	1,592,258
Interest-bearing bank and other borrowings	3,522	–	3,522
	<b>370,152</b>	<b>1,324,585</b>	<b>1,694,737</b>

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**As at December 31, 2021**

	<b>Less than 12 months or on demand RMB’000</b>	<b>1 to 5 years RMB’000</b>	<b>Total RMB’000</b>
Trade payables	3,742	–	3,742
Financial liabilities included in other payables and accruals	114,062	–	114,062
Lease liabilities	14,379	48,681	63,060
Amounts due to a related party	150	–	150
Preferred shares	2,425,646	–	2,425,646
	<u>2,557,979</u>	<u>48,681</u>	<u>2,606,660</u>

**As at May 31, 2022**

	<b>Less than 12 months or on demand RMB’000</b>	<b>1 to 5 years RMB’000</b>	<b>Total RMB’000</b>
Trade payables	2,650	–	2,650
Financial liabilities included in other payables and accruals	175,107	–	175,107
Lease liabilities	15,597	43,050	58,647
Amounts due to a related party	150	–	150
Preferred shares	2,512,770	–	2,512,770
	<u>2,706,274</u>	<u>43,050</u>	<u>2,749,324</u>

**Capital management**

The primary objectives of the Group’s capital management are to safeguard the Group’s abilities to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximise shareholders’ value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital as at the end of each of the Relevant Periods.

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**ACCOUNTANTS’ REPORT**

The asset-liability ratios as at the end of each of the Relevant Periods are as follows:

	<b>As at December 31,</b>		<b>As at May 31,</b>
	<b>2020</b>	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Total assets	<u>496,216</u>	<u>1,060,293</u>	<u>1,018,021</u>
Total liabilities	<u>1,766,031</u>	<u>3,332,855</u>	<u>3,527,850</u>
Asset-liability ratio*	<u>356%</u>	<u>314%</u>	<u>347%</u>

\* Asset-liability ratio is calculated by dividing total liabilities by total assets and multiplying the product by 100%.

**38. EVENTS AFTER THE RELEVANT PERIODS**

No significant events have occurred to the Company, or the Group or any of the companies now comprising the Group in respective of any period subsequent to May 31, 2022.

**39. SUBSEQUENT FINANCIAL STATEMENTS**

No audited financial statements have been prepared by the Company, the Group or any of the companies now comprising the Group in respect of any period subsequent to May 31, 2022.

**APPENDIX II**

**UNAUDITED PRO FORMA FINANCIAL INFORMATION**

The following information does not form part of the Accountants’ Report from Ernst & Young, Certified Public Accountants, Hong Kong, the Company’s reporting accountants, as set out in Appendix I to this Document, and is included herein for information purpose only. The unaudited pro forma financial information should be read in conjunction with the section headed “Financial Information” in this Document and the Accountants’ Report set out in Appendix I to this Document.

**A. UNAUDITED PRO FORMA STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS**

The following unaudited pro forma statement of adjusted consolidated net tangible assets of the Group prepared in accordance with paragraph 4.29 of the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited and with reference to Accounting Guideline 7 Preparation of Pro Forma Financial Information for Inclusion in Investment Circulars issued by the Hong Kong Institute of Certified Public Accountants for illustration purposes only, and is set out here to illustrate the effect of the [REDACTED] on the consolidated net tangible assets of the Group attributable to owners of the parent as if the [REDACTED] had taken place on May 31, 2022.

The unaudited pro forma statement of adjusted consolidated net tangible assets of the Group has been prepared for illustrative purpose only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of the Group to owners of the parent had the [REDACTED] been completed as of May 31, 2022 or as at any future dates.

	Consolidated net tangible liabilities of the Group attributable to owners of the Company as at May 31, 2022 <i>RMB'000</i> <i>(Note 1)</i>	Estimated net [REDACTED] from the [REDACTED] <i>RMB'000</i> <i>(Note 2)</i>	Estimated impact to the consolidated net tangible liabilities upon the conversion of preferred shares <i>RMB'000</i> <i>(Note 3)</i>	Unaudited pro forma adjusted consolidated net tangible assets as at May 31, 2022 <i>RMB'000</i>	Unaudited pro forma adjusted consolidated net tangible assets per Share as at May 31, 2022 <i>RMB</i> <i>HK\$</i> <i>(Note 4)</i> <i>(Note 5)</i>	
Based on an [REDACTED] of HK\$[REDACTED] per Share	(2,510,716)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Based on an [REDACTED] of HK\$[REDACTED] per Share	(2,510,716)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Based on an [REDACTED] of HK\$[REDACTED] per Share	(2,510,716)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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**UNAUDITED PRO FORMA FINANCIAL INFORMATION**

*Notes:*

1. The consolidated net tangible liabilities of the Group attributable to equity holders of the Company as at May 31, 2022 was arrived at after deducting intangible assets of RMB887,000 from the consolidated net liabilities attributable to owners of the Company as at May 31, 2022 of RMB2,509,829,000 set out in the Accountants’ Report in Appendix I to this document.
2. The estimated net [REDACTED] from the [REDACTED] are based on an [REDACTED] of HK\$[REDACTED] per Share, HK\$[REDACTED] per Share and HK\$[REDACTED] per Share, after deduction of the [REDACTED] fees and other related expenses payable by the Company and do not take into account any Shares which may be issued upon the exercise of the [REDACTED].
3. Upon the [REDACTED] and the completion of the [REDACTED], all preferred shares will be automatically converted into Ordinary Shares. The preferred shares will then be transferred from liabilities to equity. Accordingly, for the purpose of the unaudited pro forma financial information, the unaudited pro forma adjusted net tangible liabilities attributable to owners of the parent will be decreased by RMB3,276,433,000, being the carrying amounts of the preferred shares as at May 31, 2022.
4. The unaudited pro forma adjusted consolidated net tangible assets per Share is arrived at after adjustments referred to notes 2 and 3 above and on the basis that (i) [REDACTED] Shares are in issue, assuming the [REDACTED] has been completed on May 31, 2022, and (ii) 32,693,837 Shares allotted and issued to three BVI entities, namely Immunal Medixin US Limited, Immunal Medixin Cino L. Limited and Immunal Medixin Cino Limited were not included in the calculation since they were recognized as treasury shares in the Accountants’ Report in Appendix I to this document.
5. The unaudited pro forma adjusted consolidated net tangible assets per Share is converted into HK\$ at an exchange rate of HK\$1.00 to RMB0.8592 prevailing on July 18, 2022.
6. No adjustment has been made to the unaudited pro forma adjusted consolidated net tangible assets to reflect any trading results or other transactions of the Group entered into subsequent to May 31, 2022.

[REDACTED]



[REDACTED]

[REDACTED]



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*(ii) Variation of rights of existing shares or classes of shares*

Subject to the Companies Act, if at any time the share capital of the Company is divided into different classes of shares, all or any of the special rights attached to the shares or any class of shares may (unless otherwise provided for by the terms of issue of that class) be varied, modified or abrogated either with the consent in writing of the holders of not less than three-fourths in nominal value of the issued shares of that class or with the sanction of a special resolution passed at a separate general meeting of the holders of the shares of that class. To every such separate general meeting the provisions of the Articles relating to general meetings will *mutatis mutandis* apply, but so that the necessary quorum (other than at an adjourned meeting) shall be two persons holding or representing by proxy not less than one-third in nominal value of the issued shares of that class and at any adjourned meeting two holders present in person or by proxy (whatever the number of shares held by them) shall be a quorum. Every holder of shares of the class shall be entitled to one vote for every such share held by him.

Any special rights conferred upon the holders of any shares or class of shares shall not, unless otherwise expressly provided in the rights attaching to the terms of issue of such shares, be deemed to be varied by the creation or issue of further shares ranking *pari passu* therewith.

*(iii) Alteration of capital*

The Company may by ordinary resolution of its members:

- (i) increase its share capital by the creation of new shares;
- (ii) consolidate all or any of its capital into shares of larger amount than its existing shares;
- (iii) divide its shares into several classes and attach to such shares any preferential, deferred, qualified or special rights, privileges, conditions or restrictions as the Company in general meeting or as the directors may determine;
- (iv) subdivide its shares or any of them into shares of smaller amount than is fixed by the Memorandum; or
- (v) cancel any shares which, at the date of passing of the resolution, have not been taken and diminish the amount of its capital by the amount of the shares so cancelled.

The Company may reduce its share capital or any capital redemption reserve or other undistributable reserve in any way by special resolution.

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*(iv) Transfer of shares*

All transfers of shares may be effected by an instrument of transfer in the usual or common form or in a form prescribed by The Stock Exchange of Hong Kong Limited (the "Stock Exchange") or in such other form as the board may approve and which may be under hand or, if the transferor or transferee is a clearing house or its nominee(s), by hand or by machine imprinted signature or by such other manner of execution as the board may approve from time to time.

Notwithstanding the foregoing, for so long as any shares are listed on the Stock Exchange, titles to such listed shares may be evidenced and transferred in accordance with the laws applicable to and the rules and regulations of the Stock Exchange that are or shall be applicable to such listed shares. The register of members in respect of its listed shares (whether the principal register or a branch register) may be kept by recording the particulars required by Section 40 of the Companies Act in a form otherwise than legible if such recording otherwise complies with the laws applicable to and the rules and regulations of the Stock Exchange that are or shall be applicable to such listed shares.

The instrument of transfer shall be executed 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 transferee. The transferor shall be deemed to remain the holder of the share until the name of the transferee is entered in the register of members in respect of that share.

The board may, in its absolute discretion, at any time transfer any share upon 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 decline to recognise any instrument of transfer unless a fee (not exceeding the maximum sum as the Stock Exchange may determine to be payable) determined by the Directors is paid to the Company, the instrument of transfer is properly stamped (if applicable), it is in respect of only one class of share and is lodged at the relevant registration office or registered office or such other place at which the principal register is kept accompanied by the relevant share certificate(s) and such other evidence as the board may reasonably require 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 registration of transfers may be suspended and the register closed on giving notice by advertisement in any newspaper or by any other means in accordance with the requirements of the Stock Exchange, at such times and for such periods as the board may determine. The register of members must not be closed for periods exceeding in the whole thirty (30) days in any year.

Subject to the above, fully paid shares are free from any restriction on transfer and free of all liens in favour of the Company.

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*(v) Power of the Company to purchase its own shares*

The Company is empowered by the Companies Act and the Articles to purchase its own shares subject to certain restrictions and the board may only exercise this power on behalf of the Company subject to any applicable requirements imposed from time to time by the Stock Exchange.

The board may accept the surrender for no consideration of any fully paid share.

*(vi) Power of any subsidiary of the Company to own shares in the Company*

There are no provisions in the Articles relating to ownership of shares in the Company by a subsidiary.

*(vii) Calls on shares and forfeiture of shares*

The board may from time to time make such calls upon the members in respect of any monies unpaid on the shares held by them respectively (whether on account of the nominal value of the shares or by way of premium). A call may be made payable either in one lump sum or by installments. If the sum payable in respect of any call or instalment is not paid on or before the day appointed for payment thereof, the person or persons from whom the sum is due shall pay interest on the same at such rate not exceeding twenty per cent. (20%) per annum as the board may agree to accept from the day appointed for the payment thereof to the time of actual payment, but the board may waive payment of such interest wholly or in part. The board may, if it thinks fit, receive from any member willing to advance the same, either in money or money's worth, all or any part of the monies uncalled and unpaid or installments payable upon any shares held by him, and upon all or any of the monies so advanced the Company may pay interest at such rate (if any) as the board may decide.

If a member fails to pay any call on the day appointed for payment thereof, the board may serve not less than fourteen (14) clear days' notice on him requiring payment of so much of the call as is unpaid, together with any interest which may have accrued and which may still accrue up to the date of actual payment and stating that, in the event of non-payment at or before the time appointed, the shares in respect of which the call was made will be liable to be forfeited.

If the requirements of any such notice are not complied with, any share in respect of which the notice has been given may at any time thereafter, before the payment required by the notice has been made, be forfeited by a resolution of the board to that effect. Such forfeiture will include all dividends and bonuses declared in respect of the forfeited share and not actually paid before the forfeiture.

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A person whose shares have been forfeited shall cease to be a member in respect of the forfeited shares but shall, notwithstanding, remain liable to pay to the Company all monies which, at the date of forfeiture, were payable by him to the Company in respect of the shares, together with (if the board shall in its discretion so require) interest thereon from the date of forfeiture until the date of actual payment at such rate not exceeding twenty per cent. (20%) per annum as the board determines.

**(b) Directors**

*(i) Appointment, retirement and removal*

At each annual general meeting, one third of the Directors for the time being (or if their number is not a multiple of three, then the number nearest to but not less than one third) shall retire from office by rotation provided that every Director shall be subject to retirement at an annual general meeting at least once every three years. The Directors to retire by rotation shall include any Director who wishes to retire and not offer himself for re-election. Any further Directors so to retire shall be those who have been longest in office since their last re-election or appointment but as between persons who became or were last re-elected Directors on the same day those to retire will (unless they otherwise agree among themselves) be determined by lot.

Neither a Director nor an alternate Director is required to hold any shares in the Company by way of qualification. Further, there are no provisions in the Articles relating to retirement of Directors upon reaching any age limit.

The Directors have the power to appoint any person as a Director either to fill a casual vacancy on the board or as an addition to the existing board. 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.

A Director may be removed by an ordinary resolution of the Company before the expiration of his term of office (but without prejudice to any claim which such Director may have for damages for any breach of any contract between him and the Company) and members of the Company may by ordinary resolution appoint another in his place. Unless otherwise determined by the Company in general meeting, the number of Directors shall not be less than two. There is no maximum number of Directors.

The office of director shall be vacated if:

(aa) he resigns by notice in writing delivered to the Company;

(bb) he becomes of unsound mind or dies;

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- (cc) without special leave, he is absent from meetings of the board for six (6) consecutive months, and the board resolves that his office is vacated;
- (dd) he becomes bankrupt or has a receiving order made against him or suspends payment or compounds with his creditors;
- (ee) he is prohibited from being a director by law; or
- (ff) he ceases to be a director by virtue of any provision of law or is removed from office pursuant to the Articles.

The board may appoint one or more of its body to be managing director, joint managing director, or deputy managing director or to hold any other employment or executive office with the Company for such period and upon such terms as the board may determine and the board may revoke or terminate any of such appointments. The board may delegate any of its powers, authorities and discretions to committees consisting of such Director or Directors and other persons as the board thinks fit, and it may from time to time revoke such delegation or revoke the appointment of and discharge any such committees either wholly or in part, and either as to persons or purposes, but every committee so formed must, in the exercise of the powers, authorities and discretions so delegated, conform to any regulations that may from time to time be imposed upon it by the board.

*(ii) Power to allot and issue shares and warrants*

Subject to the provisions of the Companies Act and the Memorandum and Articles and to any special rights conferred on the holders of any shares or class of shares, any share may be issued (a) with or have attached thereto such rights, or such restrictions, whether with regard to dividend, voting, return of capital, or otherwise, as the Directors may determine, or (b) on terms that, at the option of the Company or the holder thereof, it is liable to be redeemed.

The board may issue warrants or convertible securities or securities of similar nature conferring the right upon the holders thereof to subscribe for any class of shares or securities in the capital of the Company on such terms as it may determine.

Subject to the provisions of the Companies Act and the Articles and, where applicable, the rules of the Stock Exchange and without prejudice to any special rights or restrictions for the time being attached to any shares or any class of shares, all unissued shares in the Company are at the disposal of the board, which may offer, allot, grant options over or otherwise dispose of them to such persons, at such times, for such consideration and on such terms and conditions as it in its absolute discretion thinks fit, but so that no shares shall be issued at a discount to their nominal value.



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Neither the Company nor the board is 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 with registered addresses in any particular territory or territories being a territory or territories where, in the absence of a registration statement or other special formalities, this would or might, in the opinion of the board, be unlawful or impracticable. Members affected as a result of the foregoing sentence shall not be, or be deemed to be, a separate class of members for any purpose whatsoever.

***(iii) Power to dispose of the assets of the Company or any of its subsidiaries***

There are no specific provisions in the Articles relating to the disposal of the assets of the Company or any of its subsidiaries. The Directors may, however, exercise all powers and do all acts and things which may be exercised or done or approved by the Company and which are not required by the Articles or the Companies Act to be exercised or done by the Company in general meeting.

***(iv) Borrowing powers***

The board may exercise all the powers of the Company to raise or borrow money, to mortgage or charge all or any part of the undertaking, property and assets and uncalled capital of the Company and, subject to the Companies Act, to issue debentures, bonds and other securities of the Company, whether outright or as collateral security for any debt, liability or obligation of the Company or of any third party.

***(v) Remuneration***

The ordinary remuneration of the Directors is to be determined by the Company in general meeting, such sum (unless otherwise directed by the resolution by which it is voted) to be divided amongst the Directors in such proportions and in such manner as the board may agree or, failing agreement, equally, except that any Director holding office for part only of the period in respect of which the remuneration is payable shall only rank in such division in proportion to the time during such period for which he held office. The Directors are also entitled to be prepaid or repaid all travelling, hotel and incidental expenses reasonably expected to be incurred or incurred by them in attending any board meetings, committee meetings or general meetings or separate meetings of any class of shares or of debentures of the Company or otherwise in connection with the discharge of their duties as Directors.

Any Director who, by request, goes or resides abroad for any purpose of the Company or who performs services which in the opinion of the board go beyond the ordinary duties of a Director may be paid such extra remuneration as the board may determine and such extra remuneration shall be in addition to or in substitution for any ordinary remuneration as a Director. An executive Director appointed to be a managing director, joint managing director, deputy managing director or other executive officer shall receive such remuneration and such other benefits and allowances as the board may from time to time decide. Such remuneration may be either in addition to or in lieu of his remuneration as a Director.

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The board may establish or concur or join with other companies (being subsidiary companies of the Company or companies with which it is associated in business) in establishing and making contributions out of the Company's monies to any schemes or funds for providing pensions, sickness or compassionate allowances, life assurance or other benefits for employees (which expression as used in this and the following paragraph shall include any Director or past Director who may hold or have held any executive office or any office of profit with the Company or any of its subsidiaries) and ex-employees of the Company and their dependents or any class or classes of such persons.

The board may pay, enter into agreements to pay or make grants of revocable or irrevocable, and either subject or not subject to any terms or conditions, pensions or other benefits to employees and ex-employees and their dependents, or to any of such persons, including pensions or benefits additional to those, if any, to which such employees or ex-employees or their dependents are or may become entitled under any such scheme or fund as is mentioned in the previous paragraph. Any such pension or benefit may, as the board considers desirable, be granted to an employee either before and in anticipation of, or upon or at any time after, his actual retirement.

The board may resolve to capitalise all or any part of any amount for the time being standing to the credit of any reserve or fund (including a share premium account and the profit and loss account) whether or not the same is available for distribution by applying such sum in paying up unissued shares to be allotted to (i) employees (including directors) of the Company and/or its affiliates (meaning any individual, corporation, partnership, association, joint-stock company, trust, unincorporated association or other entity (other than the Company) that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, the Company) upon exercise or vesting of any options or awards granted under any share incentive scheme or employee benefit scheme or other arrangement which relates to such persons that has been adopted or approved by the members in general meeting, or (ii) any trustee of any trust to whom shares are to be allotted and issued by the Company in connection with the operation of any share incentive scheme or employee benefit scheme or other arrangement which relates to such persons that has been adopted or approved by the members in general meeting.

*(vi) Compensation or payments for loss of office*

Pursuant to the Articles, payments to any Director or past Director of any sum by way of compensation for loss of office or as consideration for or in connection with his retirement from office (not being a payment to which the Director is contractually entitled) must be approved by the Company in general meeting.

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*(vii) Loans and provision of security for loans to Directors*

The Company must not make any loan, directly or indirectly, to a Director or his close associate(s) if and to the extent it would be prohibited by the Companies Ordinance (Chapter 622 of the laws of Hong Kong) as if the Company were a company incorporated in Hong Kong.

*(viii) Disclosure of interests in contracts with the Company or any of its subsidiaries*

A Director may hold any other office or place of profit with the Company (except that of the auditor of 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 therefor in addition to any remuneration provided for by or pursuant to the Articles. A Director may be or become a director or other officer of, or otherwise interested in, any company promoted by the Company or 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, profits or other benefits received by him as a director, officer or member of, or from his interest in, such other company. The board may also cause the voting power conferred by the shares in any other company held or owned by the Company to be exercised in such manner in all respects as it thinks fit, including the exercise thereof in favour of any resolution appointing the Directors or any of them to be directors or officers of such other company, or voting or providing for the payment of remuneration to the directors or officers of such other company.

No Director or proposed or intended Director shall be disqualified by his office from contracting with the Company, either with regard to his tenure of any office or place of profit or as vendor, purchaser or in any other manner whatsoever, nor shall any such contract or any other contract or arrangement in which any Director is in any way interested be liable to be avoided, nor shall any Director so contracting or being so interested be liable to account to the Company or the members for any remuneration, profit or other benefits realised by any such contract or arrangement by reason of such Director holding that office or the fiduciary relationship thereby established. A Director who to his knowledge is in any way, whether directly or indirectly, interested in a contract or arrangement or proposed contract or arrangement with the Company must declare the nature of his interest at the meeting of the board at which the question of entering into the contract or arrangement is first taken into consideration, if he knows his interest then exists, or in any other case, at the first meeting of the board after he knows that he is or has become so interested.

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A Director shall not vote (nor be counted in the quorum) on any resolution of the board approving any contract or arrangement or other proposal in which he or any of his close associates is materially interested, but this prohibition does not apply to any of the following matters, namely:

- (aa) the giving of any security or indemnity either:-
  - (aaa) 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; or
  - (bbb) 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 himself/themselves assumed responsibility in whole or in part and whether alone or jointly under a guarantee or indemnity or by the giving of security;
- (bb) any proposal concerning an offer of shares or 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;
- (cc) any proposal or arrangement concerning the benefit of employees of the Company or its subsidiaries including:-
  - (aaa) the adoption, modification or operation of any employees' share scheme or any share incentive or share option scheme under which the Director or his close associate(s) may benefit; or
  - (bbb) the adoption, modification or operation of a pension fund or retirement, death, or disability benefits scheme which relates to the Directors, his close associate(s) and employee(s) of the Company or any of its subsidiaries and does not provide in respect of any Director, or his close associate(s), as such any privilege or advantage not generally accorded to the class of persons to which such scheme or fund relates;
- (dd) 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 or debentures or other securities of the Company by virtue only of his/their interest in shares or debentures or other securities of the Company.

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**(c) Proceedings of the Board**

The board may meet for the despatch of business, adjourn and otherwise regulate its meetings as it considers appropriate. 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 an additional or casting vote.

**(d) Alterations to constitutional documents and the Company's name**

The Articles may be rescinded, altered or amended by the Company in general meeting by special resolution. The Articles state that a special resolution shall be required to alter the provisions of the Memorandum, to amend the Articles or to change the name of the Company.

**(e) Meetings of members**

**(i) *Special and ordinary resolutions***

A special resolution of the Company must be passed by a majority of not less than three-fourths of the votes cast by such members as, being entitled so to do, vote in person or, in the case of such members as are corporations, by their duly authorised representatives or, where proxies are allowed, by proxy at a general meeting of which notice has been duly given in accordance with the Articles.

Under the Companies Act, a copy of any special resolution must be forwarded to the Registrar of Companies in the Cayman Islands within fifteen (15) days of being passed.

An ordinary resolution is defined in the Articles to mean a resolution passed by a simple majority of the votes of such members of the Company as, being entitled to do so, vote in person or, in the case of corporations, by their duly authorised representatives or, where proxies are allowed, by proxy at a general meeting of which notice has been duly given in accordance with the Articles.

**(ii) *Voting rights and right to demand a poll***

Subject to any special rights or restrictions as to voting for the time being attached to any shares, at any general meeting on a poll every member present in person or by proxy or, in the case of a member being a corporation, by its duly authorised representative shall have one vote for every fully paid share of which he is the holder but so that no amount paid up or credited as paid up on a share in advance of calls or installments is treated for the foregoing purposes as paid up on the share. A member entitled to more than one vote need not use all his votes or cast all the votes he uses in the same way.

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At any general meeting a resolution put to the vote of the meeting is to be decided by way of a poll save that the chairman of the meeting may in good faith, allow a resolution which relates purely to a procedural or administrative matter to be voted on by a show of hands in which case every member present in person (or being a corporation, is present by a duly authorized representative), or by proxy(ies) shall have one vote provided that where more than one proxy is appointed by a member which is a clearing house (or its nominee(s)), each such proxy shall have one vote on a show of hands. Votes (whether on a show of hands or by way of poll) may be cast by such means, electronic or otherwise, as the Directors or the chairman of the meeting may determine.

Any corporation which is a member may by resolution of its directors or other governing body authorise such person as it thinks fit to act as its representative at any meeting of the Company or at any meeting of any class of members. The person so authorised shall be entitled to exercise the same powers on behalf of such corporation as the corporation could exercise if it were an individual member and such corporation shall for the purposes of these Articles be deemed to be present in person at any such meeting if a person so authorised is present thereat.

If a recognised clearing house (or its nominee(s)) is a member of the Company it may authorise such person or persons as it thinks fit to act as its representative(s) at any meeting of the Company 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 authorised pursuant to this provision shall be deemed to have been duly authorised without further evidence of the facts and be entitled to exercise the same powers on behalf of the recognised clearing house (or its nominee(s)) as if such person was the registered holder of the shares of the Company held by that clearing house (or its nominee(s)) including, the right to speak and to vote, and where a show of hands is allowed, the right to vote individually on a show of hands.

All members have the right to speak and vote at a general meeting except where a member is required, by the rules of the Stock Exchange, to abstain from voting to approve the matter under consideration.

Where the Company has any knowledge that any member is, under the rules of the Stock Exchange, required to abstain from voting on any particular resolution of the Company or restricted to voting only for or only against any particular resolution of the Company, any votes cast by or on behalf of such member in contravention of such requirement or restriction shall not be counted.

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*(iii) Annual general meetings and extraordinary general meetings*

The Company must hold an annual general meeting of the Company every financial year and such general meeting must be held within six (6) months after the end of the Company's financial year unless a longer period would not infringe the rules of the Stock Exchange.

Extraordinary general meetings may be convened on the requisition of one or more members holding, at the date of deposit of the requisition, not less than one-tenth of the paid up capital of the Company having the right of voting at general meetings, on a one vote per share basis. Such requisition shall be made in writing to the board or the secretary for the purpose of requiring an extraordinary general meeting to be called by the board for the transaction of any business or resolution specified in such requisition. Such meeting shall be held within 2 months after the deposit of such requisition. If within 21 days of such deposit, the board fails to proceed to convene such meeting, the requisitionist(s) himself/herself (themselves) may do so in the same manner, and all reasonable expenses incurred by the requisitionist(s) as a result of the failure of the board shall be reimbursed to the requisitionist(s) by the Company.

*(iv) Notices of meetings and business to be conducted*

An annual general meeting must be called by notice of not less than twenty-one (21) clear days. All other general meetings must be called by notice of at least fourteen (14) clear days. The notice is 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 time and place of the meeting and particulars of resolutions to be considered at the meeting and, in the case of special business, the general nature of that business.

In addition, notice of every general meeting must be given to all members of the Company other than to such members as, under the provisions of the Articles or the terms of issue of the shares they hold, are not entitled to receive such notices from the Company, and also to, among others, the auditors for the time being of the Company.

Any notice to be given to or by any person pursuant to the Articles may be served on or delivered to any member of the Company personally, by post to such member's registered address or by advertisement in newspapers in accordance with the requirements of the Stock Exchange. Subject to compliance with Cayman Islands law and the rules of the Stock Exchange, notice may also be served or delivered by the Company to any member by electronic means.

All business that is transacted at an extraordinary general meeting and at an annual general meeting is deemed special, save that in the case of an annual general meeting, each of the following business is deemed an ordinary business:

- (aa) the declaration and sanctioning of dividends;

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(bb) the consideration and adoption of the accounts and balance sheet and the reports of the directors and the auditors;

(cc) the election of directors in place of those retiring;

(dd) the appointment of auditors and other officers; and

(ee) the fixing of the remuneration of the directors and of the auditors.

**(v) *Quorum for meetings and separate class meetings***

No business shall be transacted at any general meeting unless a quorum is present when the meeting proceeds to business, but the absence of a quorum shall not preclude the appointment of a chairman.

The quorum for a general meeting shall be two members present in person (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy or, for quorum purposes only, two persons appointed by the clearing house as authorized representative or proxy, and entitled to vote. In respect of a separate class meeting (other than an adjourned meeting) convened to sanction the modification of class rights the necessary quorum shall be two persons holding or representing by proxy not less than one-third in nominal value of the issued shares of that class.

**(vi) *Proxies***

Any member of the Company entitled to attend and vote at a meeting of the Company is entitled to appoint another person as his proxy to attend and vote instead of him. 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 is entitled to exercise the same powers on behalf of a member who is an individual and for whom he acts as proxy as such member could exercise. In addition, a proxy is 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 an individual member. Votes may be given either personally (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy.

**(f) *Accounts and audit***

The board shall cause true accounts to be kept of the sums of money received and expended by the Company, and the matters in respect of which such receipt and expenditure take place, and of the property, assets, credits and liabilities of the Company and of all other matters required by the Companies Act or necessary to give a true and fair view of the Company's affairs and to explain its transactions.



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The accounting records must be kept at the registered office or at such other place or places as the board decides and shall always be open to inspection by any Director. No member (other than a Director) shall have any right to inspect any accounting record or book or document of the Company except as conferred by law or authorised by the board or the Company in general meeting. However, an exempted company must make available at its registered office in electronic form or any other medium, copies of its books of account or parts thereof 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 of the Cayman Islands.

A copy of every balance sheet and profit and loss account (including every document required by law to be annexed thereto) which is to be laid before the Company at its general meeting, together with a printed copy of the Directors' report and a copy of the auditors' report, shall not less than twenty-one (21) days before the date of the meeting and at the same time as the notice of annual general meeting be sent to every person entitled to receive notices of general meetings of the Company under the provisions of the Articles; however, subject to compliance with all applicable laws, including the rules of the Stock Exchange, the Company may send to such persons summarised financial statements derived from the Company's annual accounts and the directors' report instead provided that any such person may by notice in writing served on the Company, demand that the Company sends to him, in addition to summarised financial statements, a complete printed copy of the Company's annual financial statement and the directors' report thereon.

At the annual general meeting or at a subsequent extraordinary general meeting in each year, the members shall by ordinary resolution appoint an auditor to audit the accounts of the Company and such auditor shall hold office until the next annual general meeting. Moreover, the members may, at any general meeting, by ordinary resolution remove the auditor at any time before the expiration of his terms of office and shall by ordinary resolution at that meeting appoint another auditor for the remainder of his term. The remuneration of the auditors shall be fixed by an ordinary resolution passed at a general meeting or in such manner as the members may by ordinary resolution determine.

The financial statements of the Company shall be audited by the auditor in accordance with generally accepted auditing standards which may be those of a country or jurisdiction other than the Cayman Islands. The auditor shall make a written report thereon in accordance with generally accepted auditing standards and the report of the auditor must be submitted to the members in general meeting.

**(g) Dividends and other methods of distribution**

The Company in general meeting may declare dividends in any currency to be paid to the members but no dividend shall be declared in excess of the amount recommended by the board.

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The Articles provide dividends may be declared and paid out of the profits of the Company, realised or unrealised, or from any reserve set aside from profits which the directors determine is no longer needed. With the sanction of an ordinary resolution dividends may also be declared and paid out of share premium account or any other fund or account which can be authorised for this purpose in accordance with the Companies Act.

Except in so far as the rights attaching to, or the terms of issue of, any share may otherwise provide, (i) all dividends shall be declared and paid according to the amounts paid up on the shares in respect whereof the dividend is paid but no amount paid up on a share in advance of calls shall for this purpose be treated as paid up on the share and (ii) all dividends shall be apportioned and paid pro rata according to the amount paid up on the shares during any portion or portions of the period in respect of which the dividend is paid. The Directors may deduct from any dividend or other monies payable to any member or in respect of any shares all sums of money (if any) presently payable by him to the Company on account of calls or otherwise.

Whenever the board or the Company in general meeting has resolved that a dividend be paid or declared on the share capital of the Company, the board may further resolve either (a) that such dividend be satisfied wholly or in part in the form of an allotment of shares credited as fully paid up, 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 members entitled to such dividend will be entitled to elect to receive an allotment of shares credited as fully paid up in lieu of the whole or such part of the dividend as the board may think fit.

The Company may also upon the recommendation of the board by an ordinary resolution resolve in respect of any one particular dividend of the Company that it may be satisfied wholly in the form of an allotment of shares credited as fully paid up without offering any right to members to elect to receive such dividend in cash in lieu of such allotment.

Any dividend, interest or other sum payable in cash to the holder of shares may be paid by cheque or warrant sent through the post addressed to the holder at his registered address, or in the case of joint holders, addressed to the holder whose name stands first in the register of the Company in respect of the shares at his address as appearing in the register or addressed to such person and at such addresses as the holder or joint holders may in writing direct. Every such cheque or warrant shall, unless the holder or joint holders otherwise direct, be made payable to the order of the holder or, in the case of joint holders, to the order of the holder whose name stands first on the register in respect of such shares, and shall be sent at his or their risk and payment of the cheque or warrant by the bank on which it is drawn shall constitute a good discharge to the Company. Any one of two or more joint holders may give effectual receipts for any dividends or other moneys payable or property distributable in respect of the shares held by such joint holders.

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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 wholly or in part by the distribution of specific assets of any kind.

All dividends or bonuses unclaimed for one year after having been declared may be invested or otherwise made use of by the board for the benefit of the Company until claimed and the Company shall not be constituted a trustee in respect thereof. All dividends or bonuses unclaimed for six years after having been declared may be forfeited by the board and shall revert to the Company.

No dividend or other monies payable by the Company on or in respect of any share shall bear interest against the Company.

**(h) Inspection of corporate records**

Pursuant to the Articles, the register and branch register of members shall be open to inspection for at least two (2) hours during business hours by members without charge, or by any other person upon a maximum payment of HK\$2.50 or such lesser sum specified by the board, at the registered office or such other place at which the register is kept in accordance with the Companies Act or, upon a maximum payment of HK\$1.00 or such lesser sum specified by the board, at the office where the branch register of members is kept, unless the register is closed in accordance with the Articles.

**(i) Rights of minorities in relation to fraud or oppression**

There are no provisions in the Articles relating to rights of minority shareholders in relation to fraud or oppression. However, certain remedies are available to members of the Company under Cayman Islands law, as summarised in paragraph 3(f) of this Appendix.

**(j) Procedures on liquidation**

A resolution that the Company be wound up by the court or, unless otherwise provided by the Companies Act, be wound up voluntarily shall be a special resolution.

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Subject to any special 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:

- (i) if the Company is wound up and the assets available for distribution amongst the members of the Company shall be more than sufficient to repay the whole of the capital paid up at the commencement of the winding up, the excess shall be distributed *pari passu* amongst such members in proportion to the amount paid up on the shares held by them respectively; and
- (ii) if the Company is wound up and the assets available for distribution amongst the members as such shall be insufficient to repay the whole of the 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 which ought to have been paid up, at the commencement of the winding up on the shares held by them respectively.

If the Company is wound up (whether the liquidation is voluntary or by the court) the liquidator may, with the authority of a special resolution and any other sanction required by the Companies Act divide among the members in specie or kind the whole or any part of the assets of the Company whether the assets shall consist of property of one kind or shall consist of properties of 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 divided as aforesaid and may determine how such division shall be carried out as between the members or different classes of members. The liquidator may, with the like authority, vest any part of the assets in trustees upon such trusts for the benefit of members as the liquidator, with the like authority, shall think fit, but so that no contributory shall be compelled to accept any shares or other property in respect of which there is a liability.

**(k) Subscription rights reserve**

The Articles provide that to the extent that it is not prohibited by and is in compliance with the Companies Act, if warrants to subscribe for shares have been issued by the Company and the Company does any act or engages in any transaction which would result in the subscription price of such warrants being reduced below the par value of a share, a subscription rights reserve shall be established and applied in paying up the difference between the subscription price and the par value of a share on any exercise of the warrants.

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**3. CAYMAN ISLANDS COMPANY LAW**

The Company is incorporated in the Cayman Islands subject to the Companies Act and, therefore, operates subject to Cayman Islands law. Set out below is a summary of certain provisions of Cayman Islands company law, although this does not purport to contain all applicable qualifications and exceptions or to be a complete review of all matters of Cayman Islands company law and taxation, which may differ from equivalent provisions in jurisdictions with which interested parties may be more familiar:

**(a) Company operations**

As an exempted company, the Company's operations must be conducted mainly outside the Cayman Islands. The Company is required to file an annual return each year with the Registrar of Companies of the Cayman Islands and pay a fee which is based on the amount of its authorised share capital.

**(b) Share capital**

The Companies Act provides that where a company issues shares at a premium, whether for cash or otherwise, a sum equal to the aggregate amount of the value of the premiums 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 premiums on shares of that company allotted pursuant to any arrangement in consideration of the acquisition or cancellation of shares in any other company and issued at a premium.

The Companies Act provides that the share premium account may be applied by the company subject to the provisions, if any, of its memorandum and articles of association in (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) the redemption and repurchase of shares (subject to the provisions of section 37 of the Companies Act); (d) writing-off the preliminary expenses of the company; and (e) writing-off the expenses of, or the commission paid or discount allowed on, any issue of shares or debentures of the company.

No distribution or dividend may be paid to members out of the share premium account unless immediately following the date on which the distribution or dividend is proposed to be paid, the company will be able to pay its debts as they fall due in the ordinary course of business.

The Companies Act provides that, subject to confirmation by the Grand Court of the Cayman Islands (the "**Court**"), a company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, by special resolution reduce its share capital in any way.

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**(c) Financial assistance to purchase shares of a company or its holding company**

There is no statutory restriction in the Cayman Islands on the provision of financial assistance by a company to another person for the purchase of, or subscription for, its own or its holding company's shares. Accordingly, a company may provide financial assistance if the directors of the company consider, in discharging their duties of care and acting in good faith, for a proper purpose and in the interests of the company, that such assistance can properly be given. Such assistance should be on an arm's-length basis.

**(d) 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 shareholder and the Companies Act expressly provides that 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. However, if the articles of association do not authorise the manner and terms of purchase, a company cannot purchase any of its own shares unless the manner and terms of purchase have first been authorised by an ordinary resolution of the company. At no time may a company redeem or purchase its shares unless they are fully paid. A company may not redeem or purchase any of its shares if, as a result of the redemption or purchase, there would no longer be any issued shares of the company other than shares held as treasury shares. A payment out of capital by a company for the redemption or purchase of its own shares is not lawful unless immediately following the date on which the payment is proposed to be made, the company shall be able to pay its debts as they fall due in the ordinary course of business.

Shares purchased by a company is to be treated as cancelled unless, subject to the memorandum and articles of association of the company, the directors of the company resolve to hold such shares in the name of the company as treasury shares prior to the purchase. Where shares of a company are held as treasury shares, the company shall be entered in the register of members as holding those shares, however, notwithstanding the foregoing, the company is not to be treated as a member for any purpose and must not exercise any right in respect of the treasury shares, and any purported exercise of such a right shall be void, and a treasury share must not be voted, directly or indirectly, at any meeting of the company and must not be counted in determining the total number of issued shares at any given time, whether for the purposes of the company's articles of association or the Companies Act.

A company is not prohibited from purchasing and may purchase its own warrants subject to and in accordance with the terms and conditions of the relevant warrant instrument or certificate. There is no requirement under Cayman Islands law that a company's memorandum or articles of association contain a specific provision enabling such purchases and the directors of a company may rely upon the general power contained in its memorandum of association to buy and sell and deal in personal property of all kinds.

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Under Cayman Islands law, a subsidiary may hold shares in its holding company and, in certain circumstances, may acquire such shares.

**(e) Dividends and distributions**

The Companies Act permits, subject to a solvency test and the provisions, if any, of the company's memorandum and articles of association, the payment of dividends and distributions out of the share premium account. With the exception of the foregoing, there are no statutory provisions relating to the payment of dividends. Based upon English case law, which is regarded as persuasive in the Cayman Islands, dividends may be paid only out of profits.

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 to the company, in respect of a treasury share.

**(f) Protection of minorities and shareholders' suits**

The Courts ordinarily would be expected to follow English case law precedents which permit a minority shareholder to commence a representative action against or derivative actions in the name of the company to challenge (a) an act which is ultra vires the company or illegal, (b) an act which constitutes a fraud against the minority and the wrongdoers are themselves in control of the company, and (c) an irregularity in the passing of a resolution which requires a qualified (or special) majority.

In the case of a company (not being a bank) having 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 into the affairs of the company and to report thereon in such manner as the Court shall direct.

Any shareholder 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 or, as an alternative to a winding up order, (a) an order regulating the conduct of the company's affairs in the future, (b) an order requiring the company to refrain from doing or continuing an act complained of by the shareholder petitioner or to do an act which the shareholder petitioner has complained it has omitted to do, (c) an order authorising civil proceedings to be brought in the name and on behalf of the company by the shareholder petitioner on such terms as the Court may direct, or (d) an order providing for the purchase of the shares of any shareholders of the company by other shareholders or by the company itself and, in the case of a purchase by the company itself, a reduction of the company's capital accordingly.

Generally claims against a company by its shareholders must be based on the general laws of contract or tort applicable in the Cayman Islands or their individual rights as shareholders as established by the company's memorandum and articles of association.

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**(g) Disposal of assets**

The Companies Act contains no specific restrictions on the power of directors to dispose of assets of a company. However, as a matter of general law, every officer of a company, which includes a director, managing director and secretary, in exercising his powers and discharging his duties must do so honestly and in good faith with a view to the best interests of the company and exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.

**(h) Accounting and auditing requirements**

A company must cause proper books of account to be kept with respect to (i) all sums of money received and expended by the company and the matters in respect of which the receipt and expenditure takes place; (ii) all sales and purchases of goods by the company; and (iii) the assets and liabilities of the company.

Proper books of account shall not be deemed to be kept if there are not kept such books as are necessary to give a true and fair view of the state of the company's affairs and to explain its transactions.

An exempted company must make available at its registered office in electronic form or any other medium, copies of its books of account or parts thereof 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 of the Cayman Islands.

**(i) Exchange control**

There are no exchange control regulations or currency restrictions in the Cayman Islands.

**(j) Taxation**

Pursuant to the Tax Concessions Act of the Cayman Islands, the Company has obtained an undertaking:

- (1) that no law which is enacted in the Cayman Islands imposing any tax to be levied on profits, income, gains or appreciation shall apply to the Company or its operations; and
- (2) that the aforesaid tax or any tax in the nature of estate duty or inheritance tax shall not be payable on or in respect of the shares, debentures or other obligations of the Company.

The undertaking for the Company is for a period of twenty years from 6 June 2018.



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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 executed in or brought within the jurisdiction of the Cayman Islands. The Cayman Islands are a party to a double tax treaty entered into with the United Kingdom in 2010 but otherwise is not party to any double tax treaties.

**(k) Stamp duty on transfers**

No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies except those which hold interests in land in the Cayman Islands.

**(l) Loans to directors**

There is no express provision in the Companies Act prohibiting the making of loans by a company to any of its directors.

**(m) Inspection of corporate records**

The notice of registered office is a matter of public record. A list of the names of the current directors and alternate directors (if applicable) is made available by the Registrar of Companies for inspection by any person on payment of a fee. The register of mortgages is open to inspection by creditors and members.

Members of the Company have no general right under the Companies Act to inspect or obtain copies of the register of members or corporate records of the Company. They will, however, have such rights as may be set out in the Company's Articles.

**(n) Register of members**

An exempted company may maintain its principal register of members and any branch registers at such locations, whether within or without the Cayman Islands, as the directors may, from time to time, think fit. The register of members shall contain such particulars as required by Section 40 of the Companies Act. A branch register must be kept in the same manner in which a principal register is by the Companies Act required or permitted to be kept. The company shall cause to be kept at the place where the company's principal register is kept a duplicate of any branch register duly entered up from time to time.

There is no requirement under the Companies Act for an exempted company to make any returns of members to the Registrar of Companies of the Cayman Islands. The names and addresses of the members are, accordingly, not a matter of public record and are not available for public inspection. 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 members, 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 of the Cayman Islands.

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**(o) Register of Directors and Officers**

The Company is required to maintain at its registered office a register of directors and officers which is not available for inspection by the public. A copy of such register must be filed with the Registrar of Companies in the Cayman Islands and any change must be notified to the Registrar within thirty (30) days of any change in such directors or officers.

**(p) Beneficial Ownership Register**

An exempted company is required to maintain a beneficial ownership register at its registered office that records details of the persons who ultimately own or control, directly or indirectly, 25% or more of the equity interests or voting rights of the company or have rights to appoint or remove a majority of the directors of the company. The beneficial ownership register is not a public document and is only accessible by a designated competent authority of the Cayman Islands. Such requirement does not, however, apply to an exempted company with its shares listed on an approved stock exchange, which includes the Stock Exchange. Accordingly, for so long as the shares of the Company are listed on the Stock Exchange, the Company is not required to maintain a beneficial ownership register.

**(q) Winding up**

A company may be wound up (a) compulsorily by order of the Court, (b) voluntarily, or (c) under the supervision of the Court.

The Court has authority to order winding up in a number of specified circumstances including where the members of the company have passed a special resolution requiring the company to be wound up by the Court, or where the company is unable to pay its debts, or where it is, in the opinion of the Court, just and equitable to do so. Where a petition is presented by members of the company as contributories on the ground that it is just and equitable that the company should be wound up, the Court has the jurisdiction to make certain other orders as an alternative to a winding-up order, such as making an order regulating the conduct of the company's affairs in the future, making an order authorising civil proceedings to be brought in the name and on behalf of the company by the petitioner on such terms as the Court may direct, or making an order providing for the purchase of the shares of any of the members of the company by other members or by the company itself.

A company (save with respect to a limited duration company) may be wound up voluntarily when the company so resolves by special resolution or when the company in general meeting resolves by ordinary resolution that it be wound up voluntarily because it is unable to pay its debts as they fall due. In the case of a voluntary winding up, such company is obliged to cease to carry on its business (except so far as it may be beneficial for its winding up) from the time of passing the resolution for voluntary winding up or upon the expiry of the period or the occurrence of the event referred to above.

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For the purpose of conducting the proceedings in winding up a company and assisting the Court therein, there may be appointed an official liquidator or official liquidators; and the court may appoint to such office such person, either provisionally or otherwise, as it thinks fit, and if more persons than one are appointed to such office, the Court must 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.

As soon as the affairs of the 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 how the property of the company has been disposed of, and thereupon call a general meeting of the company for the purposes of laying before it the account and giving an explanation thereof. This final general meeting must be called by at least 21 days' notice to each contributory in any manner authorised by the company's articles of association and published in the Gazette.

**(r) Reconstructions**

There are statutory provisions which facilitate reconstructions and amalgamations approved by a majority in number representing seventy-five per cent. (75%) in value of shareholders or class of shareholders or creditors, as the case may be, as are present at a meeting called for such purpose and thereafter sanctioned by the Court. Whilst a dissenting shareholder would have the right to express to the Court his view that the transaction for which approval is sought would not provide the shareholders with a fair value for their shares, the Court is unlikely to disapprove the transaction on that ground alone in the absence of evidence of fraud or bad faith on behalf of management.

**(s) Take-overs**

Where an offer is made by a company for the shares of another company and, within four (4) months of the offer, the holders of not less than ninety per cent. (90%) of the shares which are the subject of the offer accept, the offeror may at any time within two (2) months after the expiration of the said four (4) months, by notice in the prescribed manner require the dissenting shareholders to transfer their shares on the terms of the offer. A dissenting shareholder may apply to the Court within one (1) month of the notice objecting to the transfer. The burden is on the dissenting shareholder 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 shareholders.

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**(t) Indemnification**

Cayman Islands law does not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Court to be contrary to public policy (e.g. for purporting to provide indemnification against the consequences of committing a crime).

**(u) Economic Substance Requirements**

Pursuant to the International Tax Cooperation (Economic Substance) Act, 2018 of the Cayman Islands ("ES Act") that came into force on January 1, 2019, a "relevant entity" is required to satisfy the economic substance test set out in the ES Act. A "relevant entity" includes an exempted company incorporated in the Cayman Islands as is the Company; however, it does not include an entity that is tax resident outside the Cayman Islands. Accordingly, for so long as the Company is a tax resident outside the Cayman Islands, including in Hong Kong, it is not required to satisfy the economic substance test set out in the ES Act.

**4. GENERAL**

Conyers Dill & Pearman, the Company's special legal counsel on Cayman Islands law, have sent to the Company a letter of advice summarising certain aspects of Cayman Islands company law. This letter, together with a copy of the Companies Act, is available for inspection as referred to in the paragraph headed "Documents Available on Display" in Appendix V to this document. Any person wishing to have a detailed summary of Cayman Islands company law or advice on the differences between it and the laws of any jurisdiction with which he is more familiar is recommended to seek independent legal advice.

## APPENDIX IV

## STATUTORY AND GENERAL INFORMATION

### A. FURTHER INFORMATION ABOUT OUR GROUP

#### 1. Incorporation of Our Company

We were incorporated in the Cayman Islands on January 30, 2018 under the Cayman Companies Act as an exempted company with limited liability. Accordingly, our corporate affairs and our 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 Associations are set out in the section headed “Summary of the Constitution of the Company and Cayman Islands Company Law” in Appendix III to this document.

Our registered place of business in Hong Kong is at 14th Floor, Golden Center, 188 Des Voeux Road Central, Hong Kong. We were registered as a non-Hong Kong Company under Part 16 of the Companies Ordinance on June 7, 2021. Mr. Li Ching Yi of 14th Floor, Golden Center, 188 Des Voeux Road Central, Hong Kong has been appointed as our authorized representative for the acceptance of service of process and notices in Hong Kong.

#### 2. Changes in the Share Capital of Our Company

As of the date of incorporation of our Company, our Company had an authorized share capital of US\$50,000 divided into 50,000 shares of US\$1.00 each. Upon its incorporation, one share was allotted and issued to an initial subscriber who is an Independent Third Party. On June 1, 2018, the authorized share capital of the Company was changed to HK\$110,000 divided into 11,000,000 shares of HK\$0.01 each.

On April 28, 2019, the authorized share capital of our Company was increased from HK\$110,000 divided into 11,000,000 shares of HK\$0.01 each to HK\$170,000 divided into 17,000,000 shares of HK\$0.01 each by the creation of additional 6,000,000 shares of HK\$0.01 each (the “**2019 Increase**”). Immediately following the 2019 Increase, the authorized share capital was re-classified and re-designated such that the authorized share capital of the Company was changed to HK\$170,000 divided into (i) 10,972,541 Ordinary Shares of par value HK\$0.01 each, (ii) 267,906 Series Seed Preferred Shares of par value HK\$0.01 each, (iii) 322,632 Series A Preferred Shares of par value HK\$0.01 each, (iv) 688,719 Series A+ Preferred Shares of par value HK\$0.01 each, (v) 2,059,132 Series B Preferred Shares of par value HK\$0.01 each, (vi) 937,254 Series B+ Preferred Shares of par value HK\$0.01 each and (vii) 1,751,816 Series C Preferred Shares of par value HK\$0.01 each.

On June 20, 2020, the authorized share capital of our Company was amended so that our Company was authorized to issue a maximum of 17,000,000 shares divided into (i) 10,435,371 Ordinary Shares, (ii) 267,906 Series Seed Preferred Shares, (iii) 322,632 Series A Preferred Shares, (iv) 688,719 Series A+ Preferred Shares, (v) 2,059,132 Series B Preferred Shares, (vi) 937,254 Series B+ Preferred Shares, (vii) 1,751,816 Series C Preferred Shares, and (viii) 537,170 Series D Preferred Shares, each with a par value of HK\$0.01 per share, by the re-designation of 537,170 authorized but unissued Ordinary Shares as Series D Preferred Shares.

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On November 21, 2020, the authorized share capital of our Company was increased and amended so that our Company’s authorized share capital became HK\$500,000 divided into (i) 22,559,096 Ordinary Shares, (ii) 267,906 Series Seed Preferred Shares, (iii) 322,632 Series A Preferred Shares, (iv) 688,719 Series A+ Preferred Shares, (v) 2,059,132 Series B Preferred Shares, (vi) 937,254 Series B+ Preferred Shares, (vii) 1,751,816 Series C Preferred Shares, (viii) 7,958,858 Series D Preferred Shares, (ix) 3,454,587 Series D+ Preferred Shares, and (x) 10,000,000 Series E Preferred Shares, each with a par value of HK\$0.01 per share.

On June 25, 2021, immediately prior to the completion of 2021 Financing, each of our issued and unissued shares of par value HK\$0.01 was subdivided into 10 shares of par value of HK\$0.001 (the “**Share Subdivision**”). Upon completion of the Share Subdivision, the authorized share capital of our Company became HK\$500,000 divided into (i) 225,590,960 Ordinary Shares of par value HK\$0.001 each, (ii) 2,679,060 Series Seed Preferred Shares of par value HK\$0.001 each, (iii) 3,226,320 Series A Preferred Shares of par value HK\$0.001 each, (iv) 6,887,190 Series A+ Preferred Shares of par value HK\$0.001 each, (v) 20,591,320 Series B Preferred Shares of par value HK\$0.001 each, (vi) 9,372,540 Series B+ Preferred Shares of par value HK\$0.001 each, (vii) 17,518,160 Series C Preferred Shares of par value HK\$0.001 each, (viii) 79,588,580 Series D Preferred Shares of par value HK\$0.001 each, (ix) 34,545,870 Series D+ Preferred Shares of par value HK\$0.001 each, and (x) 100,000,000 Series E Preferred Shares of par value HK\$0.001 each.

### 3. [REDACTED]

Pursuant to the resolutions passed by our shareholders on [●], our Directors were authorized to allot and issue on the [REDACTED] a total of [REDACTED] Shares credited as fully paid at par to the shareholders whose name is registered on the register of members of our Company as at the date of the shareholders’ resolutions in proportion to their respective shareholdings in our Company (as nearly as possible without fractions) by capitalizing the sum of HK\$[REDACTED] standing to the credit of the share premium account of our Company, and the Shares to be allotted and issued shall rank *pari passu* in all respects with the then existing issued Shares.

Save as disclosed in this document and as mentioned in “– 4. Resolutions of the Shareholders of the Company Passed on [●]” below, there has been no alteration in the authorized share capital of our Company since its incorporation.

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### 4. Changes in the Share Capital of Our Subsidiary

Our subsidiaries are set out in the Accountant's Report, the text of which is set out in Appendix I to this document. The following alteration in the share capital of our subsidiaries has taken place within the two years immediately preceding the date of this document:

#### (1) *3D Medicines*

On March 19, 2019, the registered capital of 3D Medicines was converted from RMB10,000,000 to US\$1,491,200, and was increased on the same day from US\$1,491,200 to US\$100,000,000.

On June 15, 2020, the registered capital of 3D Medicines was increased from US\$100,000,000 to US\$121,768,707.

On November 20, 2020, the registered capital of 3D Medicines was increased from US\$121,768,707 to US\$128,887,290.

On January 14, 2021, the registered capital of 3D Medicines was decreased from US\$128,887,290 to US\$107,118,583.

On May 24, 2021, the registered capital of 3D Medicines was increased from US\$107,118,583 to US\$119,735,390.

#### (2) *3DMed Beijing*

On August 7, 2020, the registered capital of 3DMed Beijing was increased from RMB50,000,000 to RMB200,000,000.

Save as disclosed above, there has been no alteration in the share capital of our subsidiaries within the two years immediately preceding the date of this document.

### 5. Resolutions of the Shareholders of the Company Passed on [●]

Pursuant to the resolutions passed by our shareholders on [●], among others things:

- (a) the Memorandum and Articles of Association were conditionally adopted, and will come into effect on the [REDACTED];
- (b) conditional on (1) the Listing Committee granting the [REDACTED] of, and permission to [REDACTED], the Shares in issue and to be issued as mentioned in this document; and (2) the obligations of the [REDACTED] under the [REDACTED] becoming unconditional and the [REDACTED] not being terminated in accordance with the terms therein or otherwise:

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- (i) the re-designation and the re-classification of all issued and unissued Preferred Shares into Shares on a one to one basis was approved;
  - (ii) our Directors were authorized to capitalize HK\$[REDACTED] standing to the credit of the share premium account of our Company and to apply such sum in paying up in full at par [REDACTED] Shares for allotment and issue to holders of shares whose name appear on the register of members of our Company as at the date of passing of the resolution in proportion to their then existing respective shareholdings in our Company (as near as possible without involving fractions so that no fraction of a share shall be allotted and issued);
  - (iii) the [REDACTED] was approved and our Directors were authorized to effect the same and to allot and issue the [REDACTED] pursuant to the [REDACTED];
  - (iv) the grant of the [REDACTED] by our Company to the [REDACTED] to allot and issue up to 15% of the [REDACTED] initially available under the [REDACTED] to cover, among other things, the over-allocations in the [REDACTED] was approved; and
  - (v) the proposed [REDACTED] was approved, and our Directors were authorized to implement such [REDACTED].
- (d) a general unconditional mandate was granted to our Directors to allot, issue and deal with Shares, and to make or grant offers, agreements, or options which might require such Shares to be allotted and issued or dealt with at any time subject to the requirement that the aggregate nominal value of the Shares so allotted and issued or agreed conditionally or unconditionally to be allotted and issued, shall not exceed 20% of the aggregate nominal value of the share capital of our Company in issue immediately following completion of the [REDACTED].

This mandate does not cover Shares to be allotted, issued, or dealt with under a rights issue or scrip dividend scheme or similar arrangements, or a specific authority granted by our Shareholders [or upon the exercise of the [REDACTED] or under the Share Incentive Schemes]. This general mandate to issue Shares will remain in effect until:

- (i) the conclusion of the next annual general meeting of our Company;
- (ii) the expiration of the period within which the next annual general meeting of our Company is required to be held under the applicable laws or the Articles of Association; or



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(iii) it is varied or revoked by an ordinary resolution of our Shareholders at a general meeting of our Company;

whichever is the earliest;

(e) a general unconditional mandate was granted to our Directors to exercise all powers of our Company to repurchase Shares with an aggregate nominal value of not more than 10% of the aggregate nominal value of the share capital of our Company in issue immediately following completion of the [REDACTED] (excluding Shares which may be allotted and issued upon the exercise of the [REDACTED] or under the Share Incentive Schemes).

This mandate only relates to repurchase made on the Stock Exchange or on any other stock exchange on which the Shares may be listed (and which is recognized by the SFC and the Stock Exchange for this purpose) and made in accordance with all applicable laws and regulations and the requirements of the Listing Rules. This general mandate to repurchase Shares will remain in effect until:

- (i) the conclusion of the next annual general meeting of our Company;
- (ii) the expiration of the period within which the next annual general meeting of our Company is required to be held under any applicable laws or the Articles of Association; or
- (iii) it is varied or revoked by an ordinary resolution of our Shareholders at a general meeting of our Company;

whichever is the earliest; and

(f) the general unconditional mandate as mentioned in paragraph (c) above would be extended by the addition to the aggregate nominal value of the Shares which may be allotted and issued or agreed to be allotted and issued by our Directors pursuant to such general mandate of an amount representing the aggregate nominal value of the Shares purchased by our Company pursuant to the mandate to repurchase Shares referred to in paragraph (d) above (up to 10% of the aggregate nominal value of the Shares in issue immediately following completion of the [REDACTED], excluding any Shares which may fall to be allotted and issued pursuant to the exercise of the [REDACTED] or under the Share Incentive Scheme).

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### 6. Restrictions on Repurchase

This section sets out information required by the Stock Exchange to be included in this document concerning the repurchase by us of our own Shares.

#### *(a) 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 more important of which are summarized below:

##### *(i) Shareholders' Approval*

All proposed repurchase of Shares (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.

##### *(ii) Source of Funds*

Repurchases must be funded out of funds legally available for the purpose in accordance with the constitutive documents of a listed company, the laws of the jurisdiction in which the listed company is incorporated or otherwise established. A listed company may not repurchase its own securities on the Stock Exchange for a consideration other than cash or for settlement otherwise than in accordance with the trading rules of the Stock Exchange from time to time. Subject to the foregoing, we may make repurchases out of our profits, out of sums standing to the credit of our share premium account, out of the proceeds of a fresh issue of shares for the purposes of the repurchase or, if authorised by our Articles of Association and subject to the Cayman Companies Act, out of capital. Any amount of premium payable on the repurchase over the par value must be made out of our profits, sums standing to the credit of our share premium account or, if authorised by our Articles of Association and subject to the Cayman Companies Act, out of capital.

#### *(b) 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. Such repurchases may, depending on market conditions and funding arrangements at the time, lead to an enhancement of the net asset value per Share and/or earnings per Share and will only be made where our Directors believe that such repurchases will benefit us and our Shareholders.

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### *(c) 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 and other applicable laws of the 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.

### *(d) General*

Exercise in full of the current repurchase mandate, on the basis of [REDACTED] Shares in issue after completion of the [REDACTED] and the [REDACTED] (without taking into account of the Shares which may be allotted and issued pursuant to the exercise of the [REDACTED]), could accordingly result in up to [REDACTED] Shares being repurchased by us during the period prior to:

- (i) the conclusion of our next annual general meeting;
- (ii) the expiration of the period within which the next annual general meeting of our Company is required by any applicable law or the Articles of Association to be held; or
- (iii) the date on which the repurchase mandate is varied or revoked by an ordinary resolution of our Shareholders in general meeting,

whichever is the earliest.

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 Memorandum and Articles of Association, the Cayman Companies Act and any other applicable laws of the Cayman Islands.

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.

No core connected person, as defined in the Listing Rules, has notified us that he/she or it has a present intention to sell his/her or its Shares to us, or has undertaken not to do so, if the repurchase mandate is exercised.

**APPENDIX IV STATUTORY AND GENERAL INFORMATION**

**B. FURTHER INFORMATION ABOUT THE BUSINESS OF THE COMPANY**

**1. Summary of Material Contracts**

The following contracts (not being contracts entered into in the ordinary course of business) were entered into by our Group within the two years preceding the date of this document and are or may be material:

(a) [REDACTED].

**2. Our Material Intellectual Property Rights**

*(a) Trademarks*

As of the Latest Practicable Date, our material registered trademarks were as follows:

<u>No.</u>	<u>Trademark</u>	<u>Place of registration</u>	<u>Name of registered proprietor</u>	<u>Registration no.</u>	<u>Class</u>	<u>Expiry date</u>
1	思路迪	PRC	3D Medicines	13351884	44	January 6, 2025
2	思路迪	PRC	3D Medicines	18741240	5	February 6, 2027
3	思路迪	PRC	3D Medicines	18741295	42	February 6, 2027
4	思路迪	PRC	3D Medicines	20749939	42	September 13, 2027
5	思路迪	PRC	3D Medicines	20749938	44	September 13, 2027
6	思路迪	PRC	3D Medicines	20749941	5	September 13, 2027
7	思路迪	PRC	3D Medicines	33033182	37	June 27, 2029
8	3DMed	PRC	3D Medicines	15958021	5	February 20, 2026
9	3DMed	PRC	3D Medicines	15958133	42	February 20, 2026
10	3DMed	PRC	3D Medicines	15958239	44	February 20, 2026
11	3DMed	PRC	3D Medicines	19840384	5	June 20, 2027
12	3DMed	PRC	3D Medicines	19840385	44	June 20, 2027
13	3DMed	PRC	3D Medicines	19840386	35	June 20, 2027
14	3DMed	PRC	3D Medicines	19840387	42	June 20, 2027

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No.	Trademark	Place of registration	Name of registered proprietor	Registration no.	Class	Expiry date
15	<b>3DMed</b>	PRC	3D Medicines	33033180	37	July 6, 2029
16	<b>3DMed</b>	PRC	3D Medicines	33033181	10	September 27, 2029
17	<b>思路迪</b>	PRC	3D Medicines	33033183	10	April 6, 2031
18	<b>思路迪</b>	PRC	3D Medicines	18406160	35	December 27, 2026
19		PRC	3D Medicines	58090711	5	February 6, 2032
20		PRC	3D Medicines	58072223	35	February 13, 2032
21		PRC	3D Medicines	58081704	42	February 6, 2032
22		PRC	3D Medicines	58067165	44	February 13, 2032
23	<b>思路迪医药</b>	PRC	3D Medicines	58077588	5	February 13, 2032
24	<b>思路迪医药</b>	PRC	3D Medicines	58064448	42	February 13, 2032
25	<b>思路迪医药</b>	PRC	3D Medicines	58069951	44	February 13, 2032
26	<b>易康韦</b>	PRC	3DMed Beijing	56637945	5	December 27, 2031
27	<b>易康韦</b>	PRC	3DMed Beijing	56642324	35	December 27, 2031
28	<b>易康韦</b>	PRC	3DMed Beijing	56617675	42	December 27, 2031
29	<b>易康韦</b>	PRC	3DMed Beijing	56647518	44	December 27, 2031
30	<b>易扶力</b>	PRC	3DMed Beijing	56646353	5	December 27, 2031
31	<b>易扶力</b>	PRC	3DMed Beijing	56640790	35	December 27, 2031
32	<b>易扶力</b>	PRC	3DMed Beijing	56635676	42	December 27, 2031
33	<b>易扶力</b>	PRC	3DMed Beijing	56620467	44	December 27, 2031
34	<b>易利倍特</b>	PRC	3DMed Beijing	56630078	5	December 27, 2031
35	<b>易利倍特</b>	PRC	3DMed Beijing	56632427	35	December 27, 2031
36	<b>易利倍特</b>	PRC	3DMed Beijing	56617698	42	December 27, 2031
37	<b>易利倍特</b>	PRC	3DMed Beijing	56643909	44	December 27, 2031

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No.	Trademark	Place of registration	Name of registered proprietor	Registration no.	Class	Expiry date
38	易维恩	PRC	3DMed Beijing	56637777	5	December 27, 2031
39	易维恩	PRC	3DMed Beijing	56632405	35	February 20, 2032
40	易维恩	PRC	3DMed Beijing	56617717	42	December 27, 2031
41	易维恩	PRC	3DMed Beijing	56633214	44	December 27, 2031
42	易倍朗	PRC	3DMed Beijing	56624149	35	December 27, 2031
43	易倍朗	PRC	3DMed Beijing	56617706	42	December 27, 2031
44	易倍朗	PRC	3DMed Beijing	56618080	44	December 27, 2031
45	恩法利玛	PRC	3DMed Beijing	56621166	5	December 27, 2031
46	恩法利玛	PRC	3DMed Beijing	56622902	35	December 27, 2031
47	恩法利玛	PRC	3DMed Beijing	56622949	42	December 27, 2031
48	恩法利玛	PRC	3DMed Beijing	56620481	44	December 27, 2031
49	思路康瑞	PRC	3DMed Sichuan	56638907	5	December 27, 2031
50	思路康瑞	PRC	3DMed Sichuan	56633075	35	December 27, 2031
51	思路康瑞	PRC	3DMed Sichuan	56627005	42	December 27, 2031
52	思路迪 思路迪 思路迪	Hong Kong	Our Company	304647088	5, 10, 35, 42, 44	August 24, 2028
53	思路迪 思路迪 思路迪	Hong Kong	Our Company	304647079	5, 10, 35, 42, 44	August 24, 2028
54	  	Hong Kong	Our Company	304647781	5, 10, 35, 42, 44	August 27, 2028

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As of the Latest Practicable Date, we have applied for the registration of the following trademarks in the PRC which we considered to be material to our business:

No.	Name of Applicant	Application No.	Trademark	Class	Application Date
1	3DMed Beijing	58083733		44	July 29, 2021
2	3DMed Beijing	58062576		44	July 29, 2021
3	3D Medicines	61733760	思路迪	35	December 27, 2021
4	3D Medicines	62555693	 3D Medicines	5	February 11, 2022
5	3D Medicines	62558662	 3D Medicines	42	February 11, 2022
6	3D Medicines	62558568	 3D Medicines	44	February 11, 2022
7	3D Medicines	62553716	 思路迪医药 3D Medicines	5	February 11, 2022
8	3D Medicines	62549273	 思路迪医药 3D Medicines	35	February 11, 2022
9	3D Medicines	62556148	 思路迪医药 3D Medicines	42	February 11, 2022
10	3D Medicines	62546255	 思路迪医药 3D Medicines	44	February 11, 2022
11	3D Medicines	62554726	 思路迪医药 3D Medicines	5	February 11, 2022
12	3D Medicines	62555846	 思路迪医药 3D Medicines	35	February 11, 2022
13	3D Medicines	62546264	 思路迪医药 3D Medicines	44	February 11, 2022
14	3D Medicines	62554152	 思路迪医药 3D Medicines	42	February 11, 2022
15	3D Medicines	62554152	 3D Medicines	35	February 11, 2022

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<b>No.</b>	<b>Name of Applicant</b>	<b>Application No.</b>	<b>Trademark</b>	<b>Class</b>	<b>Application Date</b>
16	3DMed Beijing	64869446	瑞思普	5	May 25, 2022
17	3DMed Beijing	64870724	替瑞安	5	May 25, 2022
18	3DMed Beijing	64858454	恩得安	5	May 25, 2022
19	3DMed Beijing	64870759	恩迪达	5	May 25, 2022
20	3DMed Beijing	64869553	泽思华	5	May 25, 2022
21	3DMed Beijing	64881064	恩瑞坦	5	May 25, 2022
22	3DMed Beijing	64877122	泽利达	5	May 25, 2022
23	3DMed Beijing	64868930	恩达信	5	May 25, 2022
24	3DMed Beijing	64879361	恩合利	5	May 25, 2022
25	3DMed Beijing	64862967	利诺克	5	May 25, 2022
26	3DMed Beijing	64864212	恩维提	5	May 25, 2022
27	3DMed Beijing	64870510	安替利	5	May 25, 2022
28	3DMed Beijing	64864568	恩替利	5	May 25, 2022
29	3DMed Beijing	64859420	恩盖利	5	May 25, 2022
30	3DMed Beijing	65366171	Enrilong	5	June 17, 2022
31	3DMed Beijing	65361227	Paren	5	June 17, 2022
32	3DMed Beijing	65371534	Rexkeylen	5	June 17, 2022

**(b) Patents**

For material patents and patent applications of our Group as of the Latest Practicable Date, please refer to the paragraphs headed “Business – Intellectual Property” in this document for more details.



**APPENDIX IV STATUTORY AND GENERAL INFORMATION**

**(c) Domain Names**

As of the Latest Practicable Date, our material domain names were as follows:

<b>No.</b>	<b>Domain name</b>	<b>Registrant</b>	<b>Date of registration</b>	<b>Expiry date</b>
1.	3d-medicines.com	3D Medicines	August 13, 2019	August 13, 2029

**(d) Copyright**

<b>No.</b>	<b>Owner of copyright</b>	<b>Name of copyright</b>	<b>Type of copyright</b>	<b>Registration number</b>	<b>Date of registration</b>
1	3D Medicines	New Drug R&D Management System V1.0 (新藥研發管理系統V1.0)	Software	2018SR1067116	March 12, 2017
2	3DMed Beijing	Medicine Medical Affairs and Drug Safety Management System Software V1.0 (醫藥醫學事物與藥物安全管理系統軟體V1.0)	Software	2020SR0956892	June 30, 2018
3	3DMed Beijing	Correlation analysis system of immunohistochemistry and drug response V1.0 (免疫組化與藥物回應的關聯分析系統V1.0)	Software	2020SR0957306	December 20, 2018
4	3DMed Beijing	Medical clinical research management system V1.0 (醫藥臨床研究管理系統V1.0)	Software	2020SR0958276	August 30, 2017
5	3D Medicines	Biomedical R&D personnel management and control system V1.0 (生物醫藥研發人員管控系統V1.0)	Software	2021SR2004344	October 15, 2020
6	3D Medicines	Biomedical electronic data collection system V1.0 (生物醫藥電子數據採集系統V1.0)	Software	2021SR1812032	March 22, 2021
7	3D Medicines	Biomedical Visualization System V1.0 (生物醫藥視覺化系統V1.0)	Software	2021SR1812031	January 20, 2021
8	3D Medicines	Biomedical data analysis system V1.0 (生物醫藥資料分析系統V1.0)	Software	2021SR1812118	June 2, 2021

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<u>No.</u>	<u>Owner of copyright</u>	<u>Name of copyright</u>	<u>Type of copyright</u>	<u>Registration number</u>	<u>Date of registration</u>
9	3D Medicines	Biomedical Safety Analysis System V1.0 (生物醫藥安全性分析系統V1.0)	Software	2021SR1812117	May 14, 2021
10	3D Medicines	High Throughput Drug Screening Analysis System V1.0 (高通量藥物篩選分析系統V1.0)	Software	2021SR1812116	August 26, 2021
11	3D Medicines	Drug Screening Data Analysis System V1.0 (藥物篩選資料分析系統V1.0)	Software	2021SR1812054	September 6, 2021
12	3D Medicines	Biomedical Risk and Management System V1.0 (生物醫藥風險與管理系統V1.0)	Software	2021SR2002249	March 10, 2020
13	3D Medicines	Biomedical report management software V1.0 (生物醫藥報告管理軟體V1.0)	Software	2021SR2002248	May 18, 2020
14	3D Medicines	Pharmaceutical basic file management and quality control software V1.0 (醫藥基本檔管理及質控軟體V1.0)	Software	2021SR2002247	June 25, 2020
15	3D Medicines	Biomedical R&D Resource Service Platform Software V1.0 (生物醫藥研發資源服務平臺軟體V1.0)	Software	2021SR2002210	July 24, 2020
16	3D Medicines	Biomedical R&D Business Management System V1.0 (生物醫藥研發業務管理系統V1.0)	Software	2021SR2002211	December 9, 2020
17	3D Medicines	Biomedical Project R&D Smart Platform V1.0 (生物醫藥項目研發智慧平臺V1.0)	Software	2021SR2004343	December 9, 2020
18	3D Med Beijing	Medical project delivery management software V1.0 (醫藥專案交付管理軟體V1.0)	Software	2021SR1991251	November 25, 2020

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<u>No.</u>	<u>Owner of copyright</u>	<u>Name of copyright</u>	<u>Type of copyright</u>	<u>Registration number</u>	<u>Date of registration</u>
19	3DMed Beijing	Biotherapeutic Monoclonal Antibody Epitope Mapping Analysis Software V1.0 (生物治療性單克隆抗體表位元作圖分析軟體V1.0)	Software	2021SR1949450	October 28, 2021
20	3DMed Beijing	Biological laboratory data management platform V1.0 (生物實驗室資料管理平臺V1.0)	Software	2021SR1949447	November 10, 2021
21	3DMed Beijing	Biological antibody sequence identification and analysis software V1.0 (生物抗體序列識別及分析軟體V1.0)	Software	2021SR1949448	October 25, 2021
22	3DMed Beijing	Automatic separation software V1.0 (自動化分離軟體V1.0)	Software	2021SR1991265	October 23, 2020
23	3DMed Beijing	Protein Drug Molecular Analysis Software V1.0 (蛋白藥物分子分析軟體V1.0)	Software	2021SR1949449	June 18, 2021
24	3DMed Beijing	Project file management in control system V1.0 (專案檔案管理於控制系統V1.0)	Software	2021SR1949376	June 18, 2020
25	3DMed Beijing	Medical risk and problem management software V1.0 (醫藥風險與問題管理軟體V1.0)	Software	2021SR1949345	December 25, 2019
26	3DMed Beijing	Medical Document Translation System V1.0 (醫藥文獻翻譯系統V1.0)	Software	2021SR1949445	September 25, 2019
27	3DMed Beijing	Medical tools and settings management software V1.0 (醫藥工具與設置管理軟體V1.0)	Software	2021SR1949377	November 28, 2019
28	3DMed Beijing	R & D inventory management software V1.0 (研發庫存管理軟體V1.0)	Software	2021SR1949446	December 28, 2020

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 business.

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**C. FURTHER INFORMATION ABOUT DIRECTORS AND SUBSTANTIAL SHAREHOLDERS**

**1. Disclosure of Interests**

*(a) Interests and short positions of the Directors and chief executive of the Company in the Shares, underlying Shares and debentures of our Company and our associated corporations*

The following table sets out the interests and short positions of our Directors and chief executive of our Company immediately following completion of the [REDACTED] (without taking into account the Shares which may be allotted and issued pursuant to the exercise of the [REDACTED]) 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, once our Shares are listed:

<u>Name of Director/ Chief Executive</u>	<u>Capacity/nature of interest<sup>(1)</sup></u>	<u>Name of company</u>	<u>Number of Shares immediately after the completion of the [REDACTED]<sup>(2)</sup></u>	<u>Approximate percentage of shareholding in the total share capital of our Company after the [REDACTED] and [REDACTED] (assuming no exercise of the [REDACTED])</u>	<u>Approximate percentage of shareholding in the total share capital of our Company after the [REDACTED] and the [REDACTED] (assuming the [REDACTED] is fully exercised)<sup>(3)</sup></u>
Dr. Gong	Interest of controlled corporation <sup>(4)</sup>	Our Company	[REDACTED]	[REDACTED]	[REDACTED]%
	Interest held through voting powers entrusted by other persons <sup>(5)</sup>		[REDACTED]	[REDACTED]	[REDACTED]%
Zhu Pai	Interest held through voting powers entrusted by other persons <sup>(6)</sup>	Our Company	[REDACTED]	[REDACTED]	[REDACTED]%

*Notes:*

(1) All interests stated are long positions.

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- (2) The calculation is based on the total number of [REDACTED] Shares in issue immediately after completion of the [REDACTED] and the [REDACTED] (without taking into account the Shares which may be issued upon the exercise of the [REDACTED]).
- (3) The calculation is based on the total number of [REDACTED] Shares in issue immediately after completion of the [REDACTED] and the [REDACTED] (including such amount of Shares to be issued assuming the exercise of [REDACTED] in full).
- (4) Dr. Gong is the sole director and sole shareholder of Dragon Prosper Holdings Limited and is deemed to be interested in the Shares held by Dragon Prosper Holdings Limited.
- (5) Immunal Medixin US Limited and certain other entities are share incentive platforms managed by KASTLE LIMITED as trustee, who, in accordance with the trust deed, acts in accordance with Dr. Gong’s instructions when exercising voting rights attached to the Shares held by itself. Dr. Gong is deemed to be interested in the Shares held by the trustee of the Immunal Medixin US Limited.
- (6) Shenzhen Efung is interested in our Shares through its affiliate, Shanghai Zhenlu Enterprise Management Consulting Partnership (Limited Partnership). Shenzhen Efung’s executive partner is Shenzhen Efung Investment Management Enterprise (L.P.), which is in turn owned as to 51% by Shenzhen Efung Holding. Shenzhen Efung Holding is in turn owned as to 54% and 23% by Mr. Zhu Jinqiao and Mr. Zhu Pai respectively. Mr. Zhu Jinqiao and Mr. Zhu Pai shall act in concert in relation to the exercising of their voting rights in Shenzhen Efung Holding. Accordingly, each of Shenzhen Efung, Shanghai Zhenlu Enterprise Management Consulting Partnership (Limited Partnership), Shenzhen Efung Investment Management Enterprise (L.P.), Shenzhen Efung Holding, Mr. Zhu Pai and Mr. Zhu Jinqiao are deemed to be interested in the Shares held by Shanghai Zhenlu Enterprise Management Consulting Partnership (Limited Partnership).

### ***(b) Interests of the substantial shareholders in the Shares***

Save as disclosed in the section headed “Substantial Shareholders,” immediately following the completion of the [REDACTED] and without taking into account any Shares which may be issued pursuant to the exercise of the [REDACTED], 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 issued voting shares of our Company.

### **2. Particulars of Directors’ Service Contracts and Letters of Appointment**

Our executive Director has entered into a service contract with our Company on [●] and we have issued letters of appointment to our non-executive Directors and each of our independent non-executive Directors. The principal particulars of these service contracts and letters of appointment are (a) for a term of 3 years commencing from [●] and (b) are subject to termination in accordance with their respective terms. The term of the service contracts and the letters of appointment may be renewed in accordance with our Articles of Association and the applicable Listing Rules.

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Save as disclosed above, none of our Directors has entered, or has proposed to enter, a service contract with any member of our Group (other than contracts expiring or determinable by the employer within one year without the payment of compensation (other than statutory compensation)).

### 3. Emoluments of Directors

The aggregate amount of fees, salaries, allowances and retirement benefit scheme contributions we paid to our Directors in respect of the financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022 were approximately RMB1,300,000, RMB2,700,000 and RMB1,125,000, respectively.

The aggregate amount of equity-settled share award expenses paid or payable by us to the Directors in respect of the financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022 were approximately nil, RMB76,973,000 and RMB29,556,000, respectively.

It is estimated that emoluments and benefits in kind equivalent to approximately RMB65.54 million in aggregate will be paid and granted to our Directors by us in respect of the financial year ended December 31, 2022 under arrangements in force at the date of this document.

The aggregate amount of fees, salaries, allowances and retirement benefit scheme contributions we paid to our five highest paid individuals (including both employees and Directors) in respect of the financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022 were approximately RMB11,667,000, RMB10,805,000 and RMB9,102,000, respectively.

The aggregate amount of equity-settled share award expenses paid or payable by us to the Directors in respect of the financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022 were approximately RMB239,000, RMB137,694,000 and RMB37,717,000, respectively.

None of our Directors or any past directors of any member of the Group has been paid any sum of money for each of the two financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022 as (a) an inducement to join or upon joining the Company; or (b) for loss of office as a director of any member of the Group or of any other office in connection with the management of the affairs of any member of the Group.

There has been no arrangement under which a Director has waived or agreed to waive any emoluments for each of the two financial years ended December 31, 2020 and 2021 and the five months ended May 31, 2022.

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### 4. Disclaimers

Save as disclosed in this document:

- (a) none of our Directors or our chief executive has any interest or short position in the Shares, underlying Shares or debentures of us or any of our associated corporations (within the meaning of Part XV 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, 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 Model Code for Securities Transactions by Directors of Listed Issuers once the Shares are listed on the Stock Exchange;
- (b) none of our Directors is aware of any person (not being a Director or chief executive of the Company) who will, immediately following completion of the [REDACTED] (without taking into account any Shares which may be allotted and issued pursuant to the exercise of the [REDACTED] [and the exercise of options which were granted under the Share Incentive Scheme]), have an interest or short position in the Shares or underlying Shares which would fall to be disclosed to us under the provisions of Divisions 2 and 3 of Part XV of the SFO or who is interested, directly or indirectly, in 10% or more of the issued voting shares of any member of our Group; and
- (c) so far as is known to our Directors, none of our Directors, their respective close associates (as defined under the Listing Rules) or Shareholders who own more than 5% of the number of issued shares of the Company have any interests in the five largest customers or the five largest suppliers of the Group.

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### D. SHARE INCENTIVE SCHEME

#### 1. Share Incentive Scheme

##### (a) *Purpose and Principal Terms*

The purpose of the Share Incentive Scheme (the “**Share Incentive Scheme**”) is to recognize and motivate the contributions the grantees under the Share Incentive Scheme (the “**Grantee(s)**”), provide incentives for them to remain with our Company, and attract suitable personnel for our further development. The Share Incentive Scheme is not subject to the provisions of Chapter 17 of the Listing Rules as it does not involve the grant of options by our Company to subscribe for new shares. The principal terms of the Share Incentive Scheme are as follows:

- (i) **Award:** An award under the Share Incentive Scheme (“**Award(s)**”) gives a Participant a conditional right upon the vesting of the Award to obtain either Shares or an equivalent value in cash with reference to the market value of the Shares on or about the date of vesting, as determined by the ESOP Department in its absolute discretion, less any tax, fees, levies, stamp duty and other applicable charges. An award may include, if so specified by the ESOP administration department (the “**ESOP Department**”) in its entire discretion, cash and non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions in respect of those Shares from the date that the Award is granted to the date that it vests.
- (ii) **Award Price:** Each Participant shall pay RMB1 as the Award price to accept the Awards granted to such Participant.
- (iii) **Scheme Limit:** Number of shares that may be delivered under the Share Incentive Scheme are no more than 20% of the total number of Shares in issue on the [REDACTED] may be delivered to the eligible Participants.
- (iv) **Participants:** Participants of the Share Incentive Scheme (the “**Participants**”) include the following:
  - (i) the Employees or officers (including executive, non-executive and independent non-executive directors of the Group);
  - (ii) any person or entity (including but not limited to consultants engaged by the company services to the Group) that provides research, development, consultancy and other technical or operational or administrative support to the Group; and



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- (iii) any other persons including former employees who, in the sole opinion of the ESOP Department, have contributed or will contribute to the Company or any of its Subsidiaries.
- (v) **Term:** The Share Incentive Scheme shall be valid and effective for the period of ten years commencing on June 22, 2021, after which period no further Awards will be granted. In spite of this, the Share Incentive Scheme in all other respects remain in full force and effect and Awards that are granted during the Term may continue to be exercisable in accordance with their terms of issue.
- (vi) **Administration:** The Share Incentive Scheme shall be subject to the administration of the ESOP Department set up and authorized by the Board of the Company. The ESOP Department has the right to (i) interpret and construe the provisions of the Share Incentive Scheme, (ii) determine the persons who will be granted Awards, the terms on which Awards are granted and the time when the Award(s) so awarded may vest, (iii) make such appropriate and equitable adjustments to the terms of the Awards granted as it deems necessary, (iv) appoint independent third party professionals and contractors to assist in the administration of the Share Incentive Scheme, delegate such powers and/or functions, and make any other decisions or determination relating to the administration of the Share Incentive Scheme as the ESOP Department deems appropriate. All decisions made by the ESOP Department is final and binding on all parties.
- (vii) **Trustee:** the ESOP Department may appoint independent trustee to assist in the administration and vesting of the Awards and has appointed KASTLE LIMITED, trustee service provider and an Independent Third Party, to administer the granting and vesting of the Award(s).

### **(b) Restrictions on Grant**

No Grant shall be made to, nor shall any Grant be capable of acceptance by, any Participant at a time when the Participant would or might be prohibited from dealing in the Shares by the Listing Rules (where applicable) or by any other applicable rules, regulations or law.

A Grant must not be made after a price sensitive event has occurred or a price sensitive matter has been the subject of a decision until such price sensitive information has been announced in accordance with the requirements of the Listing Rules. In particular, during the period commencing one month immediately preceding the earlier of:

- (i) the date of the meeting of the Board of the Company (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of the Company's results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules); and

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- (ii) the deadline for the Company to publish an announcement of its results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules), and ending on the date of the results announcement, no Award may be granted. Such period will cover any period of delay in the publication of a results announcement.

The ESOP Department may not grant any Awards to any Participants in any of the following circumstances:

- (i) the requisite approvals for that Grant from any applicable regulatory authorities have not been obtained;
- (ii) the securities laws or regulations require that a prospectus or other offering documents be issued in respect of the grant of the Awards or in respect the Share Incentive Scheme, unless the ESOP Department determines otherwise;
- (iii) the Grant would result in a breach by the Company, the Subsidiaries or any of the directors of any applicable securities laws, rules or regulations; or
- (iv) where such Grant would result in a breach of the limits of the Share Incentive Scheme.

**(c) *Grant to Directors***

Where any Award is proposed to be granted to a director of any members of the Group, it shall not be granted on any day on which the financial results of the Company are published and during the period of:

- (i) 60 days immediately preceding the publication date of the annual results or, if shorter, the period from the end of the relevant financial year up to the publication date of the results; and
- (ii) 30 days immediately preceding the publication date of the quarterly results (if any) and half-year results or, if shorter, the period from the end of the relevant quarterly or half-year period up to the publication date of the results.

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### *(d) Grant to Connected Persons*

Any grant to any director, chief executive officer or substantial shareholder of any member of the Group, or any of their respective associates (as defined in the Listing Rules), shall be subject to the prior approval of the independent non-executive directors (excluding the independent non-executive director who is the proposed grantee of the Awards in question) and shall otherwise be subject to compliance with the requirements of the Listing Rules. Notwithstanding the foregoing, any grant of an Award to a director pursuant to Rule 14A.73(6) of the Listing Rules will be exempted from reporting, announcement and independent Shareholders' approval requirements if the Award forms part of the relevant director's remuneration under his/her service contract.

### *(e) Grant to PRC resident*

If the Grantee is a PRC resident, he or she shall not be entitled to exercise any Award until:

- (i) to the extent applicable, any restriction or condition imposed by the relevant PRC laws, regulations and notices in relation to the subscription of or dealing in shares of overseas listed companies by PRC residents or any law, regulation or notice with similar effects have been abolished or removed or ceased to be applicable to the Participant or the Participant has obtained approval, exemption or waiver from the relevant PRC regulatory authorities for the subscription of and dealing in the Shares; and
- (ii) he or she has given a representation to the Company to the effect that he or she has satisfied all the relevant laws, regulations and notices in exercising the Award.

### *(f) Rights attached to Awards*

The Award(s) do not carry any right of a Shareholder unless and until such Shares underlying the Award are actually transferred to the Grantee upon the vesting of the Award(s). Unless otherwise specified by the ESOP Department in its entire discretion in the Notice of Grant, Grantees do not have any rights to any cash or non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions from any Shares underlying an Award.

### *(g) Awards to be Personal to the Grantee*

Unless otherwise approved by the Company in writing (to the extent permitted by law), an unvested AWARD shall be personal to the Grantee and shall not be assignable or transferable by the Grantee provided that following the Grantee's death, unvested Award(s) may be transferred by will or by the laws of testacy and distribution. The terms of the Scheme and the Notice of Grant shall be binding upon the executors, administrators, heirs, successors and assignees of the Grantee.

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*(h) Vesting*

Subject to the terms of the Share Incentive Scheme and the specific terms and conditions applicable to each Award, the Award(s) granted in an Award shall be subject to a vesting period (if any) and/or the satisfaction of performance and/or other conditions (if any) to be determined by the ESOP Department in its absolute discretion. If such conditions are not satisfied, the vesting date of the Award(s) shall be postponed for one year. If the vesting terms and conditions of the postponed Award(s) are not satisfied at the postponed vesting date, the Award(s) shall automatically lapse.

Upon fulfillment or waiver of the vesting period and vesting criteria (if any) applicable to a Grantee, a vesting notice shall be sent to the Grantee by the ESOP Department, or by any other means the ESOP Department so determines in its sole discretion from time to time, confirming (a) the extent to which the vesting period and conditions have been fulfilled or waived, and (b) the number of Shares (and, if applicable, the cash or non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions in respect of these Shares) or the amount of cash the Grantee will receive.

The Grantee is required to execute, after receiving the vesting notice, certain documents set out in the vesting notice that the ESOP Department considers necessary (which may include, without limitation, a certification to the Group that he or she has complied with all the terms and conditions set out in the Share Incentive Scheme and the Notice of Grant).

For the purposes of vesting of the Award(s), the ESOP Department may release the Award(s) to the selected Participants by transferring the number of underlying Shares in respect of the Award(s) to the selected Participants in such manner as determined by it from time to time. The ESOP Department shall inform the Trustee the number of underlying Shares in respect of the Award(s) being transferred and released to the selected Participant in the manner as determined by the ESOP Department.

If the vesting conditions are not satisfied and no waiver of such condition is granted, the Award(s) shall be cancelled according to conditions as determined by the ESOP Department in its absolute discretion.

In the event that the Grantee fails to execute the required documents within three months after receiving the Vesting Notice, the vested Award(s) will lapse.

Notwithstanding the foregoing, if any relevant parties of the Share Incentive Scheme would or might be prohibited from dealing in the Shares by the Listing Rules or by any other applicable laws, regulations or rules within the period specified above, the date on which the relevant Shares shall be transferred (as the case may be) to the Grantee shall occur as soon as possible after the date when such dealing is permitted by the Listing Rules or by any other applicable laws, regulations or rules.

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***(i) Rights on a Takeover***

In the event a general offer by way of voluntary offer, takeover or otherwise (other than by way of scheme of arrangement) is made to all the Shareholders (or all such Shareholders other than the offeror and/or any person controlled by the offeror and/or any person acting in association or concert with the offeror) and such offer becomes or is declared unconditional prior to the vesting date of any Award(s), the ESOP Department shall, prior to the offer becoming or being declared unconditional, determine at its absolute discretion whether such Award shall vest and the period within which such Award shall vest. If the ESOP Department determines that such Award(s) shall vest, it shall notify the Grantee that the Award(s) shall vest and the period within which such Award(s) shall vest.

***(j) Rights on a Scheme of Arrangement***

In the event a general offer for Shares by way of scheme of arrangement is made to all the Shareholders and has been approved by the necessary number of shareholders at the requisite meetings prior to the vesting of any Award(s), the ESOP Department shall, prior to such meetings, determine at its absolute discretion whether such Award(s) shall vest and the period within such Award(s) shall vest. If the ESOP Department determines that such Award(s) shall vest, it shall notify the Grantee that the Award(s) shall vest and the period within which such Award(s) shall vest.

***(k) Rights on a Voluntary Winding-up***

In the event a notice is given by the Company to its Shareholders to convene a Shareholders' meeting for the purpose of considering and, if thought fit, approving a resolution to voluntarily wind-up the Company prior to the vesting date of any Award(s), the ESOP Department shall determine at its discretion whether such Award(s) shall vest, and the period when such Award(s) shall vest and in the latter case, the unvested Award(s) must be vested and effected by no later than two Business Days before the day of the proposed shareholders' meeting. If the ESOP Department determines that such Award(s) shall vest, it shall notify the Grantee that the Award(s) shall vest and the period within which such Award(s) shall vest.

***(l) Rights on a Compromise or Arrangement***

In the event of a compromise or arrangement, other than a scheme of arrangement contemplated above, between the Company and its members and/or creditors being proposed in connection with a scheme for the reconstruction or amalgamation of the Company, the ESOP Department shall determine at its discretion whether such Award(s) shall vest, and the period when such Award(s) shall vest. If the ESOP Department determines that such Award(s) shall vest, it shall notify the Grantee that the Award(s) shall vest and the period within which such Award(s) shall vest.

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*(m) Lapse and cancellation of Award*

An unvested Award shall be lapsed and cancelled automatically upon the earliest of:

- (i) the date of the termination of Grantee's employment or service by the Company or any of its Subsidiaries for cause;
- (ii) the date of the termination of Grantee's employment or service with the Company or the Subsidiaries is terminated for any reason other than for cause (including by reason of resignation, retirement, death, disability or non-renewal of the employment or service agreement upon its expiration for any reason other than for cause);
- (iii) the date on which the offer (or, as the case may be, revised offer) made in connection with a general or voluntary offer closes;
- (iv) the record date for determining entitlements under the scheme of arrangement referred above closes;
- (v) the date of the commencement of the winding-up of the Company;
- (vi) the date on which the Grantee commits a breach of paragraph (g) above; or
- (vii) the date on which it is no longer possible to satisfy any outstanding conditions to vesting.

The ESOP Department shall have the right to determine what constitutes cause, whether the Grantee's employment has been terminated for cause, the effective date of such termination and whether someone is a Competitor, and such determination by the ESOP Department shall be final and conclusive.

Unless the ESOP Department determines otherwise in its absolute discretion, the Grantee or his/her legal personal representative is entitled to exercise vested Award(s) by serving the application for exercising unvested Award(s) within one month following the occurrence of the termination of Grantee's employment or service with the Company or the Subsidiaries which is terminated for any reason other than for cause (including by reason of resignation, retirement, death, Disability or non-renewal of the employment or service agreement upon its expiration for any reason other than for cause).

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Subject to the applicable laws, the vested Award(s) prior to being exercised and the underlying shares or proceeds obtained by the Grantee from exercising the vested Award(s) less the exercise price of the Grantee's Award(s) shall be returned by the Grantee to the Company per the ESOP Department's request following the occurrence of one or more of the following events:

- (i) the Grantee's employment is terminated by the Company or any of its Subsidiaries for Cause;
- (ii) or the Grantee either: (a) becomes an officer, director, employee, consultant, adviser, partner of or stockholder or other proprietor owning more than 5% interest in any Competitor; or (b) knowingly performs any act that may confer a competitive benefit or advantage upon any Competitor,

at any time before or within 12 months after the Grantee's employment is terminated by the Company or any of its Subsidiaries for any reason.

### *(n) Further restrictions on Award*

The Grantee shall not be entitled to sell, transfer or deal with the Shares underlying the Award(s) granted pursuant to the Share Incentive Scheme upon the occurrence of one or more of the following events:

- (i) the Grantee's employment is terminated by the Company or any of its Subsidiaries for Cause; or
- (ii) the Grantee either: (a) becomes an officer, director, employee, consultant, adviser, partner of or stockholder or other proprietor owning more than 5% interest in any Competitor; or (b) knowingly performs any act that may confer a competitive benefit or advantage upon any Competitor,

at any time before or within 12 months after the Grantee's employment is terminated by the Company or any of its Subsidiaries for any reason.

If the Grantee sells, transfers or deals with the Shares in breach of the above, the Grantee shall pay the Company the proceeds or consideration obtained (less the exercise price of the Grantee Award(s)) as a result of such breach upon demand by the Company.

The ESOP Department may at any time cancel any unvested AWARD granted to a Grantee subject to consent by the Grantee. Where the Company cancels unvested Award(s) and makes a grant of new Award(s) to the same Grantee, such Grant may only be made with available Award(s) to the extent not yet granted (excluding the cancelled Award(s)).

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Notwithstanding the aforesaid in this paragraph, in each case, the ESOP Department may in its absolute discretion decide that any Award(s) shall not be cancelled or determine subject to such conditions or limitations as the ESOP Department may decide.

***(o) Reorganization of Capital Structure***

In the event of an alteration in the capital structure of the Company, by way of capitalization of profits or reserves, bonus issue, rights issue, open offer, subdivision or consolidation of shares, reduction of the share capital, amongst others, of the Company, whilst any Award(s) has not vested, such corresponding alterations (if any) shall be made to the number or nominal amount of Shares subject to the Award(s) so far as unvested as the Auditors or an approved independent financial adviser shall certify in writing, either generally or as regard any particular Grantee, to have in their opinion, fairly and reasonably satisfied the requirement that such adjustments give a Participant the same proportion (or rights in respect of the same proportion) of the share capital of the Company as that to which that Grantee was previously entitled, but that no such adjustments be made to the extent that a Share would be issued at less than its nominal value.

However, in the case of any capitalization issue or share sub-division to be implemented by the Company as required for the purpose of the [REDACTED], no such certification by the Auditors or a financial advisor shall be required.

***(p) Amendment of the Share Incentive Scheme***

Save for any material amendments to the Share Incentive Scheme, the Scheme may be altered in any respect by a resolution of the ESOP Department. The ESOP Department's determination as to whether any proposed alteration to the terms and conditions of the Share Incentive Scheme is material shall be conclusive, provided in each case that such decision is made in accordance with the Articles of the Company and any applicable laws.

***(q) Termination of the RSU Scheme***

The Board of the Company or the ESOP Department may at any time terminate the operation of the Share Incentive Scheme and in such event no further Award(s) will be offered but in all other respects the provisions of this Scheme shall remain in full force and effect in respect of Award(s) which are granted during the life of this Scheme and which remain unvested immediately prior to the termination of the operation of the Share Incentive Scheme.



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### *(r) General*

An application has been made to the Listing Committee of the Stock Exchange for the [REDACTED] of, and permission to deal in, the Shares underlying any Awards which may be granted pursuant to the Share Incentive Scheme. As of the Latest Practicable Date, 26,068,462 RSUs have been granted to eligible participants by our Company under the Share Incentive Scheme.

The Company will issue announcements according to applicable Listing Rules, disclosing particulars of any RSUs granted under the Share Incentive Scheme, including the date of grant, number of Shares involved, the vesting period and comply with Chapter 14A of the Listing Rules. Details of the Share Incentive Scheme, including particulars and movements of the RSUs granted during each financial year of our Company, and our employee costs arising from the grant of the RSUs will be disclosed in our annual report.

## **E. OTHER INFORMATION**

### **1. Estate Duty**

Our Directors have been advised that no material liability for estate duty is likely to fall on our Company or any of our subsidiaries.

### **2. Litigation**

Except as disclosed in this document, as of the Latest Practicable Date, we were not engaged in any litigation, arbitration or claim of material importance and no litigation, arbitration or claim of material importance is known to our Directors to be pending or threatened by or against any member of our Group, that would have a material adverse effect on our Group's results of operations or financial condition, taken as a whole.

### **3. Preliminary expenses**

As of the Latest Practicable Date, our Company has not incurred any material preliminary expenses.

### **4. Promoter**

Our Company has no promoter for the purpose of the [REDACTED]. Within the two years preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given or is proposed to be paid, allotted or given to any promoter in connection with the [REDACTED] and the related transactions described in this document.

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### 5. Taxation of Holders of Shares

#### (1) *Hong Kong*

Dealings in Shares registered on our Company's Hong Kong branch register of members will be subject to Hong Kong stamp duty. The sale, purchase and transfer of Shares are subject to Hong Kong stamp duty. The current rate charged on each of the purchaser and seller is 0.13% of the consideration or, if higher, the value of the Shares being sold or transferred. Dividends paid on Shares will not be subject to tax in Hong Kong and no tax is imposed in Hong Kong in respect of capital gains. However, profits from dealings in the Shares derived by persons carrying on a business of trading or dealings in securities in Hong Kong arising in or derived from Hong Kong may be subject to Hong Kong profits tax. The Revenue (Abolition of Estate Duty) Ordinance 2005 came into effect on February 11, 2006 in Hong Kong. No Hong Kong estate duty is payable and no estate duty clearance papers are needed for a grant of representation in respect of holders of Shares whose death occurs on or after February 11, 2006.

#### (2) *Cayman Islands*

There is no stamp duty 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) *Consultation with professional advisers*

Potential investors in the [REDACTED] are urged to consult their professional tax advisers if they are in any doubt as to the taxation implications of subscribing for, purchasing, holding or disposing of or dealing in our Shares (or exercising rights attached to them). None of us, the Joint Sponsors, the [REDACTED], the [REDACTED], the [REDACTED], or any other person or party involved in the [REDACTED] accept responsibility for any tax effects on, or liabilities of, any person, resulting from the subscription, purchase, holding or disposal of, dealing in or the exercise of any rights in relation to our Shares.

### 6. Application for [REDACTED]

The Joint Sponsors has made an application on behalf of our Company to the Listing Committee of the Stock Exchange for the [REDACTED] of, and permission to [REDACTED] in, the Shares in issue and to be issued as mentioned in this document. All necessary arrangements have been made to enable the securities to be admitted into CCASS.

### 7. No Material Adverse Change

Our Directors confirmed that up to the date of this document, there has been no material adverse change in the financial or trading position or prospect of our Group since May 31, 2022 (being the date to which the latest audited consolidated financial statements of our Group were prepared).

## APPENDIX IV

## STATUTORY AND GENERAL INFORMATION

### 8. Qualifications of Experts

The qualifications of the experts (as defined under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance) who have given their opinion and/or advice in this document are as follows:

<u>Name</u>	<u>Qualifications</u>
China International Capital Corporation Hong Kong Securities Limited	A licensed corporation to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 4 (advising on securities), Type 5 (advising on futures contracts) and Type 6 (advising on corporate finance) regulated activities under the SFO
China Securities (International) Corporate Finance Company Limited	A licensed corporation to conduct Type 1 (dealing in securities) and Type 6 (advising on corporate finance) regulated activities as defined under the SFO
Ernst & Young	Certified public accountants Registered public interest entity auditor
Commerce & Finance Law Offices	PRC Legal Advisers
Conyers Dill & Pearman	Cayman Islands attorneys-at-law
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.	Industry consultant

As of the Latest Practicable Date, none of the experts named above had any shareholding interest in our Company or any of our subsidiaries or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group.

### 9. Consents

Each of the experts named in paragraph headed “8. Qualifications of Experts” above has given and has not withdrawn their respective written consents to the issue of this document with the inclusion of their reports and/or letters and/or the references to their names included herein in the form and context in which they are respectively included.

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## STATUTORY AND GENERAL INFORMATION

### 10. Joint Sponsors’ Independence

The Joint Sponsors satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules. Particularly, China Securities (International) Corporate Finance Company Limited as one of the Joint Sponsors satisfies the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules, considering that (i) CSCI sponsor group (CSCI and China Securities (International) Corporate Finance Company Limited, together with other fellow subsidiaries, collectively, the “**CSCI sponsor group**”) through CSCI holds 2.24% (less than 5%) of the number of issued shares of the Company as of the date of this document; (ii) CSCI sponsor group has no representative at the Board of the Company and is not involved in the management of the Company; and (iii) as disclosed in the paragraphs headed “History, Development and Corporate Structure – Pre-[REDACTED] Investments – Pre-[REDACTED] Exchangeable Loan” in this document, CNCB is an Independent Third Party of China Securities (International) Corporate Finance Company Limited and therefore if CNCB elects to exercise its Exchange Right in full within the Exchange Period, its potential shareholding in the Company immediately following the [REDACTED] will not cause any impact on the satisfaction of the independence criteria under Rule 3A.07 by China Securities (International) Corporate Finance Company Limited.

The Joint Sponsors’ fees payable by us in respect of the Joint Sponsors’ services as sponsor for the [REDACTED] are USD[REDACTED].

### 11. Agency Fees and Commissions Received

The [REDACTED] will receive an [REDACTED] commission as referred to in the section headed “[REDACTED].”

### 12. Bilingual Document

The English language and Chinese language versions of this document are being published separately, in reliance upon the exemption provided under section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

### 13. Binding Effect

This document shall have the effect, if an application is made in pursuance of it, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

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## STATUTORY AND GENERAL INFORMATION

### 14. Miscellaneous

Save as otherwise disclosed in this document:

- (a) none of our Directors or experts referred to in the paragraph headed "E. Other Information – 8. Qualifications of Experts" of this appendix has any direct or indirect interest in the promotion of us, or in any assets which have within two years immediately preceding the date of this document been acquired or disposed of by or leased to any member of our Group, or are proposed to be acquired or disposed of by or leased to any member of our Group;
- (b) none of our Directors or experts referred to in the paragraph headed "E. Other Information – 8. Qualifications of Experts" of this appendix is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of our Group taken as a whole;
- (c) within the two years preceding the date of this document, no share or loan capital of the Company or any of its subsidiaries has been issued or has been agreed to be issued fully or partly paid either for cash or for a consideration other than cash;
- (d) within the two years 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 capital of any member of the Group;
- (e) within the two years preceding the date of this document, no commission has been paid or is payable (except commissions to sub-[REDACTED]) for subscribing or agreeing to subscribe, or procuring or agreeing to procure the subscriptions, for any Shares in our Company;
- (f) no share or loan capital of the Company or any of its subsidiaries is under option or is agreed conditionally or unconditionally to be put under option;
- (g) no founder, management or deferred shares of the Company or any of its subsidiaries have been issued or have been agreed to be issued;
- (h) none of the equity and debt securities of the Company is listed or dealt in on any stock exchange (other than the Stock Exchange) nor is any listing or permission to deal being or proposed to be sought;
- (i) the Group has no outstanding convertible debt securities or debentures;
- (j) there is no arrangement under which future dividends are waived or agreed to be waived;

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- (k) the English text of this document shall prevail over their respective Chinese text; and
- (l) there has not been any interruption in the business of the Group which may have or has had a significant effect on the financial position of the Group in the 12 months preceding the date of this document.

### *Resignation of Directors during the Track Record Period*

Dr. Xiong Lei, Mr. Chen Lei, Mr. Xiong Minghua, Mr. He Ming, Mr. Zhang Liang, Mr. Wang Feng, Mr. Tang Renhong, Mr. Yan Shi and Mr. Wu Gang resigned as Directors during the Track Record Period for the following reasons:

#### (a) *The Shareholder-appointed Directors*

Dr. Xiong Lei, Mr. Chen Lei, Mr. Xiong Minghua, Mr. He Ming, Mr. Zhang Liang, Mr. Wang Feng, and Mr. Tang Renhong (the "**Shareholder-appointed Directors**") were appointed as Directors by certain of the then shareholders of the Company pursuant to the then effective articles of association and shareholders' agreements. Dr. Xiong Lei and Mr. Zhang Liang were appointed by Hopeway Development Limited. Mr. Wang Feng and Mr. Tang Renhong were appointed by Simcere. Mr. Chen Lei was jointly appointed by Lucion VC 5 Limited and Glory Gain Engineering Limited. Mr. Xiong Minghua was jointly appointed by Pavilion Soar Limited, JAS Investment Group Limited and Aves Capital Holdings Limited. Mr. He Ming was appointed by Tasly International Capital Limited.

The Shareholder-appointed Directors were not involved in the day-to-day management of the Company during their tenure.

Upon the introduction of each Pre-[REDACTED] Investment, new shareholders' agreements were agreed and entered into among the then shareholders, which stipulated the director nomination rights of certain shareholders. As a result of the change in the Pre-[REDACTED] Investors' director nomination rights due to dilution to such shareholders or at the unilateral decision of such shareholders, each of the Shareholder-appointed Directors resigned on a voluntary and amicable basis to release seats from the Board to be occupied by the new Directors appointed by the Pre-[REDACTED] Investors who were granted director nomination rights following the completion of the relevant Pre-[REDACTED] Investments. Each of the Shareholder-appointed Directors has confirmed that he/she has no disputes with the Group and its shareholders.

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**STATUTORY AND GENERAL INFORMATION**

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(b) *Mr. Yan Shi*

Mr. Yan Shi was appointed as an independent non-executive Director (with effect from [REDACTED]), and resigned on December 20, 2021 since he would be a proposed director and chairman of Qingdao Hainuo Investment Development Co., Ltd. (青島海諾投資發展有限公司), who holds 10.54% equity interest in our subsidiary 3D Medicines as at the Latest Practicable Date. Mr. Yan has confirmed that he has no disputes with the Group and its Shareholders.

(c) *Mr. Wu Gang*

Mr. Wu Gang was appointed as a Director on June 24, 2021. He voluntarily resigned on July 8, 2022 to focus on his other personal commitments. Mr. Wu has confirmed that he has no disputes with the Group and its Shareholders.

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**APPENDIX V**

**DOCUMENTS DELIVERED TO THE REGISTRAR OF  
COMPANIES AND AVAILABLE ON DISPLAY**

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**DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES**

The documents attached to a copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were (i) a copy of the **GREEN [REDACTED]**; (ii) copies of each of the material contracts referred to in the section headed “Appendix IV – Statutory and General Information – B. Further Information about the Business of the Company – 1. Summary of material contracts”; and (iii) the written consents issued by each of the experts and referred to in section headed “Appendix IV – Statutory and General Information – E. Other information – 8. Qualifications of Experts.”

**DOCUMENTS AVAILABLE ON DISPLAY**

Copies of the following documents will be available on display on the website of the Stock Exchange at [www.hkexnews.hk](http://www.hkexnews.hk) and our website at [www.3d-medicines.com](http://www.3d-medicines.com) during a period of 14 days from the date of this document:

- (a) the Memorandum and Articles of Association;
- (b) the accountant’s report of the Group for the two years ended December 31, 2020 and 2021 and the five months ended May 31, 2022 prepared by Ernst & Young, the text of which is set out in Appendix I to this document;
- (c) the report received from Ernst & Young on the unaudited pro forma financial information of our Group, the text of which is set out in Appendix II to this document;
- (d) the audited consolidated financial statements of the Group for the years ended December 31, 2020 and 2021 and the five months ended May 31, 2022;
- (e) the PRC legal opinion issued by Commerce & Finance Law Offices, our PRC Legal Advisers, in respect of general matters of our PRC subsidiaries;
- (f) the letter issued by Conyers Dill & Pearman, our legal adviser on Cayman Islands laws, summarizing certain aspects of Cayman Islands company law referred to in the section headed “Appendix III – Summary of the Constitution of the Company and Cayman Islands Company Law”;
- (g) the Companies Act (2022 Revision) of the Cayman Islands;
- (h) the industry report prepared by Frost & Sullivan referred to in the section headed “Industry Overview” in this document;



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**APPENDIX V**

**DOCUMENTS DELIVERED TO THE REGISTRAR OF  
COMPANIES AND AVAILABLE ON DISPLAY**

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- (i) the material contracts referred to in the section headed “Appendix IV – Statutory and General Information – B. Further Information about the Business of the Company – 1. Summary of Material Contracts”;
- (j) the service agreements and letters of appointment referred to in “Appendix IV – Statutory and General Information – C. Further Information about Directors and Substantial Shareholders – 2. Particulars of Directors’ Service Contracts and Letters of Appointment”;
- (k) the written consents referred to in the section headed “Appendix IV – Statutory and General Information – E. Other Information – 9. Consents”; and
- (l) the rules of the Share Incentive Scheme.