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Post Hearing Information Pack of



CANbridge Pharmaceuticals Inc. 北海康成製藥有限公司

(Incorporated in the Cayman Islands with limited liability)

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CANbridge Pharmaceuticals Inc. 北海康成製藥有限公司

(Incorporated in the Cayman Islands with limited liability)

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IMPORTANT

[REDACTED]

IMPORTANT

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

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SUMMARY

This summary aims to give you an overview of the information contained in this document. As this is a summary, it does not contain all the information that may be important to you. You should read the entire document before you decide to [REDACTED] in the [REDACTED]. In particular, we are a biotechnology company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05 (1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with [REDACTED] in companies such as ours. In addition, we have incurred significant operating losses since our inception, and we expect to remain loss making in the near term. We had negative net cash flow from operating activities during the Track Record Period. We did not declare or pay any dividends during the Track Record Period and do not intend to pay any dividends in the near future. Your [REDACTED] decision should be made in light of these considerations.

There are risks associated with any [REDACTED]. Some of the particular risks in [REDACTED] in the [REDACTED] are set out in the section headed “Risk Factors” in this document. You should read that section carefully before you decide to [REDACTED] in the [REDACTED].

BUSINESS OVERVIEW

We are a China-based, rare disease-focused biopharmaceutical company founded in 2012 that is committed to the research, development and commercialization of biotech therapies. As of the Latest Practicable Date, we had developed a comprehensive pipeline of 13 drug assets with significant market potential, including three marketed products, four drug candidates at clinical stage, one at IND-enabling stage, two at preclinical stage and another three gene therapy programs at lead identification stage⁽¹⁾. Our products and product candidates target some of the most prevalent rare diseases as well as rare oncology indications, including but not limited to glioblastoma (GBM) and Mucopolysaccharidosis Type II (MPS II or Hunter syndrome). GBM represents 46.6% of the total incidence of brain cancer in China and has reached 54.7 thousand in 2020 with a CAGR of 2.0% from 2016 to 2020, and is expected to grow steadily to 59.8 thousand in 2025 and 64.4 thousand in 2030 at a CAGR of 1.8% and 1.5%, respectively. MPS II is the most common form of MPS disorders in East Asian countries. The prevalence of MPS II in Greater China reached 8,005 in 2020 and is estimated to reach 8,175 in 2030. CAN008, our Core Product, is a glycosylated CD95-Fc fusion protein being developed for the treatment of GBM. We are developing the other 12 of the drug candidates in our pipeline as of the Latest Practicable Date. As of the Latest Practicable Date, we had exclusive rights to 2 granted patents and 1 patent application for CAN008 owned by Apogenix, our collaboration partner. We are also conducting R&D works for other indications beyond GBM, which may be the subject of additional patent filings by ourselves in the short to mid-term.

(1) lead identification stage is when we are identifying the chemical that will interact with the target with the potential to treat the disease studied.

SUMMARY

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCT CANDIDATE, OR ANY OF OUR PIPELINE PRODUCTS.

OUR BUSINESS MODEL

We strategically combine global collaborations and internal research to build and diversify our drug portfolio. As the Chinese rare disease market rapidly expands, many international biopharmaceutical companies are interested in accessing this growing and untapped market but lack the local expertise. Leveraging our global collaborations and R&D capabilities, we believe we can serve as a gateway to China and a preferred partner for international biopharmaceutical companies. As of the Latest Practicable Date, our global partners include but not limited to Apogenix, GC Pharma, Mirum, Wuxi Biologics, Privus, University of Massachusetts Medical School (UMass) and LogicBio. In 2019, we in-licensed Hunterase[®] (CAN101) from an international biopharmaceutical company, GC Pharma, which is our first commercialized rare disease product to address unmet needs in China, supported by clinical validation and marketing authorization in over 10 countries worldwide by GC Pharma. We are working with our research partner UMass on sponsored research programs to develop gene therapy solutions for neuromuscular disorders, with the exclusive option to license-in the assets for development. We also seek to collaborate with China-based academic institutions. In addition, our experienced research team continues our efforts in identifying and developing drug candidates to further expand our portfolio. For example, our internal research team is developing gene therapy solutions for neuromuscular disorders. We leverage our commercialization capabilities to maximize the market potential of our drug candidates. We established key operation hubs in Beijing and Shanghai and offices in other locations in Greater China, and plan to expand to each of the key target provinces with local offices in mainland China. We are currently expanding our targeted, in-house commercialization team, which is expected to expand into over 300 members in the next five years.

Leveraging our experienced management team, a comprehensive product portfolio and an integrated platform with access to industry leading rare disease technologies, we believe we are well positioned to capture the vast rare disease market in China and globally.

SUMMARY

The following chart summarizes our portfolio and the development status of each drug asset as of the Latest Practicable Date:

Product	Modality (Drug Category (Drug Category (Drug Category Administration Law) ⁽¹⁾) ⁽²⁾)	Mechanism	Indication	Discovery/Pre-clinical	IND-enabling	Ph I	Ph II/III	NDA	Marketed	Partner	Commercial Rights ⁽³⁾	In-licensing Date	Granted Patents FN ⁽⁴⁾	Patent Applications FN ⁽⁵⁾
CAN008 (Aumerep)	Biologic (Cat.1 of Biological Drugs)	CD95-Fc fusion protein	Glioblastoma Multiforme ⁽²⁾	Taiwan Phase I trial completed China Phase 2 trial initiated						apogenix	Greater China	June 26, 2015 (with exclusive rights to develop, manufacture and commercialize)	3	2
Heritase[®] (CAN100) (Maralixibat beta)	Biologic (Cat.3 of Biological Drugs)	ERT diuronate-2-sulfonate (IDS)	Hunter syndrome (Mucopolysaccharidosis type II) ⁽¹⁾	China Phase 2 trial initiated						GUC Pharma	Greater China	January 3, 2019 (with exclusive rights to develop and commercialize; commercialization commenced in May 2020)	1	2
CAN 108 (maralixibat)	Small Molecule (ALGS, Cat.5 of Chemical Drugs, PFC: Cat.2,4 of Chemical Drugs)	ASBT-inhibitor	Progressive Familial Intrahepatic Cholestasis ⁽⁴⁾	China Phase 1 trial initiated China Phase 2 trial initiated						Amgen	Greater China	April 28, 2021 (with exclusive rights to develop, manufacture and commercialize)	2	5
CAN 106	Biologic (Cat.1 of Biological Drugs)	Anti-C5 mAb	Biliary Atresia ⁽⁴⁾	Global (U.S., Europe and China) Phase 2 initiated						WuXi Biologics / Privus	Greater China	January 7, 2019 (with exclusive rights to develop and commercialize)	0	23
CAN 103	Biologic (Cat.1 of Biological Drugs)	ERT GBA	Paroxysmal nocturnal hemoglobinuria (PNH) and other Complement Disorders ⁽⁴⁾	Singapore Phase 1 trial initiated China Phase 1 trial IND approved by NMPA						WuXi Biologics	Global	October 25, 2018 (with exclusive rights to develop and commercialize)	0	2
CAN 107	Biologic (Cat.1 of Biological Drugs)	Anti-FGF23 mAb	X-linked hypophosphatemia							WuXi Biologics / Privus	Greater China / Global ⁽¹⁾	January 7, 2019 (with exclusive rights to develop and commercialize)	0	2
CAN 104	Biologic	ERT GLA	Fabry Disease							WuXi Biologics	Global	January 7, 2019 (with exclusive rights to develop and commercialize)	0	0
CAN 105	Biologic	Anti-Factor DaxX hexab	Fabry Disease							WuXi Biologics	Greater China	January 7, 2019 (with exclusive rights to develop and commercialize)	0	0
Undiscovered⁽⁶⁾	Gene Therapy	AAV	Neuromuscular Disorders ⁽⁶⁾							University of Maryland System	Global	September 1, 2021 (sponsored rights to develop and commercialize)	0	0
CAN 201	Gene Therapy	AAV ΔL65 GLA	Fabry Disease ⁽⁶⁾							University of Maryland System	Global	April 26, 2021 (with exclusive rights to develop, manufacture and commercialize)	0	3
CAN 202	Gene Therapy	AAV ΔL65 GNA	Pompe Disease ⁽⁶⁾							LogicBio	Global	April 26, 2021 (with exclusive rights to develop, manufacture and commercialize)	0	3
Capbio⁽¹⁾	Medical Device ⁽¹⁾ (Class III Medical Device)	Calcium phosphate rinse	Oral Mucositis							TESA/Pharma	China	July 20, 2018 (commercialization commenced in October 2018)	0	0
Nerlynx[®] (Neratinib)	Small molecule (Cat.2,1 of Chemical Drugs)	Tyrosine kinase inhibitor	HER2+ Breast Cancer HER2+ Metastatic Breast Cancer							Pierre Fabre	Hong Kong, Taiwan, Mexico ⁽¹⁾	February 24, 2021 (commercialization commenced in December 2019)	12	7

★ Core Product █ Clinical trials performed by license partner ▨ Next Milestone

SUMMARY

Notes:

1. Greater China includes mainland China, Hong Kong, Taiwan and Macau.
2. After in-licensing, we have completed Phase 1 trial in Taiwan and obtained IND approval for the first line GBM Phase 2 clinical trial in China, for which we dosed the first patient in October 2021.
3. After in-licensing, we obtained a clinical trial waiver on the pivotal trial and the NDA approval for Humera[®] (CAN101) for MPS II from the NMPA in September 2020.
4. Mirum received the FDA approval for CAN108 for the treatment of cholestatic pruritus in patients with ALGS in September 2021. Mirum has also filed an MAA for ALGS for CAN108 with the EMA in September 2021. After in-licensing, we have started preparation of NDA for ALGS for CAN108 and expect to file NDA in Greater China in December 2021 based on data obtained by our license partner in global studies.
5. For BA, we are supporting the patient recruitment and clinical site management in China for a global Phase 2 clinical trial initiated by our license partner in the U.S. and Europe. IND approval was obtained from the NMPA in May 2021 and we plan to begin patient enrollment in China as part of the global Phase 2 trial in the first half of 2022.
6. After in-licensing, initiated a Phase 1 clinical trial for CAN106 in Singapore in February 2021 and obtained the IND approval from the NMPA for PNH for a Phase 1 study in China in July 2021.
7. Greater China rights granted from Wuxi Biologics. Worldwide excluding Greater China rights granted from Privus.
8. The Company obtained IND approval from NMPA in October 2021 for Gaucher Disease for a Phase 1 study in China. We plan to initiate patient enrollment in the first half of 2022.
9. Gene therapy programs at lead identification stage, including two programs (CAN201 and CAN202) licensed from LogicBio and one undisclosed program with exclusive option to enter into a licensing agreement with UMass (the program name is not available yet).
10. Caphosol[™] is an oral electrolyte solution and designated as a prescription medical device.
11. We have entered into a distribution agreement with Pierre Fabre pursuant to which Pierre Fabre appointed us as its distributor with exclusive rights to sell Nerlynx[®] (CAN030) for Pierre Fabre in Hong Kong, Macau, and Taiwan Pierre Fabre has the exclusive rights to develop and commercialize Nerlynx[®] (CAN030) in Greater China.
12. Patents were granted on each drug and patent applications were filed on each drug by the collaboration partners.
13. Each category refers to different registration pathway of a drug's approval process. For the drug assets not assigned a category, they are still at early stage and the Company has not yet decided the registration process in applying for the NDA. Each assigned category is referring to the following:
 - Cat.1 of Biological Drugs: Innovative therapeutic biologics not commercialized in China or overseas;
 - Cat.3 of Biological Drugs: Domestically or overseas marketed biological products;
 - Cat.2.4 of Chemical Drugs: Drugs with new indications containing known active ingredients that are not commercialized in China or overseas;
 - Cat.3 of Chemical Drugs: Generic drugs applied by domestic applicant, with an innovative drug that has been marketed overseas but not marketed domestically. Such drugs should be consistent with the quality and efficacy of the reference listed drug;
 - Cat.5.1 of Chemical Drugs: Domestic application for an innovative drug or a modified drug that has been marketed overseas. The modified drug should have obvious clinical advantages.

SUMMARY

OUR CORE PRODUCT

CAN008 CD95-Fc fusion protein for GBM

CAN008, our Core Product, is a glycosylated CD95-Fc fusion protein being developed for the treatment of GBM. We commenced a Phase 1 trial of CAN008 in combination with radiation therapy (RT) and temozolomide (TMZ) in patients with newly diagnosed GBM in September 2016 in Taiwan under the authorization of the Taiwan Food and Drug Administration (“TFDA”). A Phase 2 trial of CAN008 was completed by Apogenix AG (Apogenix) in recurrent GBM in Europe in September 2014. We completed the Phase 1 trial in Taiwan in September 2018 after 24 months of clinical research and development and results show CAN008 was generally well tolerated in patients with GBM. No dose-limiting toxicity was observed and no treatment-related serious adverse events were reported. We received the IND approval for CAN008 from the NMPA in March 2018 for a second-line Phase 2 trial and subsequently amended our IND application to a first-line Phase 2 trial based on the positive preliminary efficacy results obtained in the Phase 1 trial in Taiwan, which suggested the potential of CAN008 to become a standard-of-care treatment⁽¹⁾. We received the approval for a first-line Phase 2 trial in China on patients with GBM in April 2021 and dosed the first patient in China in October 2021. The Phase 2 clinical trial is designed to be multi-center, randomized, double-blind and placebo-controlled to investigate the efficacy and explore the correlation of different biomarkers with treatment outcome. We expect to commercialize CAN008 in China as a combination therapy with the standard of care for GBM (radiotherapy plus chemotherapy).

There are currently three targeted drugs for GBM marketed in China and seven being developed in China and worldwide. For details, see “Industry Overview – Glioblastoma Multiforme (GBM)”.

Core Product Candidate Development Process

Since in-licensing CAN008 from Apogenix in June 2015, we have led all R&D strategy and been primarily responsible for all clinical development activities related to CAN008 in Greater China, which include the biomarker study, the Phase 1 study and the Phase 2 study. We have engaged in substantial R&D work for more than 12 months on CAN008, primarily including:

- (a) From July 2015 to January 2016, we completed a biomarker study for expression of CD95L, the first of its kind in China, in over 60 Chinese patients with GBM, which confirmed the existence of CD95L in Chinese GBM patients and demonstrated a high degree of consistency of CD95L expression between geographically diverse Chinese and Western GBM patients;

(1) According to National Cancer Institute, standard of care treatment refers to treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. It is usually included and defined in the expert consensus or treatment guidelines, and in other words, is the level of care widely accepted in the medical community with proved efficacy and good safety in clinical practice.

SUMMARY

- (b) From April 2016 to July 2016, we submitted the Taiwan IND application in March 2016 and received approval from the TFDA in July 2016;
- (c) From September 2016 to September 2018, we completed a Phase 1 trial of CAN008 in combination with RT and TMZ in 10 patients with newly diagnosed GBM in three hospitals in Taiwan under the authorization of the TFDA. On the back of the Phase 1 trial, we filed an IND application with the NMPA in June 2017, which was accepted in July 2017. In applying for IND, we were responsible for all regulatory interactions with the NMPA's CDE and led pre-IND consultation, protocol design, medical advisory board and IND dossier preparation;
- (d) Since April 2016, in parallel with the Phase 1 trial of CAN008 in Taiwan, we have invested significant development efforts into the CMC tech transfer of CAN008 to manufacture it in China;
- (e) Since we received IND approval from the NMPA for CAN008's Phase 2 trial in March 2018, we have continued to dedicate extensive R&D efforts into the preparation of the trial, including:
 - (i) engaging experts from over 15 hospitals in China and Europe, to evaluate and refine the clinical trial protocol design;
 - (ii) assessing 9 trial clinical sites for potential participation in the trial based on their patient flow, medical capabilities and doctors' experience;
 - (iii) holding site-initiation visits at Beijing Tiantan Hospital, Tianjin Medical University General Hospital, Huashan Hospital Fudan University, Peking Union Medical College Hospital, Tongji Medical College of Huazhong University of Science & Technology and Harbin Medical University Cancer Hospital and discussed with principal investigators on study design, safety monitoring and mitigation plan, efficacy endpoints, as well as patient screening and enrollment; and
 - (iv) engaging a reputable Chinese CRO in December 2020 in preparation of our multi-center, randomized, double-blind, and placebo-controlled phase II clinical trial, for which we will design the trials, oversee clinical processes, monitor CRO's performance, and jointly share responsibility with the CRO for protocol development and investigational product management while the CRO will be responsible for clinical monitoring, pharmacovigilance, medical monitoring and data management.

SUMMARY

- (f) We had a team of 9 members, 11 members and 17 members for the research and development of CAN008 for the year ended 2019, 2020 and the six months ended June 30, 2021, respectively, covering the full life cycle of drug development including pre-clinical research, clinical operation, regulatory affair, CMC development, quality assurance, medical assistance and project management.

For more details, see “Business – Our Portfolio – CAN008 CD95-Fc fusion protein for GBM – Our R&D Efforts since In-Licensing.”

While the Phase 2 trial previously approved by the NMPA was for a second-line trial, we submitted updated Phase 2 first-line clinical trial application for CAN008 in December 2020 based on the R&D efforts as mentioned above and have received CDE clearance in April 2021. The Phase 2 trial is a mandatory trial required by the NMPA. We will independently develop CAN008 in China, and Apogenix will only play a passive role in the development process of CAN008 in China. We have engaged an industry leading CRO for the Phase 2 clinical trial, for which we will design the trials, provide guidance to the CRO’s activities, oversee clinical processes, monitor CRO’s performance, while the CRO will be responsible for clinical monitoring, pharmacovigilance, medical monitoring and data management. We have also engaged a CMO to produce raw materials for the trial. We dosed first patient in the Phase 2 clinical trial of CAN008 for the first-line treatment of GBM patients in China in October 2021. It is designed to be multi-center, randomized, double-blind and placebo-controlled to investigate the efficacy and explore the correlation of different biomarkers with treatment outcome. The trial will compare standard-of-care (tumor removal, followed by RT plus TMZ) with placebo, to standard-of-care with CAN008.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN008 SUCCESSFULLY.

OUR OTHER DRUG CANDIDATES

Late Stage Drug Products and Candidates

Hunterase[®] (CAN101) targeting MPS II/Hunter syndrome

Hunterase[®] (CAN101) is an enzyme replacement therapy (ERT) being developed for the treatment of mucopolysaccharidosis type II (“MPS II”). We in-licensed Hunterase[®] (CAN101) from GC Pharma (or “GC”) in January 2019. Multiple clinical trials have been conducted to date by GC to evaluate the safety and efficacy of Hunterase[®] (CAN101), including the pivotal Phase 1/2 trial for the approval from MFDS (formerly known as the Korea Food & Drug Administration or KFDA) and certain post-approval studies. The pivotal study indicated significant subject benefit, a significant decrease in uGAG level from baseline, and an improvement in the primary endpoints. Hunterase[®] (CAN101) is currently marketed in over 10 countries worldwide by GC Pharma. It received marketing authorization as an orphan drug from the MFDS in January 2012. As of the Latest Practicable Date, Hunterase[®] (CAN101) has received marketing authorization from authorities in Algeria, Belarus, Kazakhstan and Russia

SUMMARY

and has been available for prescription in Brazil, Egypt, India, Malaysia, Oman, Turkey and Venezuela, for treatment of MPS II. We obtained a clinical trial waiver on the pivotal trial and the NDA approval for Hunterase[®] (CAN101) for MPS II from the NMPA in September 2020. We are currently engaged in a risk screening project for CAN101 in Zhejiang Province, which has obtained the approval from the ethnics committee and Human Genetic Resources Administration of China (HGRAC), to examine the risks associated and better improve the diagnosis practice from clinical perspective. We are mainly responsible for screening patients under different tests.

We plan to conduct a post-approval study in China as required by the NMPA in the first half of 2023. For more details, please see “Business – Late Stage Drug and Drug Candidates – Hunterase[®] (CAN101) targeting MPS II/Hunter syndrome”.

Hunterase[®] (CAN101) is currently the only targeted therapy to MPS II available in China. There are eight targeted drugs for MPS II in clinical stage in China and worldwide. For details, see “Industry Overview – Mucopolysaccharidosis Type II (MPS II or Hunter syndrome)”.

CAN108 (maralixibat)

CAN108 (maralixibat) is an oral, minimally-absorbed agent designed to selectively inhibit apical sodium-dependent bile acid transporter (ASBT) and treat rare cholestatic liver diseases, including Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA). In April 2021, we obtained an exclusive license from Mirum to develop, manufacture and commercialize CAN108 (maralixibat) in Greater China for ALGS, PFIC and BA. ASBT is primarily responsible for recycling bile acids from the intestine back to the liver. ASBT inhibition results in more bile acids being excreted in the feces, leading to lower levels of bile acids systemically, thereby reducing bile acid mediated effects and liver damage. By targeting bile acids in these settings, maralixibat has the potential to improve long-term outcomes and symptoms in our targeted settings and provide an alternative treatment to liver transplant. Maralixibat possesses an extensive safety dataset, having been evaluated in more than 1,600 human subjects. Maralixibat has been studied in a number of completed and ongoing clinical trials in ALGS and PFIC conducted by Mirum with over 120 children treated and some on study for over seven years. Mirum obtained FDA approval for maralixibat for ALGS in September 2021.

We have started preparation of NDA for ALGS for CAN108 and expect to file a NDA in December 2021 in mainland China and Taiwan based on data obtained by Mirum, our collaboration partner, in global studies. For BA, we are supporting the patient recruitment and clinical site management in China for a Phase 2 global multi-center clinical trial initiated in May 2021 by Mirum, our collaboration partner. We target to initiate patient enrollment in China for such Phase 2 trial in the first half of 2022.

SUMMARY

Maralixibat is currently the only targeted drug for ALGS worldwide. There is currently no approved product in China or worldwide for PFIC or BA. There are one targeted drugs for ALGS, two for PFIC and four for BA being developed in China and worldwide respectively. For details, see “Industry Overview – Rare Cholestatic Liver Diseases”.

CAN106 long-acting anti-C5 antibody for complement disorders

CAN106 is a humanized monoclonal antibody against complement C5 being developed for the treatment of complement-mediated diseases including paroxysmal nocturnal hemoglobinuria (PNH), and various other complement-mediated diseases that are targeted by approved anti-C5 antibodies and other new potential indications. The molecule is originated from discovery works conducted by Privus, and Wuxi Biologics is responsible for the CMC development. We have global rights to develop and commercialize this drug candidate from both Privus and Wuxi Biologics. Based on preclinical data, CAN106 has demonstrated a favorable PK/PD profile and tolerability, indicating that CAN106 has the potential to effectively inhibit C5 in patients with PNH and potentially with reduced dosing frequency. We submitted an IND application for a Phase 1 clinical trial of CAN106 in Singapore in October 2020 and received IND approval from Health Sciences Authority (HSA) in December 2020. We initiated a Phase 1 clinical trial in healthy volunteers for CAN106 in Singapore in February 2021. This first-in-human study is designed to be a randomized, double-blind, placebo-controlled and single ascending dose study in 31 healthy volunteers to evaluate the safety, pharmacokinetics, pharmacodynamics and development of anti-drug antibodies of CAN106. A Phase 1 study is planned in China and the data readout is expected to be obtained in the first quarter of 2023. We obtained the IND approval from the NMPA for PNH in July 2021 for the Phase 1 study.

SOLIRIS is currently the only approved product in China targeting PNH. There are eight C5 inhibitors targeting PNH being developed in China and worldwide. For details, see “Industry Overview – Complement Mediated Diseases”.

We initiated a Phase 1 clinical trial in healthy volunteers for CAN106 in Singapore in February 2021, and obtained the IND approval from the NMPA for CAN106 for PNH in July 2021 for a Phase 1 study⁽¹⁾.

CAN103

CAN103 is an ERT for Gaucher disease (GD) originated from discovery works conducted by Wuxi Biologics and currently being locally developed in China by us. It is the first rare disease asset we acquired in 2018 from WuXi Biologics, which we have global proprietary rights to develop and commercialize. It is produced in an engineered cell line that produces recombinant beta-glucocerebrosidase (GCCase) with highly exposed mannose for efficient uptake by macrophage and Kupfer cells in Gaucher patients to break down glucocerebrosides

(1) The IND approval from the NMPA for CAN106 for PNH is not based on the Phase I clinical data from Singapore.

SUMMARY

(GL1), the lipids that accumulate in the body of patients with GD. GD is a lysosomal storage disorder due to mutations in the GBA gene. It is one of the best known rare diseases evidenced by a large number of research literatures and has more approved drugs available as compared to other rare diseases, according to Frost & Sullivan. There were approximately 3,000 GD patients in 2020 in China.

We obtained the IND approval for CAN103 from the NMPA in October 2021. We are in preparation of a Phase 1 trial in adult and adolescent GD patients and plan to initiate patient enrollment in the first half of 2022.

There are currently six targeted drugs for GD marketed in the U.S. and seven being developed in China and worldwide. For details, see “Industry Overview – Gaucher Disease (GD)”.

Our Preclinical Candidates

CAN107

CAN107 is recombinant humanized anti-FGF23 mAb for X-linked hypophosphatemia (XLH) being developed in China currently at CMC stage in preparation to initiate IND-enabling studies. XLH is an inherited disease of phosphate metabolism where mutations inactivating the Phosphate Regulating Endopeptidase Homolog, X-Linked (PHEX) gene lead to inactivation of the PHEX protein. The lack of PHEX protein/activity prevents it from correctly regulating fibroblast growth factor 23 (FGF23), resulting in overactivity of FGF-23 that reduces vitamin D1 α -hydroxylation and phosphate reabsorption by the kidneys, leading to hypophosphatemia and the related features of hereditary hypophosphatemic rickets, local and systemic effects including impaired growth, rickets, bone abnormalities and muscular dysfunction. The prevalence of the disease is estimated at 1 in 20,000 people in 2020 and the prevalence of such inherited genetic disorder remains relatively stable over time, according to Frost & Sullivan.

CAN104

CAN104 is an ERT being developed in China for the treatment of Fabry disease (FD). FD is an inherited lysosomal storage disorder of glycosphingolipid metabolism due to the absence or deficiency of β -Gal A which can lead to life-threatening heart and kidney problems. CAN104 is a recombinant humanized β -galactosidase A enzyme (β -Gal A). Its mechanism of action is through internalization of cells by first binding to the mannose-6-phosphate receptors (M6PRs) and then transporting to the lysosome. In the lysosome, CAN104 catalyses the hydrolysis of globotriaosylceramide (GL-3) and other β -galactyl-terminated neutral glycosphingolipids. We are accelerating CAN104's preclinical development and it is currently under cell line development for IND-enabling studies. FD is one of the most common LSDs which usually starts in childhood and is more common in men than women. China has a relatively large number of patients with FD, accounting for about one-fifth of patients in the world.

SUMMARY

CAN105

CAN105 is being developed for the treatment of Hemophilia A with massive market potential. It is a recombinant, humanized, bispecific antibody that bridges activated factor IX and factor X to restore the function of the missing activated factor VIII, which is not expected to be affected by existing factor VIII inhibitors or induce new development of such inhibitors. There were over 120,000 Hemophilia A patients in China in 2020 with an expected growth at a CAGR of 0.5% from 2020 to 2025 and 0.1% from 2025 to 2030. CAN105 is expected to enter preclinical research phase in the first half of 2022.

Gene Therapy – CAN201 and CAN202

sL65 is a next generation liver-tropic AAV capsid platform for use in gene editing and gene therapy. At the American Society of Gene & Cell Therapy (“ASGCT”) conference in May 2020, data was presented showing that the capsids delivered highly efficient functional transduction of human hepatocytes in a humanized mouse model and non-human primates. The data also showed the capsids exhibited improved manufacturability and more resistance to pre-existing neutralizing antibodies in human serum samples. We are devising preclinical strategies on CAN201 as we and our collaboration partner, LogicBio, conduct preclinical evaluations of this drug candidate. Our development plan on CAN202 is subject to the development status of CAN201 to de-risk the process.

OUR PLATFORM

We are led by a management team with significant industry experience in rare diseases, spanning R&D, clinical development, regulatory affairs, business development and commercialization, supported by a pool of talent of 173 employees where 22 had a Ph.D. and/or M.D. degree and more than 80% of our employees had experience working at multinational biopharmaceutical companies as of the Latest Practicable Date. Our management team collectively has a track record of successfully commercializing rare disease therapies across the key markets including China, the United States, Europe, Latin America, and Southeast Asia. Leveraging our management’s expertise, we play an active role in advancing the rare disease industry and shaping the rare disease ecosystem in China. For example, our founder Dr. Xue is currently serving as the Deputy Director General of China’s Alliance for Rare Disease (CHARD).

Since our inception in 2012, we have built a comprehensive portfolio targeting diseases with validated mechanisms of action with significant market potential, consisting of biologics, small molecules and gene therapy solutions. We adopted an in-licensing business model and apart from our internal efforts in developing gene therapy solutions for neuromuscular disorders, all of our product pipeline as of the Latest Practical Date have been in-licensed from our business partners. We will continue to enrich it via, business partnerships and collaborations with academic institutions together with in-house research and development.

SUMMARY

- In the rare disease area, we have seven biologics and small molecules products and product candidates for the treatment of Hunter Syndrome (MPS II) and other lysosomal storage disorders (LSDs), complement mediated disorders, hemophilia A, metabolic disorders, and rare cholestatic liver diseases including Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA). Among these, we obtained the marketing approval for Hunterase[®] (CAN101) for MPS II in mainland China in September 2020.
- In the rare oncology area, we are developing CAN008 for the treatment of glioblastoma multiforme (GBM). In 2018, we completed a Phase 1 clinical trial for CAN008 in Taiwan, which has successfully bridged CAN008 to Asian patients with newly diagnosed GBM on the back of clinical data previously obtained in overseas trials. We have obtained IND approval from the NMPA to commence first-line Phase 2 clinical trial of CAN008 and dosed the first patient in a Phase 2 clinical trial of CAN008 for the first-line treatment of GBM patients in mainland China in October 2021. We also obtained marketing approval for two other oncology products, Caphosol[™] (CAN002) in mainland China and Nerlynx[®] (CAN030) in Greater China.

In addition to biologics and small molecules, we are investing in next-generation technology for gene therapies. Gene therapies provide a potentially one-time, durable treatment for various rare genetic diseases. As of the Latest Practicable Date, we are using AAV sL65 capsid vector licensed in from LogicBio Therapeutics to develop two gene therapy products for the treatment of Fabry disease and Pompe disease, with options to develop two additional indications using the same vector and a clinical-stage gene editing program for the treatment of methylmalonic acidemia (MMA) pursuant to our collaboration agreements with LogicBio Therapeutics. We are also working with our research partner UMass on sponsored research programs to develop gene therapy solutions for neuromuscular disorders, with the exclusive option to license-in the assets for development. In addition, we are internally developing an adeno-associated virus (AAV) delivery platform targeting different tissues such as the central nervous system (CNS) and muscle.

COMPETITION

The pharmaceutical and biopharmaceutical industries are characterized by rapidly advancing technologies, competition and a strong emphasis on proprietary drugs. While we believe that our development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biopharmaceutical companies, academic institutions and public and private research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future.

SUMMARY

GBM, the indication for CAN008, currently has targeted therapy treatment options for GBM in China including surgery, radiotherapy combined with TMZ concurrent chemotherapy, tumor treating field (TTF), bevacizumab (Avastin) and a bevacizumab biosimilar. The incidence of GBM in China has reached 54.7 thousand in 2020 with a CAGR of 2.0% from 2016 to 2020, and is expected to grow steadily to 59.8 thousand in 2025 and 64.4 thousand in 2030 at a CAGR of 1.8% and 1.5%, respectively. According to Frost & Sullivan, the incidence represents the total addressable market size of CAN008 for GBM. See “Industry Overview – Rare Oncology – Glioblastoma Multiforme (GBM) – Market Overview” for more details. The epidemiology of GBM was estimated by Frost & Sullivan based on the incidence rate reported by literatures and interviews from relevant experts. The expected increase in the incidence of GBM in China is primarily due to the aging of population, ionizing radiation and air pollution in the future ten years. There are currently three drugs targeting GBM marketed in China, and 22 targeted drugs for GBM being developed in China and worldwide. Our CAN008 fusion protein has competitive advantages in the treatment of GBM over other treatment options, including a validated novel mechanism of action, improved efficacy and the potential for combination therapy. For more details, see “Industry Overview – Rare Oncology – Glioblastoma Multiforme (GBM).”

MPS II, the indication for Hunterase[®] (CAN101), is also known as Hunter syndrome, which is an X-linked recessive lysosomal storage disorder. The prevalence of MPS II in Greater China reached 8,005 in 2020 and is estimated to reach 8,175 in 2030. According to Frost & Sullivan, the prevalence of MPS II represents the total addressable market size of Hunterase[®] (CAN101). See “Industry Overview – Rare Diseases – Mucopolysaccharidosis Type II (MPS II or Hunter syndrome) – Market Overview” for more details. The epidemiology of MPS II was estimated by Frost & Sullivan based on the prevalence rate reported by literatures and interviews from relevant experts. MPS II is an inherited genetic disorder, so the expected steady increase in the prevalence of MPS II in Greater China is primarily due to the increasing overall population in the future ten years. Our Hunterase[®] (CAN101) is the only approved treatment for Hunter syndrome or MPS II in China and there are three other targeted drugs approved for MPS II globally. For more details, see “Industry Overview – Rare Diseases – Mucopolysaccharidosis Type II (MPS II or Hunter syndrome).”

For the addressable market of our other product candidates, see “Industry Overview.”

RESEARCH AND DEVELOPMENT

We believe that R&D is key to driving our therapeutics strategy and maintaining our competitiveness in the biopharmaceutical industry. We are dedicated to enhancing our rare disease drugs portfolio by leveraging our strong in-house R&D capabilities, which span from preclinical research to clinical development.

SUMMARY

Our R&D team members have extensive preclinical and clinical development experience, including a proven track record in the development of drugs for the treatment of different types of rare diseases. As of the Latest Practicable Date, we had a total of 173 employees, among whom 22 have a Ph.D. and/or M.D. degree, and more than 80% of our employees had experience working at multinational biopharmaceutical companies. Our R&D team members have an average of approximately 10 years of relevant industry experience.

To leverage the capabilities of our R&D team, we promote company-wide cross-function collaboration to identify and mitigate inherent risks early in the development of innovative therapies with massive market potential. For example, in implementing such approach, our senior R&D members serve across different functional teams, and our medical team are involved from the project inception and throughout the preclinical development of our research projects. This enables our team to be familiar with the assets at an early stage so that they can formulate development ideas early on and provide feedback to the internal R&D team.

Our R&D team is led by our founder, Chairman and CEO, Dr. Xue (Ph.D., M.B.A.), a veteran entrepreneur with over 22 years of experience in medical and pharmaceutical companies. Serving as the founding general manager of Genzyme China, he had successfully managed the launch of several life-saving drugs for the treatment of hematologic cancer and rare metabolic diseases in China, including but not limited to Thymoglobulin and Cerezyme. He is also the Deputy Director General at CHARD, Vice Chair of R&D Committee of China Pharmaceutical Innovation and Research Development Association (PhIRDA) and a member of Leadership Council of Joint Institute of Peking University Health Science Center and University of Michigan Medical School.

For the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, our R&D expenses were RMB55.4 million, RMB109.6 million and RMB274.8 million, respectively. For our Core Product CAN008, our R&D expenses were RMB11.9 million, RMB4.3 million and RMB17.9 million for the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, accounting for 21.5%, 3.9% and 6.5% of our total R&D expenses, respectively.

INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights are important to the success of our business. Our success depends, in part, on our ability to obtain and maintain patent and other intellectual property and proprietary protections for commercially important technologies, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

As of the Latest Practicable Date, we own or otherwise have exclusive rights to 17 granted patents and 47 pending patent applications worldwide. We believe there is no material legal impediment for us to obtain the approvals for these pending patents and trademarks.

SUMMARY

The following table includes the information on our key patent rights for our Core Product:

Product	Scope of Patent Protection	Patent Applicant/ Holder	Jurisdiction	Status	Patent Expiration*
CAN008	CD95-Fc Variants	Apogenix	China, Hong Kong	Granted	2033
	Reagents and methods of detecting cancer	Apogenix	China	Granted	2033
	CD95-Fc isoforms	Apogenix	China, Hong Kong	Pending	N/A

Our Directors confirm that, as of the Latest Practicable Date, we were not a party to any material legal or administrative proceedings in connection with intellectual property rights or otherwise, and we are not aware of any instances of infringement of any third parties’ intellectual property rights by us which could materially and adversely affect our business.

For details on the portfolio of patent applications material to our business operations, see “Business – Intellectual Property”.

COLLABORATION AND LICENSING ARRANGEMENTS

Development and License Agreement with Apogenix

On June 26, 2015, we entered into a development and license agreement with Apogenix AG (previously known as Apogenix GmbH) (“Apogenix”) as amended in December 2015, May 2021 and August 2021, respectively (the “Apogenix Agreement”) concerning our exclusive right to develop, manufacture and commercialize the compound known as APG101 (CAN008) and pharmaceutical products containing APG101 (“Apogenix Licensed Products”) in Greater China.

Pursuant to the Apogenix Agreement, Apogenix granted us an exclusive, royalty-bearing, license under specified Apogenix patent rights, materials and know-how to develop (not including any modification to the compound), manufacture and commercialize, including to market, promote, label, package, distribute, import, export, offer to sell and sell the Apogenix Licensed Products in Greater China for the treatment of patients with glioblastoma disease (the “GBM”) and/or other indications. Any sublicense to a third party by us (excluding to affiliates of us and Apogenix) requires the prior written consent of Apogenix. Pursuant to the Apogenix Agreement, should we, our affiliates or sublicensees outside the scope of the agreement commence clinical trials or commercialize any CD95 ligand inhibitor for the treatment of GBM within Greater China, then Apogenix may terminate and convert our exclusive license into a non-exclusive license and may independently exploit the Apogenix Licensed Products in Greater China, and we must grant to Apogenix a non-exclusive license to our development data.

* Patent expiration does not include any applicable patent term extensions

SUMMARY

Under the Apogenix Agreement, we are responsible for the development, manufacturing and commercialization of APG101 for the treatment of GBM in Greater China. We must use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize the Apogenix Licensed Products in Greater China, and we are responsible for all costs and expenses incurred by us, or by Apogenix under the development plan and technology transfer⁽¹⁾ as specified in the Apogenix Agreement associated with such activities. We will independently develop CAN008 in China, and Apogenix will only play a passive role in the development process of CAN008 in China.

For more details, see “Business – Collaboration and Licensing Arrangements – Development and License Agreement with Apogenix.”

Exclusive License Agreement with GC Pharma

On January 3, 2019, we entered into a license agreement (the “GC Pharma Agreement”) with Green Cross Corporation (“GC Pharma”) concerning the exclusive right to develop and commercialize⁽²⁾ any biopharmaceutical products containing the compound Idursulfase- β developed by GC Pharma as an active pharmaceutical ingredient that is formulated for intravenous administration in the treatment of Mucopolysaccharidosis Type II (also known as Hunter Syndrome) (the “GC Pharma Licensed Products”) in all indications except for the indication specifically for CNS symptoms (the “GC Pharma Licensed Field”). The GC Pharma Licensed Products represent the product currently marketed by or on behalf of GC Pharma outside Greater China under the product name Hunterase[®] (CAN101).

Pursuant to the GC Pharma Agreement, GC Pharma granted to us an exclusive, sublicensable (subject to certain conditions), royalty-bearing right and license under certain patent rights, know-how and product names and trademarks relating to the GC Pharma Licensed Products to develop and commercialize (excluding manufacturing activities) the GC Pharma Licensed Products in the GC Pharma Licensed Field in Greater China. We elected under the GC Pharma Agreement not to commercialize in the following provinces: Shanxi, Guizhou, Gansu, Qinghai, Xizang, Jilin and Yunnan⁽³⁾, and are required, upon written request of GC Pharma, to enter into a sublicense agreement licensing our commercialization rights under the GC Pharma Agreement to a designated GC Pharma affiliate in one or more of such provinces. GC Pharma has granted to us a right of first negotiation with respect to collaborations in the licensed territory regarding development and commercialization of the GC Pharma Licensed Products for treatment of Mucopolysaccharidosis Type II in the CNS

- (1) Technology transfer under the Apogenix Agreement mainly involved transfer of all materials relevant for the CMC process (including monochlorobimane and assay components) and information on assays. Such technology transfer was completed in 2018 according to the terms and payment schedule under the Apogenix Agreement.
- (2) GC Pharma is responsible for the manufacturing of CAN101.
- (3) We believe such provinces are less commercially attractive with lower patient affordability and health awareness. The GC Pharma Agreement does not preclude us to commercialize in these provinces if the market becomes more mature.

SUMMARY

indication. GC Pharma has also granted to us a right of first refusal with respect to GC Pharma granting to, or obtaining an offer from, a third party to develop or commercialize the GC Pharma Licensed Products in the licensed territory for treatment of Mucopolysaccharidosis Type II in the CNS indication.

Under the GC Pharma Agreement, we are responsible, and must use commercially reasonable efforts, to develop, obtain regulatory approval for and commercialize the GC Pharma Licensed Products, and we are responsible for all costs and expenses incurred by us or on behalf of us associated with such activities. Unless separately agreed, we agree to purchase and GC Pharma agrees to supply to us GC Pharma Licensed Products at a fixed price as set forth in the GC Pharma Agreement and supply samples to us for regulatory approval at no charge. We also agreed not to directly or indirectly develop, manufacture or commercialize any product indicated for the treatment of Mucopolysaccharidosis Type II in China, other than the GC Pharma Licensed Products.

For more details, see “Business – Collaboration and Licensing Arrangements – Exclusive License Agreement with GC Pharma.”

Exclusive License Agreement with WuXi Biologics

On January 7, 2019, we entered into a license agreement (the “WuXi Biologics Agreement”) with WuXi Biologics Ireland Limited (“WuXi Biologics”), wherein WuXi Biologics granted to us (i) an exclusive, transferable (subject to certain conditions), royalty-bearing license under (a) all patents and patent applications controlled by WuXi Biologics or its affiliates during the term of agreement in Greater China that claim any aspect of the anti-C5 antibody that binds specifically to the C5 protein or a pharmaceutical composition containing the anti-C5 antibody (the “WuXi Biologics Licensed Product”, representing CAN106) and (b) know-how solely pertaining to the WuXi Biologics Licensed Product, and (ii) a non-exclusive, royalty-bearing license under certain know-how that relates to both the WuXi Biologics Licensed Product and other products, in each case of (i) and (ii), with the right to sublicense through multiple tiers (subject to certain conditions), and to make, have made, use, register, sell, offer to sell, have sold, import, export, exploit, research, improve, develop and commercialize the WuXi Biologics Licensed Product (including all improvements and/or modifications) in Greater China for all indications related to the anti-C5 antibody. We granted back to WuXi Biologics a co-exclusive, irrevocable, fully paid, royalty-free license under all patent rights and know-how controlled by us, our affiliates or sublicensees at any time during the term of the agreement that is solely related to the WuXi Biologics Licensed Product or anti-C5 antibody or the research, development, manufacture, commercialization, sale or use thereof. WuXi Biologics has granted to us a right of first negotiation with respect to a global license for the WuXi Biologics Licensed Product and a right of first refusal with respect to a third party granting to or receiving from WuXi Biologics a global license, in each case outside of Greater China.

SUMMARY

Under the WuXi Biologics Agreement, we will be responsible for the development and commercialization of the WuXi Biologics Licensed Product. We must use commercially reasonable efforts to develop, obtain regulatory approval and commercialize the WuXi Biologics Licensed Product, and we are responsible for all costs and expenses incurred by us or on behalf of us associated with such activities. Unless separately agreed, WuXi Biologics is our exclusive clinical supplier and primary commercial supplier for the WuXi Biologics Licensed Product.

For more details, see “Business – Collaboration and Licensing Arrangements – Exclusive License Agreement with WuXi Biologics.”

Exclusive License Agreement with Privus

On May 9, 2020, we entered into a license agreement (the “Privus Agreement”) with Privus Biologics, LLC (“Privus”), wherein Privus granted to us (i) an exclusive, transferable (subject to certain conditions), royalty-bearing license under (a) all patents and patent applications controlled by Privus or its affiliates during the term of agreement in worldwide except for Greater China with regard to a terminal complement inhibitor of the C5a and C5b proteins, and all other terminal complement inhibitors of the C5a and C5b proteins controlled by Privus (the “Privus Licensed Product”) and (b) know-how solely pertaining to the Privus Licensed Product, and the right to sublicense through multiple tiers in worldwide except for Greater China for all Privus Licensed Product.

Under the Privus Agreement, we will have sole control over and responsibility and decision-making authority for, at our sole cost and expenses, all development and commercialization of the Privus Licensed Product. We must use commercially reasonable efforts to develop, seek regulatory approval and commercialize the Privus Licensed Product, and we are responsible for all costs and expenses incurred by us or on behalf of us associated with such activities.

For more details, see “Business – Collaboration and Licensing Arrangements – Exclusive License Agreement with Privus.”

Collaboration with UMass

On June 1, 2020, we entered into a sponsored research agreement with The University of Massachusetts as represented by and solely on behalf of its medical school (“UMass”), pursuant to which we were granted an exclusive option to obtain a worldwide, royalty-bearing, exclusive license (with the right to sublicense through multiple tiers) under certain of UMass’ patent rights and future patent rights related thereto, to use and practice such rights for the prevention, treatment, cure or control of conditions relating to certain neuromuscular disorders. Our exercise of the exclusive option obligates us and UMass to negotiate in good faith a license agreement containing reasonable terms. In consideration of the performance of research projects and the rights granted, we are obligated to provide financial support to UMass in periodic advance biannual payments as set forth in the sponsored research agreement. Pursuant

SUMMARY

to the sponsored research agreement, UMass granted to us a royalty-free, fully paid-up, perpetual, non-exclusive, worldwide license, without the right to grant sublicenses, under all of UMass' patent rights arising from the sponsored research project to make, have made, use, lease, sell, have sold, offer for sale and import products and otherwise practice such patent rights, provided that we agree to (a) demonstrate reasonable efforts to commercialize such products in the public interest and (b) pay a pro rata portion (in equal portions with each other non-exclusive licensee) of patent prosecution and maintenance costs in all countries, including the United States, in which we are granted a non-exclusive license right. Unless terminated earlier, the sponsored research agreement remains in effect until the later of two years from June 1, 2020 or completion of the research project. We may terminate the sponsored research agreement upon 30 days' prior notice if (i) a principal investigator leave UMass and no acceptable substitute is identified within 60 days or otherwise terminated his or her involvement in the research project, or (ii) parties are unable to reach agreement on the update of the research project pursuant to relevant provisions of the sponsored research agreement. Either party may terminate the sponsored research agreement upon the material uncured breach of the agreement by the other party.

On September 1, 2020, we entered into another sponsored research agreement with UMass, as represented by and solely on behalf of its medical school, for a research project on engineering AAV capsids with lower sensitivity to antibody neutralization and enhanced CNS and muscle tropism, pursuant to which we were granted an exclusive option to obtain a worldwide, royalty-bearing, exclusive license (with the right to sublicense through multiple tiers) under certain of UMass' patent rights and future patent rights related to the sponsored research project, to use and practice such rights for the prevention, treatment, cure or control of human indications, disease, disorder or conditions. Our exercise of the exclusive option obligates us and UMass to negotiate in good faith a license agreement containing reasonable terms. In consideration of the performance of research projects and the rights granted, we are obligated to provide financial support (including, material, reagents, consumables, supply and personnel costs) to UMass in periodic advance biannual payments as set forth in the sponsored research agreement. In turn, we and UMass have joint, undivided ownership of all patent rights which is conceived or reduced to practice jointly by us and UMass. Unless terminated earlier, the sponsored research agreement remains in effect until the later of two years from June 1, 2020 or completion of the research project. We may terminate the sponsored research agreement upon 30 days' prior notice if (i) a principal investigator leave UMass without acceptable substitute is identified within 60 days or otherwise terminated his or her involvement in the research project, or (ii) parties are unable to reach agreement on the update of the research project pursuant to relevant provisions of the sponsored research agreement. Either party may terminate the sponsored research agreement upon the material uncured breach of the agreement by the other party.

For more details, see "Business – Collaboration and Licensing Arrangements – Collaboration with UMass."

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Collaboration with LogicBio

On April 26, 2021, we entered into a strategic collaboration and licensing agreement with LogicBio Therapeutics, Inc. (“LogicBio”), wherein LogicBio granted to us (i) a worldwide, royalty-bearing, sublicensable through multiple tiers (subject to certain conditions), exclusive license to certain LogicBio patents and know-how to develop, manufacture and commercialize gene therapy candidates for two targets for the treatment of Fabry and Pompe diseases, such LogicBio patents and know-how being inclusive of LogicBio’s adeno-associated virus (AAV) sL65, a capsid produced from the LogicBio sAAVy™ platform; (ii) options for the development of AAV sL65-based treatments for two additional targets; and (iii) an option to obtain an exclusive, royalty-bearing, sublicensable through multiple tiers (subject to certain conditions) license to LogicBio patents and know-how to LB-001, an investigational in-vivo gene editing technology based on GeneRide™ platform for the potential treatment of methylmalonic acidemia (MMA), in Greater China (collectively, the “LogicBio Licensed Products”). Pursuant to the agreement, we granted to LogicBio a royalty-free, non-exclusive, sublicensable, license for LogicBio to perform its obligations under the agreement.

We are required to use commercially reasonable efforts to develop and seek regulatory approval for LogicBio Licensed Product directed against each target corresponding to each licensed indication in certain countries, and upon approval of the applicable biologics license application in such country, we are obligated to use commercially reasonable efforts to obtain regulatory approval and commercialize such product in such country. Similarly, if we exercise the LB-001 option, we are required to use commercially reasonable efforts in Greater China to develop, seek regulatory approval and commercialize LogicBio Licensed Product for LB-001. Except as otherwise provided in the agreement, we are solely responsible for, and will have sole control over, preparing, filing, and maintaining regulatory submissions and communicating with regulatory authorities in Greater China with respect to LogicBio Licensed Products.

Subject to the terms of the agreement, LogicBio will have an option, on a target-by-target basis with respect to certain targets, to enter into a separate worldwide, co-exclusive (with us) co-development and co-commercialization agreement with us with regard to products that are directed to the applicable target in certain time period. We and LogicBio will have sole responsibility for the conduct of the activities allocated to us or LogicBio, respectively.

Subject to the terms of the agreement, on a product-by-product basis for products other than LB-001, during an initial LogicBio manufacturing period, LogicBio has sole responsibility for all manufacturing activities. Following the initial LogicBio manufacturing period, we will have sole responsibility for and sole decision-making authority with respect to all manufacturing activities.

For more details, see “Business – Collaboration and Licensing Arrangements – Collaboration with LogicBio.”

SUMMARY

Collaboration with Mirum

On April 28, 2021, we entered into a license agreement with Mirum Pharmaceuticals, Inc. (“Mirum”), wherein Mirum granted to us an exclusive, royalty-bearing, sublicensable (subject to certain conditions) license to certain Mirum licensed know-how and patents to develop, manufacture and commercialize maralixibat, an investigational, orally administered medication, and pharmaceutical products containing maralixibat (“Mirum Licensed Products”), which is being evaluated in several indications including Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA), within the licensed territory of Greater China for ALGS, PFIC, and BA. The licenses granted to us constitute sublicenses of upstream license agreements to Mirum which Mirum may not amend or terminate without our prior written consent.

In collaboration with Mirum, we have agreed to oversee Mirum’s clinical study sites in China, with the goal of accelerating enrollment of the global Phase 2b EMBARK study, which was recently initiated for patients with BA. We also have the right to manufacture maralixibat in Greater China under certain conditions. We are required to use commercially reasonable efforts, at our sole cost and expense, to develop and commercialize the Mirum Licensed Products in Greater China and are responsible for obtaining regulatory approval for Mirum Licensed Products in the licensed territory.

For more details, see “Business – Collaboration and Licensing Arrangements – Collaboration with Mirum.”

SALES AND MARKETING

As of the Latest Practicable Date, we had commercialized three products, Caphosol™ (CAN002) in mainland China, Nerlynx® (CAN030) in Greater China, and Hunterase® (CAN101) in mainland China. We use a combination of our in-house sales and marketing team and a network of independent distributors to sell our products in Greater China. Our management team has a track record of successfully commercializing rare disease therapies across various key markets including China, Southeast Asia, the United States, Latin America and Europe. Led by them, we have assembled an experienced commercial team to ensure the successful commercialization of our drug candidates upon approval. As of the Latest Practicable Date, we had established a commercial team jointly led by Mr. Yijun Lu, our China General Manager and Mr. Marcelo Cheresky, our Chief Business Officer, consisting of 81 members. We expect to expand our commercialization team to over 300 members in the next five years, comprising of three major functions including marketing and sales, medical affairs and patient advocacy and assistance, with the mission to execute medical engagement plan for KOL development, promote community awareness and explore industry insights for better drug development strategies.

SUMMARY

We employ a strategic marketing model to increase our market penetration and to promote our products. Under this model, we promote our products to hospitals and physicians in Greater China through academic marketing, establishing center of excellence and referral network, and providing trainings to physicians. In particular, a series of marketing activities have been carried out for our close-to-launch product candidates such as CAN108, including establishing collaboration with hospitals with expertise in our targeted rare diseases, KOL engagement through regional educational seminars held online and offline with the Primary Health Care Foundation of China. We plan to follow similar marketing strategies as CAN008 and other pipeline products approach commercialization stage. With more late-stage drug candidates entering into the commercialization stage, we also plan to set up local offices in each key province across the country. See “Our Strategies – Drive commercialization of our late-stage assets in Greater China.”

Pricing

When determining the price of our products, we consider factors such as clinical value, current unmet medical needs, product quality, production costs, health economics in the country to market in, patient affordability and competitors’ pricing strategies. The list price of Hunterase[®] (CAN101) in China is similar to its reimbursement price in South Korea, where it was previously approved and commercialized taking the afore-mentioned key factors into account. We have initiated a Hunterase[®] patient assistance program in collaboration with a medical payment services provider to improve patients’ access to Hunterase[®] (CAN101) in China. We expect to follow similar pricing strategies when CAN008 enters the commercialization stage. We believe our pricing strategy can strike a balance between the affordability of patients and a sustainable return on these products.

As of the Latest Practicable Date, CAN008, our Core Product was still at clinical stage, and our three commercialized products, CAN101, CAN002 and CAN030, had not been included under the national or provincial public medical insurance program in China or other relevant regions. In light of the current circumstances, we believe that the likelihood that our products will be included in the national public medical insurance program in China in the near future remains relatively low. However, we observed that over the years of China’s exploration in insurance mechanism of rare diseases at the local level, an aggregate of 29 provinces have implemented insurance policies for certain rare disease with various reimbursement models. If our commercialized products or Core Product upon commercialization are included in public medical insurance programs, we may face downward pricing pressure. Nevertheless, it will also increase the sales volume and therefore further promote the market growth of our products.

CUSTOMERS

For the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, the aggregate sales to our five largest customers were RMB1.5 million, RMB9.4 million and RMB6.4 million, representing 100.0%, 77.7% and 52.4% of our revenue, respectively. Sales to our largest customer for the same periods were RMB1.1 million, RMB5.3 million and RMB2.2 million, representing 72.2%, 44.2% and 17.7% of our revenue, respectively.

SUMMARY

RAW MATERIALS AND SUPPLIERS

During the Track Record Period, our suppliers primarily consisted of (i) licensors from which we obtained intellectual property rights in respect of our in-licensed drug candidates and (ii) CROs and CDMOs, who provide third-party contracting services for research and development. We select our suppliers by considering their product quality, industry reputation and compliance with relevant regulations and industry standards.

For the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, purchases from our five largest suppliers in aggregate accounted for 63.1%, 83.7% and 69.3% of our total purchases (including value added tax), respectively, and purchases from our largest supplier accounted for 42.8%, 55.6% and 23.3% of our total purchases for the same periods (including value added tax), respectively. During the Track Record Period, our purchases mainly include rights under license agreement and R&D services.

During the Track Record Period, we have not procured raw materials or equipment for commercial manufacturing.

OUR COMPETITIVE STRENGTHS

We believe the following strengths differentiate us from our competitors:

- A rare disease focused biopharmaceutical company dedicated to addressing unmet medical needs
- A comprehensive portfolio of rare disease focused therapies with significant revenue potential
- Extensive strategic partnerships to source innovative therapies globally
- A rare disease platform positioned to drive rapid and comprehensive product development and market access in China and globally
- Management team with deep industry experience and a track record of commercializing rare disease therapies globally

OUR STRATEGIES

We aspire to become a global biopharmaceutical leader that delivers targeted therapies for rare disease patients in China and worldwide. We plan to implement the following strategies to achieve our vision:

- Further solidify our position in the China’s rare disease ecosystem and build a global rare diseases franchise
- Drive commercialization of our late-stage assets in Greater China

SUMMARY

- Rapidly advance and expand our portfolio
- Maximize value creation through partnership and collaboration
- Enhance capabilities with in-house drug research, development and manufacturing infrastructure in global and Greater China markets

OUR SINGLE LARGEST SHAREHOLDER

The Company had no controlling shareholder as defined under the Listing Rules as at the Latest Practicable Date. As of the Latest Practicable Date, Dr. Xue, our founder, Chairman of the Board, executive Director and CEO, is entitled to ultimately control an aggregate of 18.84% of the voting rights of the Company, being more voting rights than any other Shareholder of the Company, through (i) Dr. Xue (holding beneficially under his own name), (ii) CTX Pharma (an investment holding entity wholly-owned by Dr. Xue), (iii) the Voting Rights Proxy Agreement and (iv) the Family Trust. The Voting Rights Proxy Agreement shall terminate upon [REDACTED]. Immediately following the completion of the Share Subdivision and the [REDACTED] (assuming that the [REDACTED] is not exercised and without taking into account any additional Shares to be issued upon the exercise of the Share Options granted under the [REDACTED] Equity Incentive Plan), Dr. Xue is expected to ultimately control an aggregate of [REDACTED]% of the voting rights of the Company, which continues to be more than any other Shareholders, through (i) himself beneficially, (ii) CTX Pharma and (iii) the Family Trust. See sections headed “History, Reorganization and Corporate Structure – Our Structure Immediately Prior to the Share Subdivision, Conversion and [REDACTED]”, “History, Reorganization and Corporate Structure – Our Structure Immediately Following the [REDACTED]” and “Substantial Shareholders” for further details.

OUR [REDACTED] INVESTORS

Since 2015, we have secured [REDACTED] investments of an aggregate amount of approximately US\$269 million pursuant to the respective investment agreements. Our [REDACTED] Investors includes certain Sophisticated Investors, such as WuXi PharmaTech Healthcare Fund I L.P., WuXi AppTec (HongKong) Limited, RA Capital Health Fund, L.P., RA Capital Nexus Fund L.P., Blackwell Partners LLC – Series A, Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P. Please refer to the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments” in this document.

SUMMARY OF KEY FINANCIAL POSITIONS

This summary historical data of financial information set forth below have been derived from, and should be read in conjunction with, our consolidated 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 “Financial Information” of this document. Our financial information was prepared in accordance with IFRSs.

SUMMARY

Summary Data from Consolidated Statements of Profit or Loss

The table below sets forth our consolidated statements of profit or loss for the periods indicated derived from our consolidated statements of profit or loss set out in the Accountants’ Report included in Appendix I to this document:

	For the year ended		For the six months	
	December 31,		ended June 30,	
	2019	2020	2020	2021
	RMB’000	RMB’000	RMB’000	RMB’000
			<i>(unaudited)</i>	
Revenue	1,469	12,032	1,944	12,192
Cost of sales	(504)	(5,154)	(838)	(5,353)
Gross profit	965	6,878	1,106	6,839
Other income and gains	580	1,359	747	11,052
Selling and distribution expenses	(28,881)	(51,008)	(16,401)	(44,768)
Administrative expenses	(53,719)	(77,716)	(29,337)	(52,928)
Research and development expenses	(55,383)	(109,642)	(35,884)	(274,837)
Fair value changes of convertible redeemable preferred shares	(73,694)	(591,385)	(79,043)	(21,848)
Fair value changes of convertible loans	(1,584)	1,689	1,689	–
Fair value changes of derivative financial instruments	(17)	(20,746)	3,175	34,454
Other expenses	(3,667)	(1,599)	(663)	(609)
Finance costs	(2,275)	(3,873)	(2,119)	(1,558)
Loss before tax	(217,675)	(846,043)	(156,730)	(344,203)
Income tax expense	–	–	–	–
Loss for the year/period	(217,675)	(846,043)	(156,730)	(344,203)
Attributable to:				
Owners of the parent	(217,675)	(846,043)	(156,730)	(344,203)

During the Track Record Period, our revenue was generated from sales of medical products, including our CaphosolTM(CAN002), Nerlynx[®] (CAN030) and Hunterase[®] (CAN101) to three countries or regions. The increase in revenue over the Track Record Period is primarily attributable to the increase in sales of our Nerlynx[®] (CAN030) since its launch in Hong Kong in December 2019, in mainland in China in November 2020 and in Taiwan in December 2020. For the year ended 2019 and 2020 and the six months ended June 30, 2021, the revenue we generated from CaphosolTM(CAN002) was RMB1.1 million, RMB0.4 million and RMB0.9 million, respectively, and the revenue we generated from Nerlynx[®] (CAN030) was RMB0.4 million, RMB11.7 million and RMB10.7 million, respectively. For the six months ended June 30, 2021, the revenue we generated from Hunterase[®] (CAN101) was RMB0.7 million.

SUMMARY

Geographical information

	Year ended December 31,				Six months ended June 30,			
	2019		2020		2020		2021	
	RMB'000	% of total revenue	RMB'000	% of total revenue	RMB'000	% of total revenue	RMB'000	% of total revenue
					<i>(unaudited)</i>			
Mainland								
China	1,061	72.2%	5,448	45.3%	117	6.0%	3,837	31.5%
Taiwan	–	–	319	2.6%	–	–	5,418	44.4%
Hong Kong	408	27.8%	6,265	52.1%	1,827	94.0%	2,937	24.1%
	<u>1,469</u>	<u>100.0%</u>	<u>12,032</u>	<u>100.0%</u>	<u>1,944</u>	<u>100.0%</u>	<u>12,192</u>	<u>100.0%</u>

The revenue information above is based on the locations of the customers.

The increase in our net losses in 2020 is primarily attributable to the increase in our fair value changes of convertible redeemable preferred shares from a loss of RMB73.7 million for 2019 to a loss of RMB591.4 million for 2020, primarily due to the increase in our Company’s valuation. The increase in our net losses for the six months ended June 30, 2021 is primarily attributed to (i) the increased license fee from RMB19.2 million for the six months ended June 30, 2020 to RMB173.3 million for the six months ended June 30, 2021, and (ii) increased testing and clinical trial expenses from RMB1.7 million for the six months ended June 30, 2020 to RMB67.0 million for the six months ended June 30, 2021, due to more CRO and CMC activities carried out for our pipeline candidates in the six months ended June 30, 2021 as compared with those in the same period of 2020. For more details, see “Financial Information – Description of Selected Components of Statements of Profit or Loss” in this document.

The fair value changes of convertible redeemable preferred shares adversely affected and will continue to affect our performance during and subsequent to the Track Record Period until the conversion of preferred shares into ordinary shares upon [REDACTED]. While the fair value loss of financial instruments issued to [REDACTED] investors has adversely impacted our financial position during the Track Record Period, the financial instruments will be automatically converted into Shares upon the [REDACTED], after which we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable preferred shares. The convertible redeemable preferred shares will be re-designated from financial liabilities to equity as a result of the automatic conversion of preferred shares into ordinary shares upon [REDACTED], thereby turning the net liabilities position into a net assets position. For more information, please refer to the section headed “Risk Factors – Risks Relating to Our Financial Position and Need for Additional Capital – Our results of operations, financial condition and prospects may be adversely affected by fair value changes in our convertible redeemable preferred shares, convertible loan and derivative financial instruments at fair value through profit or loss.”

SUMMARY

Summary Data from Consolidated Statements of Financial Position

The table below sets forth selected information from our consolidated statements of financial position as of the dates indicated, which have been extracted from the Accountants’ Report set out in Appendix I to this document:

	As of December 31,		As of
	2019	2020	June 30, 2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Total non-current assets ⁽¹⁾	50,645	195,313	70,939
Total current assets	37,905	391,045	480,432
Total assets	88,550	586,358	551,371
Total current liabilities	43,749	108,103	100,925
Total non-current liabilities	1,035,447	2,224,111	2,515,244
Total liabilities	1,079,196	2,332,214	2,616,169
Net current (liabilities)/assets	(5,844)	282,942	379,507
Net liabilities	(990,646)	(1,745,856)	(2,064,798)
Share capital	5	5	5
Reserves	(990,651)	(1,745,861)	(2,064,803)
Total equity	(990,646)	(1,745,856)	(2,064,798)

We recorded net current liabilities of RMB5.8 million and net current assets of RMB282.9 million as of December 31, 2019 and December 31, 2020, respectively. As of June 30, 2021, we had net current assets of RMB379.5 million. As of [August 31], 2021, being the latest practicable date for the purpose of liquidity disclosure in this document, we had net current assets of RMB316.7 million. The Company had net current liabilities of RMB5.8 million as of December 31, 2019, which were primarily due to large amount of other payables and accruals and Interest-bearing bank and other borrowings. The Company recorded net liabilities of RMB990.6 million, RMB1,745.9 million and RMB2,064.8 million as at December 31, 2019, 2020 and June 30, 2021, respectively, mainly due to the convertible redeemable preferred shares which were issued through several rounds of financing arrangements and are measured at fair value as at December 31, 2019, 2020 and June 30, 2021 as liabilities in the consolidated statements of financial position.

For more details, see “Financial Information – Discussion of Certain Selected Items from the Consolidated Statements of Financial Position” in this document.

SUMMARY

Summary Data from Consolidated Cash Flow Statements

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

	As of December 31,		As of June 30,	
	2019	2020	2020	2021
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Cash flows from operating activities before movements in working capital	(116,560)	(198,611)	(67,740)	(351,521)
Changes in working capital	(9,735)	45,999	(2,902)	(10,762)
Interest received	120	964	454	1,124
Net cash flows used in operating activities	(126,175)	(151,648)	(70,188)	(361,159)
Net cash flows from/(used in) investing activities	(42,420)	(153,483)	(146,104)	128,581
Net cash flows from/(used in) financing activities	96,967	679,263	397,538	315,383
Net increase/(decrease) in cash and cash equivalents	(71,628)	347,132	181,246	82,805
Cash and cash equivalents at beginning of year	85,240	13,873	13,873	360,804
Effect of foreign exchange rate changes, net	261	(27,201)	(470)	(1,509)
Cash and cash equivalents at end of year	13,873	360,804	194,649	442,100

During the Track Record Period, we incurred negative net cash flows from operations, substantially due to our research and development expenses. Our operating cash flow will continue to be affected by our research and development and selling and distribution expenses. During the Track Record Period and up to the Latest Practicable Date, we primarily funded our working capital requirements through proceeds from private equity financing. Our management closely monitors uses of cash and cash balances and has maintained a healthy liquidity for our operations and as our business develops and expands, we expect to generate more cash flow from our operating activities, through launching and commercializing our products upon approval and enhancing our operating efficiency.

Since the commencement of our business operation, we have incurred negative cash flows from our operations. Substantially all of our operating cash outflows have resulted from our R&D costs, selling and distribution expenses and administrative expenses. In view of our net operating cash outflows throughout the Track Record Period, we plan to improve such position by (i) further increase our sales of our approved products; (ii) rapidly advancing our late-stage

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pipeline products towards commercialization to generate revenue from product sales, (iii) adopting comprehensive measures to effectively control our cost and operating expenses, primarily including research and development costs, sales and distribution expenses and administrative expenses; (iv) enhancing working capital management efficiency; (v) successfully launching the [REDACTED] to obtain the [REDACTED]; and (vi) seeking additional funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources, if needed.

Our cash burn rate refers to the average monthly (i) net cash used in operating activities, which includes research and development expenses, and (ii) capital expenditures. We had bank balance and cash of RMB381.5 million as of [August 31], 2021. We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no [REDACTED] is exercised and assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED] in this Document. Assuming an average cash burn rate going forward of the same level in 2020, we estimate that our cash and cash equivalents as of [August 31], 2021 will be able to maintain our financial viability for 15 months. Assuming an average cash burn rate going forward of two times the level in 2020, we estimate that our cash and cash equivalents as of [August 31], 2021 will be able to maintain our financial viability for 36 months, if we take into account the estimated net [REDACTED] from the [REDACTED]. We will continue to monitor our working capital, cash flows, and our business development progress.

Key Financial Ratios

The table below sets forth the key financial ratios of our Group for the periods or as of the dates indicated:

	For the year ended		For the six months	
	December 31,		ended June 30,	
	2019	2020	2020	2021
Gross margin ⁽¹⁾	65.7%	57.2%	56.9%	56.1%
			As of	As of
			December 31,	June 30,
			2019	2020
Current ratio ⁽²⁾		86.6%	361.7%	476.0%

Notes:

- (1) Gross margin equals gross profit divided by revenue as of the end the year/period.
- (2) Current ratio equals current assets divided by current liabilities as of the end of the year/period.

SUMMARY

Our gross profit margin decreased from 65.7% for 2019 to 57.2% for 2020 due to adjustments in business strategy and decreases in the average selling prices of our commercialized products. Our gross profit margin stayed stable at 56.9% for the six months ended June 30, 2020 and 56.1% for the six months ended June 30, 2021. For more information on the change in our gross profit margin, see “Financial Information – Year Ended December 31, 2019 Compared to Year Ended December 31, 2020 – Gross Profit and Gross Profit Margin” and “Financial Information – Six Months Ended June 30, 2020 Compared to Six Months Ended June 30, 2021 – Gross Profit and Gross Profit Margin.”

[REDACTED]

SUMMARY

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED], after deducting [REDACTED] commissions, fees and estimated expenses payable by us in connection with the [REDACTED], assuming no [REDACTED] is exercised and assuming an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range stated in this document.

We intend to use the net [REDACTED] for the following purposes, subject to changes in light of our evolving business needs and changing market conditions:

- Approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund the ongoing and future R&D (including planned clinical trials, preparation of registration filings and milestone fees), and CMC development and manufacturing of our Core Product candidate CAN008 (primarily including facilities under construction in Suzhou that will cover the process development and clinical trial materials production in GMP environment for CAN008; the clinical trial materials production can also be transferred to Suzhou facility from current CMO);
- Approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund our major products and product candidates in our pipeline;
 - i. Approximately [REDACTED]%, or HK\$[REDACTED], is expected to fund the ongoing commercialization, post-approval study and milestone fees of Hunterase[®] (CAN101);
 - ii. Approximately [REDACTED]%, or HK\$[REDACTED], is expected to fund the ongoing and future R&D (including ongoing and planned clinical trials in Singapore and China, preparation of registration filings and milestone fees) of CAN106;
 - iii. Approximately [REDACTED]%, or HK\$[REDACTED], is expected to fund the ongoing and future R&D (including ongoing and planned clinical trials, preparation of registration filings and milestone fees) of CAN103;
 - iv. Approximately [REDACTED]%, or HK\$[REDACTED], is expected to fund the ongoing and future R&D (including ongoing and planned clinical trials, preparation of registration filings and milestone fees) and future commercial launches (including sales and marketing) of CAN108;
- Approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund ongoing and future R&D (including ongoing and planned clinical trials, preparation of registration filings and milestone fees) of other non-gene therapy products and product candidates in our pipeline;
- Approximately [REDACTED]%, or HK\$[REDACTED], is expected to fund the ongoing and future R&D (including ongoing and planned clinical trials, preparation of registration filings and milestone fees) of CAN201, CAN202 and our other gene therapy programs;

SUMMARY

The remaining [REDACTED]% of the net [REDACTED], or HK\$[REDACTED], will be allocated to fund the R&D and other general business purposes as follows:

- Approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to develop our R&D and manufacturing facilities in both China and the U.S. for all our products and drug candidates, and potential office and site expansion and upgrade in China and the U.S. The [REDACTED] allocated to the R&D and manufacturing facilities in China under this item refers to the costs associated with the facilities under construction in Suzhou that will be used to develop and manufacture our products and drug candidates other than CAN008. There is no overlap of the use of [REDACTED] for R&D and manufacturing facilities under this item and CMC development and manufacturing of CAN008;
- Approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to our other R&D activities including employment costs in both China and the U.S.;
- Approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for potential strategic acquisitions, investments, in-licensing or collaborations. We do not have any concrete acquisition target but plan to explore drug candidates in the rare disease and gene therapy area which may be complimentary to our current drug portfolio;
- Approximately [REDACTED]%, or HK\$[REDACTED], will be used for our commercialization activities, including expanding our sales and marketing team; and
- Approximately [REDACTED]%, or HK\$[REDACTED], will be used for our working capital and general corporate purposes.

For further details, see “Future Plans and Use of [REDACTED]”.

DIVIDEND

No dividend has been paid or declared by us during the Track Record Period. You should note that historical dividend distributions are not indicative of our future dividend distribution policy.

We are a holding company incorporated in the Cayman Islands. We may need dividends and other distributions on equity from our PRC subsidiary to satisfy our liquidity requirements. Current PRC regulations permit our PRC subsidiary to pay dividends to us only out of their accumulated after-tax profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiary is required to set aside at least 10% of their respective accumulated after-tax profits each year, if any, to fund certain reserve funds until the total amount set aside reaches 50% of their respective registered capital. Our PRC subsidiary may also allocate a portion of its after-tax profits based on PRC accounting standards to

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employee welfare and bonus funds at their discretion. These reserves are not distributable as cash dividends. Furthermore, if our PRC subsidiary incurs debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments to us.

We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash 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 Shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. As advised by our Cayman Islands legal adviser, under the Cayman Companies Act, a Cayman Islands company may pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in our Company being unable 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 unless the payment of such a dividend would result in our Company being unable to pay our debts as they fall due in the ordinary course of business. There is no assurance that dividends of any amount will be declared to be distributed in any year.

[REDACTED] EXPENSES

The total [REDACTED] expenses (including [REDACTED] commissions) payable by our Company are estimated to be approximately HK\$[REDACTED] (or approximately US\$ [REDACTED]) constituting approximately [REDACTED]% of the gross [REDACTED] from the [REDACTED], assuming the [REDACTED] is not exercised and based on an [REDACTED] of HK\$[REDACTED] (being the mid-point of our [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]). These [REDACTED] expenses mainly comprise legal and other professional fees paid and payable to the professional parties, commissions payable to the [REDACTED], and printing and other expenses for their services rendered in relation to the [REDACTED] and the [REDACTED].

In 2019, 2020 and for the six months ended June 30, 2021, [REDACTED] expenses charged to our consolidated statements of profit or loss were HK\$[REDACTED], HK\$[REDACTED], and HK\$[REDACTED], respectively. After June 30, 2021, approximately HK\$[REDACTED] is expected to be charged to our consolidated statements of profit or loss, and approximately HK\$[REDACTED] is expected to be charged against 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.

SUMMARY

RECENT DEVELOPMENTS

Recent Update in Clinical Development

In October 2021, we dosed the first patient in a first-line Phase 2 clinical trial for CAN008 on GBM patients in China. The trial is designed to be multi-center, randomized, double-blind and placebo-controlled to investigate the efficacy and explore the correlation of different biomarkers with treatment outcome. For details, please refer to “Business – CAN008 CD95-Fc fusion protein for GBM – Clinical Development Plan.”

We also obtained the IND approval for CAN103 from the NMPA in October 2021. We are in preparation of a Phase 1 trial in adult and adolescent GD patients and plan to initiate patient enrollment in the first half of 2022.

Newly-commercialized Product in May 2021

We obtained the marketing approval for Hunterase[®] (CAN101) for MPS II in mainland China in September 2020. We delivered the first commercial prescription of Hunterase[®] (CAN101) in China in May 2021 and the China treatment consensus that includes Hunterase[®] (CAN101) as the standard of care ERT was published in June 2021. Hunterase[®] (CAN101) was allowed to be manufactured after issuance of the Import Drug License, which we obtained after the process of manufacturing, packaging and release preparations was completed over a period of three months. In addition, Hunterase[®] (CAN101) had to pass the batch-by-batch in-country testing as required by the NMPA before commercialization, which took another three months to complete. Therefore, we were only able to deliver the first commercial prescription in May 2021 after it passed the regulatory and testing requirements in China for imported biologics. We expect to gradually commence nationwide sales of Hunterase[®] (CAN101) in Greater China.

Recent Business Development Efforts

In October 2021, we entered into a research collaboration and license agreement with Scriptr Global, Inc., which granted us exclusive worldwide rights to develop, manufacture and commercialize a gene therapy candidate for the treatment of dystrophinopathies.

In October 2021, we entered into a sponsored research agreement with the University of Washington School of Medicine, in Seattle, Washington, for gene therapy research in Duchenne muscular dystrophy (DMD), a rare neuromuscular disease.

Expected Net Loss in 2021

We expect the net loss in 2021 will substantially increase as compared with 2020, primarily due to expected increases in (i) R&D expenses in relation to both pre-clinical and clinical studies; and (ii) expenses in connection with the [REDACTED] incurred in 2021.

SUMMARY

Expected Further Change in Fair Value Change of Convertible Redeemable Preferred Shares in 2021

We expect to recognize additional loss from the fair value changes of the convertible redeemable preferred shares after June 30, 2021 to the [REDACTED]. After the automatic conversion of the convertible redeemable preferred shares into Shares upon the [REDACTED], which will result in a net asset position, we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable preferred shares in the future.

Impact of the COVID-19 Outbreak

Since the end of December 2019, the outbreak of COVID-19 has materially and adversely affected the global economy. In response, local governments has imposed widespread lockdowns, closure of work places and restrictions on mobility and travel to contain the spread of the virus. As of the Latest Practicable Date, substantially all of the Chinese cities had eased or lifted domestic travel restrictions and resumed normal social activities, work and production.

The government lockdown and other restrictive measures had resulted in significantly reduced mobility of our employees, causing most of the employees to work remotely during early phases of COVID-19 outbreak. As a result, we had implemented various precautionary measures and adjusted our employee’s work arrangements according to the relevant regulations and policies, which had allowed us to maintain a sufficient number of personnel on-site who managed to work under flexible schedule to continue our research and development activities.

There has not been any material disruption of our ongoing clinical trials and other R&D work for our product candidates since the outbreak of COVID-19 pandemic. We have not experienced and currently do not expect any material delays in regulatory affairs with respect to our clinical trials or any long-term impact on our operation or deviation from our overall development plans due to the COVID-19 pandemic. Our Directors are of the view that the COVID-19 pandemic is not expected to have any material adverse impact on the Group’s overall business operation.

To some extent, reduced transportations and disruption to manufacturing and logistics networks in China due to the COVID-19 outbreak affected our suppliers’ abilities to manufacture and transport consumables, equipment and other supplies necessary for our operations. Nevertheless, as of the Latest Practicable Date, most of our suppliers had resumed normal operations and we had not experienced any material disruption or shortage of supplies during the COVID-19 outbreak since the outbreak of COVID-19.

As of the Latest Practicable Date, we had no suspected or confirmed active COVID-19 cases on our premises or among our employees. To prevent any spread of COVID-19 in our offices and production facilities, we have implemented preventive measures such as regularly sterilizing and ventilating our offices and production facilities, checking the body temperature of our employees daily, keeping track of the travel history and health conditions of employees,

SUMMARY

and providing face masks and disinfectant to employees attending our offices and facilities. We will continue to implement our remedial measures and may implement additional measures as necessary to ease the impact of the COVID-19 outbreak on our operations. However, we cannot guarantee you that the COVID-19 pandemic will not further escalate or have a material adverse effect on our results of operations, financial position or prospects.

U.S.-China Relationship

In light of the current situations and the particular nature of the biopharmaceutical industry, we are of the view that the U.S.-China tension has not had any material impact on our business or operations, our clinical trial designs and execution, patient enrollment, data transfer, related regulatory approval processes, ability to find alternative suppliers to source, develop and manufacture our pipeline products, and prospects. We cannot guarantee, however, that the U.S.-China tension will not escalate which may have a material adverse effect on our results of operations.

No Material Adverse Change

Save as otherwise disclosed above, our Directors confirm that, as of the date of this Document, there has been no material adverse change in our financial or trading position, indebtedness, mortgage, contingent liabilities, guarantees or prospects since June 30, 2021, the end of the period reported on in the Accountants’ Report set out in Appendix I to this document. As we continue to advance the development of our pipeline and expand our clinical development programs, we expect to incur increasing research and development expenses and administrative expenses. Therefore, based on the assumptions made by and information currently available to our management, we expect to incur an increased amount of losses in 2021 compared to 2020.

RISK FACTORS

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

- The actual market size of our drug candidates might be smaller than expected and our future approved 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.
- Our business and financial prospects depend substantially on the success of our clinical stage and pre-clinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain relevant regulatory approvals or achieve their commercialization, or if we experience significant delays in any of the foregoing, our business and profitability may be adversely affected.

SUMMARY

- We may not be able to identify, discover or in-license new drug candidates, and may allocate our limited resources to pursue a particular candidate or indication and fail to capitalize drug candidates or indications that may later prove to be more profitable, or for which there is a greater likelihood of success. Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials and non-head-to-head analyses may not be predictive of future trial results. As such, we may not be able to successfully expand our drug portfolio, which could materially and adversely affect our future growth and prospects.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- We have incurred significant net losses and net operating cash outflows since our inception, and expect to continue to incur net losses and net operating cash outflows for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability. Potential [REDACTED] are at risk of losing substantially all of their [REDACTED] in our Shares.
- Our rights to develop and commercialize some of our drug candidates are subject to the terms and conditions of licenses granted to us by others.
- Even if we are able to commercialize any approved drug candidates, the drugs may become subject to national or other third-party reimbursement practices or unfavorable pricing regulations, which could materially and adversely affect our business.
- All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated and the approval process is usually lengthy, costly and inherently unpredictable. Any failure to comply with existing or future regulations and industry standards or any adverse actions by the drug-approval authorities against us could negatively impact our reputation and our business, financial condition, results of operations and prospects.
- We had net current liabilities and net liabilities during the Track Record Period, which may expose us to liquidity risk.
- We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

DEFINITIONS

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

“affiliate”	any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“Angel Investors”	Xu Ying (許瑩), Cao Wei (曹威), Liu Bing (劉兵), Chen Song (陳松), Li Mei (李玫), Xu Ping (徐萍), Song Chunsheng (宋春勝), Caroline Ann Merrifield and David Daniel Fleming and who are, other than Liu Bing (劉兵) (a former Director of our Company who resigned on June 11, 2021), Independent Third Parties
“Apogenix”	Apogenix AG
“Articles” or “Articles of Association”	the tenth amended and restated articles of association of our Company adopted by special resolution on [●] with effect from [REDACTED], as amended from time to time, a summary of which is set out in the section headed “Appendix III – Summary of the Constitution of Our Company and Cayman Companies Act” in this document
“associate”	has the meaning ascribed to it under the Listing Rules
“Audit Committee”	the audit committee of the Board
“BGI Co-win”	Nanjing BGI-Cowin No.1 Venture Investment Partnership (南京華大共贏一號創業投資企業(有限合夥)), a limited partnership established in the PRC on December 2, 2016, and Shenzhen BGI-Usum Venture Investment Centre (深圳華大渝商創業投資中心(有限合夥)), a limited partnership established in the PRC on July 18, 2017
“Board of Directors”, “Board” or “our Board”	our board of Directors
“Business Day”	any day (other than a Saturday, Sunday or public holiday) in Hong Kong on which banks in Hong Kong are open generally for normal banking business

DEFINITIONS

“BVI”	the British Virgin Islands
“CAGR”	compound annual growth rate
“CANbridge Beijing Equity Incentive Plan”	the equity incentive plan approved by the board of directors of CANbridge Life Sciences in April 2016
“CANbridge Biomed”	CANbridge Biomed Limited, a limited liability company incorporated under the laws of Hong Kong on March 31, 2014 and one of our Company’s subsidiaries
“CANbridge Shanghai”	CANbridge (Shanghai) Life Sciences Ltd. (北海康成(上海)生物科技有限公司), a limited liability company established under the laws of the PRC on June 22, 2016 and one of our Company’s subsidiaries
“CANbridge Life Sciences”	CANbridge Life Sciences Limited (北海康成(北京)醫藥科技有限公司), a limited liability company established under the laws of the PRC on June 12, 2012 and one of our Company’s subsidiaries
“CANbridge Pharma”	CANbridge Pharma Co., Ltd., a limited liability company established under the laws of Taiwan on October 5, 2019 and one of our Company’s subsidiaries
“Care Pharma Hongkong”	CANbridge Care Pharma Hongkong Limited (formerly known as Care Pharma Hongkong Limited), a limited liability company incorporated under the laws of Hong Kong on June 19, 2018 and one of our Company’s subsidiaries
“Care Pharma Shanghai”	Care Pharma Shanghai Ltd. (諾愛藥業(上海)有限公司), a limited liability company established under the laws of the PRC on January 19, 2018 and one of our Company’s subsidiaries
“Cayman Companies Act”	the Companies Act (2021 Revision) of the Cayman Islands, Cap. 22 (Law 3 of 1961), as amended or supplemented or otherwise modified from time to time

[REDACTED]

DEFINITIONS

[REDACTED]

“CEO”	the chief executive officer of our Company
“China” or “PRC”	the People’s Republic of China, which for the purpose of this document and for geographical reference only, excludes Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Companies (Winding Up and Miscellaneous Provisions) Ordinance”	the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Company”, “our Company” or “the Company”	CANbridge Pharmaceuticals Inc. (北海康成製藥有限公司), an exempted company incorporated in the Cayman Islands with limited liability on January 30, 2018
“Compliance Adviser”	Somerley Capital Limited
“connected person(s)”	has the meaning ascribed to it under the Listing Rules
“connected transaction(s)”	has the meaning ascribed to it under the Listing Rules

DEFINITIONS

“Conversion”	conversion of each Preferred Share to a Share on a one-to-one basis immediately upon completion of the Share Subdivision
“core connected person(s)”	has the meaning ascribed to it under the Listing Rules
“Corporate Governance Code”	the Corporate Governance Code and Corporate Governance Report set out in Appendix 14 to the Listing Rules
“CTX Pharma”	CTX Pharma Holdings Limited, a Shareholder of our Company an investment-holding entity wholly-owned by Dr. Xue
“Director(s)” or “our Director(s)”	the director(s) of our Company
“DNV Capital”	SACF GP I, L.P., a venture capital fund registered as an exempted limited partnership in the Cayman Islands since September 8, 2016, and Jumbo Hero Limited, an exempted company with limited liability incorporated under the laws of the British Virgin Islands on May 30, 2019
“Dr. Xue”	Dr. James Qun Xue, the founder, Chairman of the Board, executive Director and Chief Executive Officer of our Company
“EUSA Pharma”	EUSA Pharma Ltd.
“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the government of Hong Kong
“Family Trust”	JQX 2021 Gift Trust, a trust set up by Dr. Xue as settlor, the spouse of Dr. Xue as trustee and Dr. Xue’s family members as the beneficiaries
“GC Pharma”	formerly known as Green Cross Corporation
	[REDACTED]
“Greater China”	mainland China, Hong Kong, Macau and Taiwan

DEFINITIONS

[REDACTED]

“Group”, “our Group”, “we”,
“us” or “our”

our Company and its subsidiaries

“HK\$” or “Hong Kong dollars”
or “HK dollars” and
“HK cents”

Hong Kong dollars and cents respectively, the lawful
currency of Hong Kong

[REDACTED]

“Hong Kong” or “HK”

the Hong Kong Special Administrative Region of the
People’s Republic of China

[REDACTED]

“Stock Exchange”

The Stock Exchange of Hong Kong Limited

[REDACTED]

DEFINITIONS

[REDACTED]

“Independent Third Party(ies)”	any entity or person who is not a connected person of our Company or its subsidiaries, or any of their respective associates
“Industry Consultant” or “Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.

[REDACTED]

DEFINITIONS

“Janus”

Janus Henderson Biotech Innovation Master Fund Limited, a company limited by shares incorporated pursuant to the laws of the Cayman Islands on October 8, 2019, Janus Henderson Capital Funds Plc, a public limited company incorporated pursuant to the laws of the Republic of Ireland on 24 December 1999, Janus Henderson Global Life Sciences Fund, a portfolio of Janus Investment Fund, which was established pursuant to the laws of Massachusetts, United States on 24 November 1998, Janus Henderson Emerging Markets Fund, formerly, a series of Henderson Global Funds, which was established pursuant to the laws of Massachusetts, United States on December 31, 2010 and reorganized into Janus Investment Fund on June 5, 2017, Janus Henderson Investment Fund Series I – Janus Henderson Emerging Markets Opportunities Fund, a series of Janus Henderson Emerging Markets Opportunities Fund and an open-end investment company organized pursuant to the laws of the United Kingdom on February 1, 1987, and Janus Henderson Fund, a UCITS fund organized pursuant to the laws of Luxembourg on September 29, 2000

[REDACTED]

“Joint Sponsors”

Morgan Stanley Asia Limited and Jefferies Hong Kong Limited

DEFINITIONS

“Lapam Capital”	Beijing Longpan Health Medical Investment Centre L.P. (北京龍磐健康醫療投資中心(有限合夥)), a limited liability partnership established in the PRC on January 24, 2017, and Beijing Longpan Life Pharmaceutical Startup Investment Centre L.P. (北京龍磐生物醫藥創業投資中心(有限合夥)), a limited liability partnership established in the PRC on September 9, 2014
“Latest Practicable Date”	[September 7], 2021, being the latest practicable date for the purpose of ascertaining certain information contained in this document before its publication
“Leerink Partners”	SVB Leerink Holdings LLC, a company incorporated in Delaware, United States, on June 20, 2007, and Healthcare Innovation Investment Fund LLC (formerly known as Leerink Partners Co-Investment Fund, LLC), a limited liability company incorporated in Massachusetts, United States, on January 23, 2006
	[REDACTED]
“Listing Committee”	the listing sub-committee of the board of directors 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
“LogicBio”	LogicBio Therapeutics, Inc.
“Main Board”	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with the Growth Enterprise Market of the Stock Exchange

DEFINITIONS

“Memorandum” or “Memorandum of Association”	the tenth amended and restated memorandum of association of our Company adopted by special resolution on [●] with effect from the [REDACTED], as amended from time to time, a summary of which is set out in the section headed “Appendix III – Summary of the Constitution of Our Company and Cayman Companies Act” in this document
“MFDS”	South Korea Ministry of Food and Drug Safety
“Mirum”	Mirum Pharmaceuticals, Inc.
“MOFCOM”	the Ministry of Commerce of the PRC (中華人民共和國商務部)
“NDRC”	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
“NMPA”	National Medical Products Administration (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)
“Nomination and Corporate Governance Committee”	the nomination and corporate governance committee of the Board

[REDACTED]

DEFINITIONS

[REDACTED]

“Pierre Fabre”	Pierre Fabre Médicament SAS
“[REDACTED] RSU Scheme”	the RSU scheme adopted by our Company on [●] 2021, the principal terms of which are set out in “Statutory and general information – E. [REDACTED] RSU Scheme” in Appendix IV to this Document
“[REDACTED] Share Option Scheme”	the share option scheme adopted by our Company on [●] 2021, the principal terms of which are set out in “Statutory and general information – F. [REDACTED] Share Option Scheme” in Appendix IV to this Document
“PRC Legal Adviser”	King & Wood Mallesons, the PRC legal adviser of our Company
“Preferred Share(s)”	convertible preferred share(s) in the share capital of our Company, including Series A Preferred Shares, Series B Preferred Shares, Series C Preferred Shares, Series D Preferred Shares and Series E Preferred Shares
“[REDACTED] Equity Incentive Plan” or “2019 Equity Incentive Plan”	the 2019 equity incentive plan adopted by our Company on July 25, 2019, the principal terms of which are set out in the section headed “Appendix IV – Statutory and General Information – D. [REDACTED] Equity Incentive Plan” in this document
“[REDACTED] Investments”	the investments of approximately US\$269 million in aggregate made by the [REDACTED] Investors pursuant to the respective agreements, further information on which is set forth in the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments” in this document

DEFINITIONS

“[REDACTED] Investors” the Series A-1 Preferred Shareholders, the Series A-2 Preferred Shareholders, the Series B-1 Preferred Shareholders, the Series B-2 Preferred Shareholders, the Series C Preferred Shareholders, the Series D-1 Preferred Shareholders, the Series D-2 Preferred Shareholders, the Series D-3 Preferred Shareholders and the Series E Preferred Shareholders

[REDACTED]

“Principal Share Registrar” Ogier Global (Cayman) Limited

“Private Investors” Lu Ning (盧寧), Lai Chunbao (賴春寶), Qian Hui (錢輝), Xue Yintong (薛殷彤), Huang Wei (黃衛) and Ma Jikai (馬繼凱) and who are Independent Third Parties

“Privus” Privus Biologics, LLC

[REDACTED]

“Puma” Puma Biotechnology, Inc.

“QIB” a qualified institutional buyer within the meaning of Rule 144A

“Qiming Venture” Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P., each of which is an exempted limited partnership established in the Cayman Islands on March 13, 2014

“RA Capital” RA Capital Healthcare Fund, L.P., a limited partnership incorporated in Delaware, United States on September 13, 2004, RA Capital Nexus Fund, L.P., a limited partnership incorporated in Delaware, United States on February 19, 2019, and Blackwell Partners LLC – Series A, a series limited liability company incorporated in Delaware, United States, on November 3, 2014

“Regulation S” Regulation S under the U.S. Securities Act

DEFINITIONS

“Remuneration Committee”	the remuneration committee of the Board
“Reorganization”	the reorganization arrangements undertaken by our Group in preparation for the [REDACTED], the details of which are set out in the section headed “History, Reorganization and Corporate Structure – Reorganization” in this document
“RMB” or “Renminbi”	Renminbi, the lawful currency of China
“RSU”	restricted stock unit
“Rule 144A”	Rule 144A under the U.S. Securities Act
“SAIC”	the State Administration of Industry and Commerce of the PRC (中華人民共和國國家工商行政管理總局), which has been merged into the State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局)
“SAT”	the State Taxation Administration (國家稅務總局)
“Series A-1 Preferred Share(s)”	the series A-1 convertible preferred share(s) of our Company with a par value of US\$0.0001 per share, or the series A-1 convertible preferred share(s) of our Company with a par value of US\$0.00001 per share in the authorized share capital of the Company following the Share Subdivision, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series A-1 Preferred Shareholder(s)”	holder(s) of Series A-1 Preferred Shares of our Company
“Series A-2 Preferred Share(s)”	the series A-2 convertible preferred share(s) of our Company with a par value of US\$0.0001 per share, or the series A-2 convertible preferred share(s) of our Company with a par value of US\$0.00001 per share in the authorized share capital of the Company following the Share Subdivision, details of which are described in the section headed “History, Reorganization and Corporate Structure”

DEFINITIONS

“Series A-2 Preferred Shareholder(s)”	holder(s) of Series A-2 Preferred Shares of our Company
“Series B-1 Preferred Share(s)”	the series B-1 convertible preferred share(s) of our Company with a par value of US\$0.0001 per share, or the series B-1 convertible preferred share(s) of our Company with a par value of US\$0.00001 per share in the authorized share capital of the Company following the Share Subdivision, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series B-1 Preferred Shareholder(s)”	holder(s) of Series B-1 Preferred Shares of our Company
“Series B-2 Preferred Share(s)”	the series B-2 convertible preferred share(s) of our Company with a par value of US\$0.0001 per share, or the series B-2 convertible preferred share(s) of our Company with a par value of US\$0.00001 per share in the authorized share capital of the Company following the Share Subdivision, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series B-2 Preferred Shareholder(s)”	holder(s) of Series B-2 Preferred Shares of our Company
“Series C Preferred Share(s)”	the Series C-1 Preferred Share(s), the Series C-2 Preferred Share(s), the Series C-3 Preferred Share(s) and the Series C-4 Preferred Share(s)
“Series C Preferred Shareholder(s)”	holder(s) of Series C Preferred Shares of our Company
“Series C-1 Preferred Share(s)”	the series C-1 convertible preferred share(s) of our Company with a par value of US\$0.0001 per share, or the series C-1 convertible preferred share(s) of our Company with a par value of US\$0.00001 per share in the authorized share capital of the Company following the Share Subdivision, details of which are described in the section headed “History, Reorganization and Corporate Structure”

DEFINITIONS

“Series C-2 Preferred Share(s)”	the series C-2 convertible preferred share(s) of our Company with a par value of US\$0.0001 per share, or the series C-2 convertible preferred share(s) of our Company with a par value of US\$0.00001 per share in the authorized share capital of the Company following the Share Subdivision, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series C-3 Preferred Share(s)”	the series C-3 convertible preferred share(s) of our Company with a par value of US\$0.0001 per share, or the series C-3 convertible preferred share(s) of our Company with a par value of US\$0.00001 per share in the authorized share capital of the Company following the Share Subdivision, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series C-4 Preferred Shares”	the series C-4 convertible preferred share(s) of our Company with a par value of US\$0.0001 per share, or the series C-4 convertible preferred share(s) of our Company with a par value of US\$0.00001 per share in the authorized share capital of the Company following the Share Subdivision, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series C-4 Preferred Shareholders”	holder(s) of Series C-4 Preferred Shares of our Company
“Series D-1 Preferred Share(s)”	the series D-1 convertible preferred share(s) of our Company with a par value of US\$0.0001 per share, or the series D-1 convertible preferred share(s) of our Company with a par value of US\$0.00001 per share in the authorized share capital of the Company following the Share Subdivision, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series D-1 Preferred Shareholder(s)”	holder(s) of Series D-1 Preferred Shares of our Company

DEFINITIONS

“Series D-2 Preferred Share(s)”	the series D-2 convertible preferred share(s) of our Company with a par value of US\$0.0001 per share, or the series D-2 convertible preferred share(s) of our Company with a par value of US\$0.00001 per share in the authorized share capital of the Company following the Share Subdivision, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series D-2 Preferred Shareholder(s)”	holder(s) of Series D-2 Preferred Shares of our Company
“Series D-3 Preferred Share(s)”	the series D-3 convertible preferred share(s) of our Company with a par value of US\$0.0001 per share, or the series D-3 convertible preferred share(s) of our Company with a par value of US\$0.00001 per share in the authorized share capital of the Company following the Share Subdivision, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series D-3 Preferred Shareholder(s)”	holder(s) of Series D-3 Preferred Shares of our Company
“Series E Preferred Share(s)”	the series E convertible preferred share(s) of our Company with a par value of US\$0.0001 per share, or the series E convertible preferred share(s) of our Company with a par value of US\$0.00001 per share in the authorized share capital of the Company following the Share Subdivision, details of which are described in the section headed “History, Reorganization and Corporate Structure”
“Series E Preferred Shareholder(s)”	holder(s) of Series E Preferred Shares of our Company
“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

DEFINITIONS

“Share(s)”	ordinary share(s) in the share capital of our Company, each with a par value of US\$0.00001 immediately following the Share Subdivision and the Conversion
“Share Option(s)”	the share option(s) granted or to be granted pursuant to the terms and conditions of the [REDACTED] Equity Incentive Plan
“Shareholder(s)”	holder(s) of Shares
“Shareholders Agreement”	the eighth amended and restated shareholders agreement entered into between, among others, our Company and the [REDACTED] Investors dated May 7, 2021
“Sophisticated Investor(s)”	has the meaning ascribed to it under Guidance Letter HKEX-GL-92-18 issued by the Stock Exchange, and unless the context otherwise requires, refers to WuXi PharmaTech Healthcare Fund I L.P., WuXi AppTec (HongKong) Limited, RA Capital Health Fund, L.P., RA Capital Nexus Fund L.P., Blackwell Partners LLC – Series A, Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P.
“Share Subdivision”	the subdivision of each share in the Company’s issued and unissued share capital with par value of US\$0.0001 each into 10 shares of the corresponding class with par value of US\$0.00001 each
“SSVB Group”	SPD Silicon Valley Bank Co., Ltd. (浦發矽谷銀行有限公司), a Sino-foreign joint venture banking company established under the Laws of the PRC, and China Equities HK Limited, a private company limited by shares incorporated in Hong Kong on March 1, 2013
	[REDACTED]
“subsidiary(ies)”	has the meaning ascribed to it under the Listing Rules
“substantial shareholder(s)”	has the meaning ascribed to it under the Listing Rules
“Takeovers Code”	the Hong Kong Code on Takeovers and Mergers

DEFINITIONS

“TF Capital”	Maxtec Group Limited, a limited company incorporated in the British Virgin Islands with limited liabilities on September 5, 2014, and Mayfair Holdings Limited, a limited company incorporated in the British Virgin Islands with limited liabilities on October 18, 2017
“TigerMed”	Hangzhou Tigermed Consulting Co., Ltd. (杭州泰格醫藥科技股份有限公司), a company established in the PRC on December 15, 2004 whose shares are listed on the Stock Exchange (stock code: 3347.HKSE) and on the ChiNext market of the Shenzhen Stock Exchange (stock code: 300347.SZSE), and Hongkong Tigermed Co., Limited, a private company limited by shares incorporated in Hong Kong on September 14, 2011
“Track Record Period”	the periods comprising the two years ended December 31, 2019 and 2020 and the six months ended June 30, 2021
“UMass”	University of Massachusetts Medical School

[REDACTED]

“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“US\$” or “U.S. dollars”	United States dollars, the lawful currency of the United States
“U.S. Securities Act”	the United States Securities Act of 1933, as amended

[REDACTED]

DEFINITIONS

“Wuxi AppTec”	WuXi AppTec Co., Ltd. (無錫藥明康德新藥開發股份有限公司), a joint stock company with limited liability incorporated in the PRC and whose H shares are listed on the Stock Exchange (stock code: 2359) and A shares are listed on the Shanghai Stock Exchange (stock code: 603259), and, where the context so requires, any of its subsidiaries and affiliates. For details of shareholding of Wuxi AppTec in our Company, please see the section headed “Substantial Shareholders” in this document
“WuXi Biologics”	WuXi Biologics Ireland Limited
“Yuanming Capital”	Shenzhen Qianhai Yuanming Medical Industry Investment Fund L.P. (深圳前海元明醫療產業投資基金(有限合夥)), a limited partnership established in the PRC on March 10, 2017, and Yuanming Healthcare Holdings Limited, a limited liability company incorporated in the British Virgin Islands on December 27, 2017
“Yuhao”	Yuhao Holdings Limited, a BVI business company incorporated in the British Virgin Islands on April 11, 2018, and Yuhao HK Limited, a private company limited by shares incorporated in Hong Kong on February 4, 2019
“%”	per cent

In this document:

- *Unless otherwise expressly stated or the context otherwise requires, all data in this document is as of the date of this document.*
- *Unless otherwise specified, all references to any shareholdings in our Company assume that the [REDACTED] has not been exercised.*
- *The English names of the PRC entities, PRC laws or regulations, and the PRC governmental authorities referred to in this document are translations from their Chinese names and are for identification purposes only. If there is any inconsistency, the Chinese names shall prevail.*

GLOSSARY OF TECHNICAL TERMS

This glossary contains definitions of certain terms used in this document in connection with us and our business. Some of these may not correspond to standard industry definitions.

“6MWT”	The six-minute walk test (6MWT), a functional test that measures the distance an individual is able to walk over a total of six minutes on a hard, flat surface. The goal is for the individual to walk as far as possible in six minutes
“AAV”	Adeno-associated virus which has emerged as an attractive vector for gene therapy to promote sustained gene expression in a variety of tissues such as muscle, eye, brain, liver, and lung
“AAV capsid platform”	A tool that applies specific virus to investigate targeted treatment
“aHUS”	Atypical Hemolytic Uremic Syndrome
“ALGS”	Alagille syndrome, is a rare genetic disorder that can affect multiple organ systems of the body including the liver, heart, skeleton, eyes and kidneys
“AMD”	Acid maltase deficiency, also called Pompe Disease or Glycogen Storage Disease type II
“ANCOVA”	Analysis of covariance
“APG101”	Former name of CAN008 before in-licensing
“ASBT”	Apical sodium-dependent bile acid transporter
“ASGCT”	American Society of Gene & Cell Therapy
“ATG-012”	The initial scaled-down batch of CAN106
“BA”	Biliary atresia
“Biomarker study”	A Study aims to achieve the streamlining of drug discovery and development by investigating the biomarkers
“BsAb”	Bispecific antibody

GLOSSARY OF TECHNICAL TERMS

“C5”	Complement component 5, a protein that is encoded by the C5 gene
“CD95”	FasR/apoptosis antigen 1 (APO-1)
“CD95L”	CD95 ligand/FasL
“CDE”	Center for Drug Evaluation
“CDMO”	Contract Development Manufacture Organization
“cGMP”	Current Good Manufacture Practices
“CHARD”	China’s Alliance for Rare Disease (中國罕見病聯盟), a medical research alliance dedicated to the study of rare diseases in China
“CHO”	Chinese hamster ovary cell
“CMC”	Chemistry, Manufacturing, and Controls
“CNS”	Central nervous system
“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
“CRISPRs”	Clustered Regularly Interspaced Short Palindromic Repeats
“CRO”	Contract research organization
“DG44”	A CHO-DG44 subcell line derived from the original CHO-K1 cell line
“DLT”	Dose-limiting toxicity
“DMD”	Duchenne Muscular Dystrophy
“DSMB”	Data and Safety Monitoring Board
“EC”	Ethics committees

GLOSSARY OF TECHNICAL TERMS

“ELISA”	Enzyme-linked immunosorbent assay, is a commonly used analytical biochemistry assay
“EMA”	European Medicines Agency
“ERT”	Enzyme replacement therapy
“EURORDIS”	European Organization for Rare Diseases
“FcRn”	Neonatal Fc receptor, functions as a recycling or transcytosis receptor that is responsible for maintaining IgG and albumin in the circulation
“FD”	Fabry disease
“FDA” or “US FDA”	The United States Food and Drug Administration, a federal agency of the Department of Health and Human Services
“FGF23”	Fibroblast growth factor 23
“GAA”	Acid α -Glucosidase
“GAG”	Glycosaminoglycans
“GBA”	The gene encoding beta-glucosylceramidase/beta-glucocerebrosidase
“GBM”	Glioblastoma multiforme
“GC”	Green Cross Corporation
“GCase”	Glucocerebrosidase
“GD”	Gaucher Disease
“GLA”	Alpha-galactosidase
“Glycosylation”	The reaction in which a carbohydrate is attached to a hydroxyl or other functional group of another molecule in order to form a glycoconjugate. It usually refers to an enzyme-catalysed reaction, whereas glycation may refer to a non-enzymatic reaction in biology

GLOSSARY OF TECHNICAL TERMS

“gMG”	Generalized myasthenia gravis
“GOI”	Gene of interest
“HER2”	Human epidermal growth factor receptor 2
“HSA”	Health Sciences Authority, the national authority regulating health products in Singapore
“HSCT”	Hematopoietic stem cell transplantation
“humanized”	Humanized monoclonal antibodies refer to antibodies that are constructed by combining the complementarity-determining regions (CDRs) of the monoclonal antibody with human framework and constant regions, in which the human framework regions were chosen to maximize homology with the monoclonal antibody sequence
“ICONIC”	A Phase 2b placebo-controlled randomized drug withdrawal clinical trial on maralixibat conducted for ALGS by Mirum
“IDS” or “rhIDS”	Iduronate-2-sulfatase
“INDIGO”	A Phase 2 study on maralixibat conducted for PFIC by Mirum
“IND”	Investigational new drug or investigational new drug application, also known as clinical trial application in China
“LSD”	Lysosomal storage disorders
“Lyso-GL-1”	Glucosylsphingosine, the deacylated form of glucosylceramide (GL1)
“M6P”	Mannose-6-phosphate
“mAb”	Monoclonal antibodies
“MAC”	Membrane attack complex
“MAD”	Multiple ascending dose

GLOSSARY OF TECHNICAL TERMS

“MG”	Myasthenia Gravis
“MGMT”	O-6-methylguanine-DNA methyltransferase
“mITT”	Modified Intention to Treat
“MMA”	Methylmalonic acidemia
“MPS disorder”	Mucopolysaccharidosis, a group of inherited metabolic disorders in which the body is unable to properly breakdown mucopolysaccharides (long linear polysaccharides consisting of repeating disaccharide units)
“MPS II” or “Hunter Syndrome”	Mucopolysaccharidosis type II, the most prevalent MPS disorder, occurring in an estimated 1.07/100,000 in newborn
“NHFPC”	National Health and Family Planning Commission (國家衛生和計劃生育委員會), a cabinet-level executive department under the State Council which is responsible for providing information, raising health awareness and education, family planning, ensuring the accessibility of health services, monitoring the quality of health services provided to citizens and visitors in China, which has been merged into the National Health Commission (國家衛生健康委員會)
“NIFDC”	National Institutes for Food and Drug Control
“NMO”	Neuromyelitis Optica
“NMOSD”	Neuromyelitis Optica Spectrum Disorders
“NMPA”	The National Medical Products Administration (國家藥品監督管理局), which is in charge of comprehensive supervision on the safety management of food, health and cosmetics and is the competent authority of drug regulation in China
“NOD”	Nonobese diabetic
“NRDL”	National Reimbursement Drug List

GLOSSARY OF TECHNICAL TERMS

“ODD”	Orphan drug designation
“PCT”	Patent Cooperation Treaty
“PFIC”	Progressive familial intrahepatic cholestasis
“PFS”	Progression-free survival
“PHEX”	Phosphate Regulating Endopeptidase Homolog, X-Linked
“PhIRDA”	China Pharmaceutical Innovation and Research Development Association
“PNH”	Paroxysmal nocturnal hemoglobinuria
“PD”	Pharmacodynamics
“PK”	Pharmacokinetics
“PRDL”	Provincial Reimbursement Drug List
“PTRS”	Probability of technical and regulatory success
“RBC”	Red blood cells
“rhGAA”	Recombinant human acid α -glucosidase
“RP2D”	Recommended phase 2 dose
“rRt”	Reirradiation
“RT”	Radiation therapy
“SAE”	Serious adverse event
“SCID”	Severe combined immunodeficiency
“sL65”	A novel liver-tropic AAV capsid for use in gene editing and gene therapy, which can be a potential treatment of serious diseases of the liver
“SMA”	Spinal Muscular Atrophy

GLOSSARY OF TECHNICAL TERMS

“SMC”	Safety monitoring committee
“SRC”	Scientific Review Committee
“SRT”	Substrate reduction therapy
“TEAE”	Treatment emergent adverse events
“TALENS”	Transcription Activator-like Effector Nucleases
“TFDA”	Taiwan Food and Drug Administration (食品藥物管理署), who is in charge of overseeing food, drug, and medical device safety and quality
“TMDD”	Target-mediated drug disposition
“TMZ”	Temozolomide
“TNF”	Tumor necrosis factor
“t-test”	Student’s t-test, the t-test is any statistical hypothesis test in which the test statistic follows a Student’s t-distribution under the null hypothesis
“TTF”	Tumor Treating Fields
“uGAGs”	Urine Glycosaminoglycans
“UGIB”	Upper gastrointestinal bleeding
“XLH”	X-linked hypophosphatemia
“ZFNs”	Zinc Finger Nucleases

FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements that relate to our current expectations and views of future events. These forward-looking statements are contained principally in the sections entitled “Summary”, “Risk Factors”, “Future Plans and Use of [REDACTED]”, “Financial Information”, “Industry Overview” and “Business”. These statements relate to events that involve known and unknown risks, uncertainties and other factors, including those listed under “Risk Factors”, which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, these forward-looking statements can be identified by words or phrases such as “may”, “will”, “expect”, “anticipate”, “aim”, “estimate”, “intend”, “plan”, “believe”, “potential”, “continue”, “is/are likely to” or other similar expressions. These forward-looking statements include, among other things, statements relating to:

- our operations and business prospects;
- our financial conditions and our operating results and performance;
- industry trends and competition;
- our product candidates under development or planning;
- our strategies and initiatives, business plans, objectives and goals;
- our ability to attract users and further enhance our brand recognition;
- the amount and nature of, and potential for, future development of our business;
- general political and economic conditions; and
- changes to regulatory and operating conditions in the markets in which we operate.

These forward-looking statements are subject to risks, uncertainties and assumptions, some of which are beyond our control. In addition, these forward-looking statements reflect our current views with respect to future events and are not a guarantee of future performance. Actual outcomes may differ materially from the information contained in the forward-looking statements as a result of a number of factors, including, without limitation, the risk factors set forth in the section entitled “Risk Factors.”

FORWARD-LOOKING STATEMENTS

The forward-looking statements made in this document relate only to events or information as of the date on which the statements are made in this document. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this document completely and with the understanding that our actual future results or performance may be materially different from what we expect.

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

RISK FACTORS

An [REDACTED] in our Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an [REDACTED] in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition and results of operations. In any such case, the market price of our Shares could decline, and you may lose all or part of your [REDACTED]. These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as at the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in “Forward-looking Statements” in this document.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) key risks relating to our business, financial position and need for additional capital, and general operations, (ii) other risks relating to our business, comprising (a) risks relating to our financial position and need for additional capital; (b) risks relating to our business; (c) risks relating to extensive government regulations; (d) risks relating to our intellectual property rights; (e) risks relating to our reliance on third parties; (f) risks relating to our general operations; (g) risks relating to our doing business in China; and (h) 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, FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL, AND GENERAL OPERATIONS

The actual market size of our drug candidates might be smaller than expected and our future approved 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.

Our future approved 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 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 drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our drug candidates are approved;

RISK FACTORS

- physicians, hospitals, cancer treatment centers and patients considering our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our 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 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 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 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 drug candidates, are more cost-effective or render our drug candidates obsolete.

Our business and financial prospects depend substantially on the success of our clinical stage and pre-clinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain relevant regulatory approvals or achieve their commercialization, or if we experience significant delays in any of the foregoing, our business and profitability may be adversely affected.

Our ability to generate revenue and realize profitability is dependent on the successful completion of the development of our drug candidates, obtaining necessary regulatory approvals, and manufacturing and commercializing our drug candidates. We have invested a significant portion of our efforts and financial resources in the development of our existing drug candidates, and we expect to continue to incur substantial and increasing expenditures for the development and commercialization of our drug candidates.

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The success of our 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 clinical trials and other studies;
- obtaining sufficient supplies of any drug products that are used in combination with our drug candidates, competitor drugs or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- receipt of regulatory approvals;
- establishing sufficient commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- the performance by contract research organizations (“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 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 defend 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 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 drug candidates following regulatory approval.

RISK FACTORS

In addition, our gene therapy assets are based on novel technologies and represent emerging approaches to treat rare diseases that face significant development and regulatory challenges. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays in obtaining approval for and/or successfully commercializing our drug candidates, which would materially and adversely affect our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

We may not be able to identify, discover or in-license new drug candidates, and may allocate our limited resources to pursue a particular candidate or indication and fail to capitalize drug candidates or indications that may later prove to be more profitable, or for which there is a greater likelihood of success. Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials and non-head-to-head analyses may not be predictive of future trial results. As such, we may not be able to successfully expand our drug portfolio, which could materially and adversely affect our future growth and prospects.

Historically, we have in-licensed a number of drug candidates to develop and commercialize them in the APAC region or globally. These assets are important for our portfolio and in-licensing will remain important for our portfolio strategy. We cannot guarantee that we will be able to successfully identify and in-license new drug candidates with high potential for a number of reasons, including but are not limited to:

- the research methodology used may not be successful in discovering new drug candidates or formulations or developing additional potential indications;
- there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocol elements;
- potential drug candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

In addition, research programs to discover new drug candidates and new formulations or pursue the development of our drug candidates for additional indications require substantial technical, financial and human resources. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the

RISK FACTORS

clinical trial process. The results of pre-clinical studies, early clinical trials of our drug candidates and non-head-to-head analyses may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the 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. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen, other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such 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 positive results in earlier trials. Our future clinical trial results may thus not be favorable, which may materially and adversely affect our business and financial prospects.

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

The timely completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. Our products and product candidates target rare diseases, and the size and nature of the patient population for rare disease may be a challenge for us to enroll a sufficient number of patients. In addition, patient eligibility criteria defined in the protocols could be strict and it might increase the chances that we are not able to recruit and retain suitable patients for our clinical trials.

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

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We have incurred significant net losses and net operating cash outflows since our inception, and expect to continue to incur net losses and net operating cash outflows for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability. Potential [REDACTED] are at risk of losing substantially all of their [REDACTED] in our Shares.

Investment in pharmaceutical drug development is highly speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We continue to incur significant expenses related to our ongoing operations. We have incurred losses in each period since our inception. In 2019, 2020 and the six months ended June 30, 2021, we had a loss for the year/period of RMB217.7 million, RMB846.0 million and RMB344.2 million, respectively. As of December 31, 2019 and 2020 and June 30, 2021, we had an accumulated deficit attributable to owners of our Company of RMB1,004.1 million, RMB1,850.1 million and RMB2,194.3 million, respectively. Substantially all of our losses incurred during the Track Record Period resulted from costs incurred in connection with our research and development programs, administrative expenses and fair value loss on convertible redeemable preferred shares.

We expect to continue to incur losses for the foreseeable future, and we expect our operating losses to increase as we continue to expand our development of, and seek regulatory approvals for, our drug candidates, and continue to build up our manufacturing capability, commercialization and sales workforce in anticipation of the future roll-out of our drug candidates. Typically, it takes many years to develop one new drug from the drug-discovery stage to when it is available for treating patients. In addition, we will continue to incur costs associated with operating as a public company and in support of our growth as a development-stage or commercial-stage biopharmaceutical company. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of commercializing any approved products, our ability to generate revenues, and the timing and amount of milestones and other payments we make or receive with or through arrangements with third parties. If any of our drug candidates fails in clinical trials or does not gain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. In addition, we experienced a decrease in the average selling price of certain of our commercialized products during the Track Record Period due to our market expansion plan and active participation in the patient assistance programs. We may experience a decrease in average selling price of other newly-commercialized products in the future due to our marketing strategies and market condition of the region we sell in, which may have an adverse effect on our profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations. A decline in the value of our Company may also cause you to lose substantially all or part of your [REDACTED].

RISK FACTORS

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

All jurisdictions in which we intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We intend to focus our activities in China while pursuing global opportunities, particularly in the APAC region and the United States. These geopolitical areas all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. However, there are differences in the regulatory regimes – some minor, some significant – that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in each of these regions.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure 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 drug 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, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any occurrence of the foregoing could therefore materially and adversely affect our business, financial condition, results of operations and prospects. The regulatory approval processes of the NMPA, FDA, TFDA, EMA, HSA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our drug candidates in our targeted markets, our business will be substantially harmed.

The time required to obtain approval by the NMPA, FDA, TFDA, EMA, HSA, and other comparable regulatory authorities is unpredictable but typically takes 10-15 years following the commencement of pre-clinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities.

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Our drug candidates could fail to receive regulatory approval for many reasons, including:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that a drug candidate is safe and effective or, if it is a biologic, that it is safe, pure and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from pre-clinical studies or clinical trials;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; 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.

The NMPA, FDA, TFDA, EMA, HSA or a comparable regulatory authority may require more information, including additional pre-clinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. Additionally, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in various jurisdictions could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. While we plan to leverage our Collaboration Partners' data and FDA approvals to obtain approvals in other jurisdictions, we cannot assure you that we can also satisfy all regulatory requirements. If we experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates, the commercial prospects of that drug candidate will be harmed, and our ability to generate product sales revenues from any of those drug candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and

RISK FACTORS

generate related revenues for that drug candidate. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. Any of these occurrences may materially and adversely affect our business, financial condition and prospects.

Uncertainties or failures of the clinical trials of our product candidates may have a material and adverse effect on our business operations.

Situations surrounding clinical trials are dynamic and subject to changes. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including but not limited to:

- regulators or ethics committees may not authorize us or our investigators to commence a clinical trial;
- our inability to reach agreements on acceptable terms with prospective CROs/SMOs and hospitals as trial centers, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs/SMOs and hospitals as trial centers;
- clinical trials of our product candidates may fail to demonstrate the efficacy and safety as anticipated, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our product development programs;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics, a finding that participants are being exposed to unacceptable health risks or reasons outside of our control, such as occurrences of epidemics like the outbreak of COVID-19; and
- the initial or interim results of the clinical trial may not be predictive of the final results.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our product candidates if applicable, the commercial prospects of that product candidate will be harmed, and our ability to generate product sales revenues from any of those product candidates will be weakened. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that candidate. Any of these occurrences may harm our business, financial condition and prospects significantly.

RISK FACTORS

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

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development, manufacture or commercialization of our drug candidates and certain of these third parties from which we have been granted licenses themselves rely on licenses from other third parties. These and other licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use or in all territories in which we may wish to develop or commercialize our future approved drugs. As a result, we may not be able to develop, export or sell our drug products outside of the fields or territories as stipulated by the collaboration agreements or prevent competitors from developing and commercializing competitive drug products in territories included in all of our licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the drug candidates that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensing partners fail to prosecute, maintain, enforce or defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are subject to such licensed rights could be adversely affected.

Our licensing partners may have relied on third-party consultants or collaborators or on funds from third parties, or on upstream licenses from third parties, such that our licensing partners are not the sole and exclusive owners of the intellectual property rights we in-license. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensing partners might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize drug products covered by these license agreements. If any of our licensing partners goes bankrupt, some or all of our rights under the licensing agreements may be terminated during the bankruptcy proceeding. For details, see "Business-Collaboration and Licensing Arrangements." As such, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensing partners in a manner that may be more favorable to the licensing partners, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

RISK FACTORS

Even if we are able to commercialize any approved drug candidates, the drugs may become subject to national or other third-party reimbursement practices or unfavorable pricing regulations, which could materially and adversely affect our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. In some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug or negatively impact our revenues.

Our ability to commercialize any approved drug candidates successfully will also 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 payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

For example, 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 China's National Drug Catalog for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List, the NRDL, or provincial or local medical insurance catalogues for the Provincial Reimbursable Drug List, the PRDL, regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that any of our future approved drug candidates will be included in the NRDL or the PRDL.

If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL or the PRDL, our revenue from commercial sales would be highly dependent on patient self-payment, which can make our products less competitive. Additionally, even if the Ministry of Human Resources and Social Security of the PRC or any of its local counterparts were to accept our application for the inclusion of products in the NRDL or the PRDL, our potential revenue from the sales of these products could still decrease as a result of the significantly lowered prices we may be required to charge for our products to be included in the NRDL or the PRDL.

Increasingly, third-party payors 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 candidate 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 candidate that we commercialize. Obtaining or maintaining reimbursement for approved drug candidates 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 candidate that we in-license or successfully develop.

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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, TFDA, EMA, HSA 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 payors 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 payors for any future approved drug candidates could have a material adverse effect on our business, operating results and financial condition.

We intend to seek approval to market our drug candidates in China and other jurisdictions. In China the pricing of drugs is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Market acceptance and sales of any of our future approved drug candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for drugs, and may be affected by existing and future health care reform measures.

If we and our licensing partners are unable to obtain and maintain adequate patent and other intellectual property protection for our drug candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our drug candidates 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 the drug candidates and technology that we consider commercially important by filing patent applications in China 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 and Hong Kong for our Core Product. For further information on our patent portfolio, see “Business – Intellectual Property.” If we or our licensors are unable to obtain and maintain patent and other intellectual property protection with respect to our drug candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed.

RISK FACTORS

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.

It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, 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 were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Furthermore, China and, 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, third parties may be granted a patent relating to a technology which we invented.

In addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the State Intellectual Property Office, or SIPO, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold may be challenged, narrowed, circumvented, or invalidated by third parties. In addition, the patent

RISK FACTORS

position of biopharmaceutical and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Furthermore, although various extensions may be available, the life of a patent and the protection it affords is limited. 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 and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Our issued patents for our drug candidates are expected to expire on various dates as described in “Business – Intellectual Property” of this document. Upon the expiration of these patents, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Additionally, patent rights we own currently or in the future or may license in the future may be subject to a reservation of rights by one or more third parties.

We may not be able to protect our intellectual property rights throughout the world or prevent unfair competition by third parties.

Filing, prosecuting, maintaining and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some non-U.S. countries can have a different scope and strength. In addition, the laws of certain non-U.S. countries do not protect intellectual property rights to the same extent as the laws of the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions or from selling or importing drugs made using our inventions in all countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and, further, may export otherwise infringing drugs to other countries where we have patent protection, but where enforcement rights are relatively weaker. 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.

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We currently have trademark applications pending in China, the United States and other jurisdictions, any of which may be the subject of a governmental or third-party objection, which could prevent the registration of the same. 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, 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.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including China. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions 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. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us.

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 significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

As a result, we may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful. Patent rights relating to our drug candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable non-U.S. authority.

RISK FACTORS

We face substantial competition and our competitors may discover, develop or commercialize competing drugs earlier or more successfully than we do.

The development and commercialization of new drugs is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies worldwide. There are a number of large pharmaceutical and biopharmaceutical companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of rare diseases, cancer or autoimmune diseases or other indications for which we are developing our drug candidates. Some of these competitors have greater resources and expertise than us. 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. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

Competition in therapeutic areas such as oncology and rare diseases to which our Core Products and most of our other pipeline assets belong is fierce given the abundance of existing competing drugs and drug candidates that continue to increase competition in the market. 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 of the drugs that we may develop or commercialize. Our competitors also may obtain approval from the NMPA, FDA, TFDA, EMA, HSA 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 the 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.

RISK FACTORS

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We had net current liabilities and net liabilities during the Track Record Period, which may expose us to liquidity risk.

While we had net current assets of RMB282.9 million and RMB379.5 million as of December 31, 2020 and June 30, 2021, we had net current liabilities of RMB5.8 million as of December 31, 2019. For details, see “Financial Information.” A net current liabilities position may expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources including the [REDACTED], and/or other sources such as external debt, which may not be available on terms favorable or commercially reasonable to us or at all.

We also had net liabilities of RMB990.6 million, RMB1,745.9 million and RMB2,064.8 million as at December 31, 2019, 2020 and June 30, 2021, respectively, mainly due to the convertible redeemable preferred shares which were issued through several rounds of financing arrangements and are measured at fair value as at December 31, 2019, 2020 and June 30, 2021 as liabilities in the consolidated statements of financial position. For details, see “Financial Information – Discussion of Certain Selected Items from the Consolidated Statements of Financial Position”. Our Preferred Shares will automatically convert into ordinary shares upon [REDACTED], at which time we expect to reclassify them from liabilities to equity and, accordingly, turn into net asset position. However, there can be no assurance that we will not experience liquidity problems in the future.

Any difficulty or failure to meet our liquidity needs as and when needed may have a material adverse effect on our business, financial condition, results of operations and prospects.

If we determine our intangible assets to be impaired, our results of operations and financial condition may be adversely affected.

As of June 30, 2021, we had intangible assets of RMB54.9 million which comprised of RMB54.6 million related to patents and licenses and RMB0.2 million related to software. Our intangible assets are primarily related to the patents and licenses we in-licensed from our collaboration partners. The value of intangible assets is based on a number of assumptions made by the management. For a detailed discussion on the intangible assets, see Note 15 to the Accountants’ Report in Appendix I to this document. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, we may be required to have a significant decrease in the value of our intangible assets and record a significant impairment loss. Furthermore, our determination on whether intangible assets are impaired requires an estimation of the carrying amount and recoverable amount of an intangible asset.

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If the carrying amount exceeds its recoverable amount, our other intangible assets may be impaired. The impairment of intangible assets could have a material adverse effect on our business, financial condition and results of operations. For more information regarding our impairment policy in relation to intangible assets, see Note 2.4 “Summary of Significant Accounting Policies – Intangible assets (other than goodwill)” and Note 3 “Significant Accounting Judgments and Estimates – Impairment of non-financial assets (other than goodwill)” to the Accountants’ Report in Appendix I to this document.

We had net operating cash outflow during the Track Record Period.

We had net cash used in operating activities of RMB126.2 million, RMB151.6 million and RMB361.2 million for the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, respectively. While we believe we have sufficient working capital to fund our current operations, we expect that we may continue to experience net cash outflows from our operating activities for the foreseeable future. If we are unable to maintain adequate working capital, we may default on our payment obligations, be unable to meet our capital expenditure requirements, be forced to scale back our operations, and/or experience other negative impacts on our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

We may need additional capital to meet our operating cash requirements, and financing may not be available on terms acceptable to us, or at all.

We believe our current cash and cash equivalents and the estimated net [REDACTED] from the [REDACTED] will be sufficient to meet our anticipated cash needs for at least the next 12 months from the date of this document. We may, however, require additional cash resources to meet our continued operating cash requirements in the future, especially to fund our research and development activities. Our cash operating costs mainly consist of (i) research and development costs including employee costs, third party contracting costs, direct clinical trial expenses and others, and (ii) workforce employment costs. Employee costs consist of employees’ salaries, benefits, allowances and performance related bonus. Third-party contracting costs represent the expenses relating to our pre-clinical and clinical research and development outsourcing activities. Direct clinical trial expenses represent costs incurred directly from our clinical trials. Others mainly include experimental material costs, rental expenses, traveling expenses and expenses related to intellectual property rights. Workforce employment costs represent total non-R&D staff costs mainly including salaries and bonus. For the six months ended June 30, 2021, we incurred total cash operating costs of RMB376.8 million. We expect our cash operating costs for the rest of 2021 will increase significantly in light of our expanding clinical trial programs. If the financial resources available to us after the [REDACTED] are insufficient to satisfy our cash requirements, we may seek additional funding through equity offerings, debt financings, collaborations and licensing arrangements. It is uncertain whether financing will be available in the amounts or on terms acceptable to us, if at all. If we were not able to obtain additional capital to meet our cash requirements in the future, our business, financial condition, results of operations and prospects could be materially and adversely affected.

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

We are a China-based, rare disease-focused biopharmaceutical company committed to the research, development and commercialization of life-changing therapeutics and our predecessor CANbridge Life Sciences Limited was founded in 2012. Our operations to date have focused on organizing and staffing, business planning, raising capital, establishing our intellectual property portfolio, and conducting pre-clinical studies and clinical trials of our drug candidates. As of the Latest Practicable Date, we had three products approved for commercial sale and had started to generate revenue from product sales. Our limited operating history, particularly in light of the rapidly evolving biopharmaceutical industry, may make it difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other business uncertainties. If we do not address these business uncertainties and difficulties successfully, our business will suffer. These risks may cause potential [REDACTED] to lose substantially all or part of their [REDACTED].

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

Our drug candidates will require the completion of clinical development, regulatory review, significant marketing efforts and substantial investment before they can provide us with product sales revenue. Our operations have consumed substantial amounts of cash since inception. Our operating activities used RMB126.2 million, RMB151.6 million and RMB361.2 million of net cash during the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, respectively. We expect to continue to spend substantial amounts on preclinical research, advancing the clinical development of our drug candidates, and launching and commercializing any approved drug candidates for which we receive regulatory approval. Our existing cash and cash equivalents may not be sufficient to enable us to complete all development or commercially launch all of our current drug candidates for the currently anticipated indications and to invest in additional research and development programs. Accordingly, we will require further funding through public or private offerings, debt financing, collaboration, and licensing arrangements or other sources. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our drug candidates;
- the costs related to preclinical research and early development of additional drug candidates;

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- the cost and timing of development and completion of commercial-scale internal or outsourced manufacturing activities;
- the number and characteristics of drug candidates that we may develop;
- 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 or pay to our current or future collaborators;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future development of other pipeline drug candidates; and
- our headcount growth and associated costs.

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. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. Our inability to obtain additional funding when we need it could materially and adversely affect our business.

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

We adopted the 2019 Equity Incentive Plan for the benefit of our employees (including directors) and non-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 further details, please see the section headed “Appendix IV – Statutory and General Information – D. [REDACTED] Equity Incentive Plan” in this document. For the years ended 2019 and 2020, and the six months ended June 30, 2021, we incurred share-based compensation of RMB16.7 million, RMB14.7 million and RMB6.7 million, respectively. To further incentivize our employees and non-employees to contribute to us, we may grant additional share-based compensation in the future. Issuance of additional Shares with respect to such share-based payment may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payment may also increase our operating expenses and therefore have a negative effect on our financial performance.

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Our results of operations, financial condition and prospects may be adversely affected by fair value changes in our convertible redeemable preferred shares, convertible loan and derivative financial instruments at fair value through profit or loss.

The derivative financial instruments represented warrants issued by the Company to the holders who will be entitled to exercise the warrants in exchange for the Company’s Preferred Shares during the Track Record Period. The derivative financial instruments issued to investors were not traded in an active market and the respective fair value is determined by using valuation techniques. The prior transaction method under market approach was used to determine the fair value of the total equity value of our Company and the equity allocation model was adopted to determine the fair value of the derivative financial instruments. The Group applied the back-solve method to determine the underlying equity value of the Company and adopted the option-pricing method and equity allocation model to determine the fair value of the warrants. Key valuation assumptions used to determine the fair value of the preferred shares, the convertible loan included volatility and the exit plan of the investors. The valuation of our convertible redeemable preferred shares is subject to uncertainty due to the various assumptions, please refer to the paragraphs headed “Financial Information – Description of Selected Components of Statements of profit or loss – Fair Value Changes” and Note 25, 26 and 33 of the Accountant’s Report set out in Appendix I to this document for more details. Any change in the assumptions may lead to different valuation results and, in turn, changes in the fair value of these financial instruments issued to investors.

During the Track Record Period, we issued convertible redeemable preferred shares, which are designated as financial liabilities. For the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, we realized net fair value changes in convertible redeemable preferred shares of RMB73.7 million, RMB591.4 million and RMB21.8 million, respectively. We expect to recognize additional loss from the fair value changes of the convertible redeemable preferred shares after June 30, 2021 to the [REDACTED]. After the automatic conversion of the convertible redeemable preferred shares into Shares upon the [REDACTED], which will result in a net asset position, we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable preferred shares in the future. If we continue to incur such fair value losses, our results of operations, financial condition and prospects may be adversely affected.

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

During the Track Record Period, we invested in financial products which represent wealth management products issued by banks in the PRC. 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, 2018, 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

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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 or losses, 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 stable and 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.

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 the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that may adversely affect your rights as a holder of our Shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could 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, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our Shares to decline. In the event that 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 on unfavorable terms our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future arrangements when we might be able to achieve more favorable terms.

RISKS RELATING TO OUR BUSINESS

Risks Relating to the Pre-Clinical and Clinical Development of Our Drug Candidates

If clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or 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. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including but not limited to: regulators, institutional review boards or

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ethics committees not authorizing us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; manufacturing issues relating to our third-party CDMOs or after we establish our own facilities, including problems with manufacturing, supply quality, compliance with good manufacturing practice, or GMP, or obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial; clinical trials of our drug candidates producing negative or inconclusive results, and additional clinical trials or abandoning drug development programs being required; the number of patients required for clinical trials of our drug candidates being larger than we anticipate, enrollment being insufficient or slower than we anticipate, or patients dropping out at a higher rate than we anticipate; our third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; our having to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks; the cost of clinical trials of our drug candidates being greater than we anticipate; and the supply or quality of our drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates being insufficient or inadequate.

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, or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may (i) be delayed in obtaining regulatory approval for our drug candidates; (ii) not obtain regulatory approval at all; (iii) obtain approval for indications that are not as broad as intended; (iv) have the drug removed from the market after obtaining regulatory approval; (v) be subject to additional post-marketing testing requirements; (vi) be subject to restrictions on how the drug is distributed or used; or (vii) be unable to obtain reimbursement for the use of the drug.

Significant clinical trial delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do. This could impair our ability to commercialize our drug candidates and may materially and adversely affect our business and results of operations.

Adverse events or undesirable side effects 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.

Drug-related adverse events and serious adverse events have been reported in our clinical trials. See “Business – Our Portfolio.” 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;

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

In addition, oncology and autoimmune therapies such as our CAN008 are still considered as emerging and relatively novel therapeutics for treating GBM. Their mechanisms of action are yet to be thoroughly understood, and side effects have been observed in clinical studies and reported by medical practitioners in connection with their usage in patients. For example, the NMPA, FDA, TFDA, EMA, HSA or other comparable authorities could order us to suspend or terminate our studies or to cease further development of or deny approval of our drug candidates. Any drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete trials or may result in potential product liability claims, which could prevent us from obtaining regulatory approvals or achieving or maintaining market acceptance of a particular drug candidate, and could materially and adversely our business, results of operations and prospects.

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Our drug development progress may be affected by the clinical development progress of our collaboration partners, including but not limited to Apogenix, GC Pharma, Mirum, WuXi Biologics, Privus, UMass and LogicBio (collectively, our “Collaboration Partners”). If the collaboration partners are unable to successfully complete clinical development, obtain relevant regulatory approvals or achieve commercialization, or if they experience significant delays in any of the foregoing, our business and profitability may be adversely affected.

We have entered into collaboration agreements with our Collaboration Partners granting us exclusive licenses to our three clinical-stage assets. See “Business – Collaboration and Licensing Arrangements.” The success of our collaborations with our Collaboration Partners and drug development may be affected by our Collaboration Partners to the extent they are responsible for performance of collaboration activities or their clinical development activities may facilitate or accelerate our drug development process. Each Collaboration Partner may not be successful in the performance of such activities, including, for example, obtaining approvals for the product candidates developed under the collaboration or in marketing, or arranging for necessary supply, manufacturing, or distribution relationships for, any approved products. Our Collaboration Partners may change their strategic focus or pursue alternative technologies in a manner that results in reduced, delayed, or no additional costs to us under the collaboration agreements. Our Collaboration Partners have a variety of marketed products and product candidates under collaboration with other companies, possibly including some of our competitors, and our Collaboration Partners’ own corporate objectives may not be consistent with our interests. If any of our Collaboration Partners experiences significant delays in or fail to develop, obtain regulatory approval for, or ultimately commercialize any product candidate under our collaborations, our business, financial condition, results of operations and prospects could be materially and adversely affected.

We may not be successful in developing, enhancing or adapting to new technologies and methodologies.

We must keep pace with new technologies and methodologies to maintain our competitive position. For the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, our research and development costs were RMB55.4 million, RMB109.6 million and RMB274.8 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 research, 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 materially and adversely affect our business and prospects.

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

We face an inherent risk of product liability as a result of the clinical trials and any future commercialization of our drug candidates inside and outside China. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. As of the Latest Practicable Date, we had not been subject to any such product liability claim. 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 labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any approved drug candidate; and a decline in the market price of our Shares.

To cover such liability claims arising from clinical studies, we have purchased clinical trial insurance in the conduct of our clinical trials and also maintain product liability insurance. 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 claims 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.

Our business and reputation may be adversely affected by negative publicity involving us, our Shareholders, Directors, officers, employees, Collaboration Partners, suppliers or other third parties that we work with or rely on.

We, our Shareholders, Directors, officers, employees, Collaboration Partners, suppliers, or other third parties we cooperate with or rely on may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our employees, Collaboration Partners, suppliers or other third parties we work with or rely on were non-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. Any negative publicity regarding our industry could also affect our reputation

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and commercialization. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity that may or may not directly related to us, and may not be able to diffuse them to the satisfaction of our current or future investors, customers, patients and business partners.

Risks Relating to Extensive Government Regulations

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

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, and results of operations or 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 damage 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 be always 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. We also cooperate with third parties including hospitals, CROs and other third-party contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as a result of our failure. In particular, certain industry-specific laws and regulations may affect the collection and transfer of personal data in China, including Administrative Regulations on

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Human Genetic Resources of the People’s Republic of China (《中華人民共和國人類遺傳資源管理條例》) issued by the State Council. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our clinical trial practices, potentially resulting in the confiscation of human genetic resources samples and associated data and administrative fines. 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 or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims.

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 any of our drug candidates is approved in the future, it will be subject to ongoing or additional regulatory requirements for manufacturing, labelling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including requirements of regulatory authorities in China and other jurisdictions.

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, TFDA, EMA, HSA 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, TFDA, EMA, HSA 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.

The NMPA, FDA, TFDA, EMA, HSA 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, TFDA, EMA, HSA 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.

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

We have entered into license agreements with third parties providing us with rights to various intellectual properties, including rights in patents and patent applications that relate to our drug assets. See “Business – Collaboration and Licensing Arrangements.” These license agreements impose diligence obligations in development or commercialization of the licensed intellectual properties, payment obligations when certain development, commercialization or regulatory milestones and sales are achieved and other obligations on us. 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, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. 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 us having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

In addition, the agreements under which we license intellectual properties or technologies from third parties are 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 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 prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, or if our licensors fail to fully perform their obligations or meet or expectations under the such in-licensing agreements or terminate their relationship with us, we may be unable to successfully develop and commercialize the affected drug candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our and/or others’ 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 the relevant laws, regulations and relevant regulatory practice by governmental, we and/or other parties related to our operations, such as landlords or managers of premises on or local science parks in which we operate, are required to obtain and maintain various approvals, licenses, permits and certificates (e.g. drainage permits) 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

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may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities causing operations to cease, and may include corrective measures requiring capital expenditure or remedial actions, which in the future could materially and adversely affect our business, financial condition and results of operations. There is also no assurance that the relevant authorities would not take any enforcement action against us. In the event that such enforcement action is taken, our business operations could be materially and adversely disrupted.

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

If we participate in compassionate-use programs or expanded access programs, current regulatory discrepancies among competent authorities of different countries may lead to increased risk of adverse drug reactions and serious adverse events arising from the use of our products.

Expanded access programs are regulatory programs that facilitate access to investigational drugs for the treatment of patients with serious or immediately life-threatening diseases or conditions that lack therapeutic alternatives. Currently, there is no unified approach or standard practice to regulate expanded access programs among competent authorities in different countries for access to investigational drugs. In China, currently there is no officially approved regulation to oversee expanded access programs. In the U.S., expanded access programs are limited to patients who have a life-threatening disease or serious disease or condition, who may gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available.

The regulatory discrepancy for expanded access programs among competent authorities in different countries may lead to uneven patient entry criteria and protocols for expanded access programs. This may create increased risk of serious adverse events because of enrolled patients' advanced disease or comorbidities. In addition, because the products in expanded access programs are investigational drugs, many of which are still in experimental stages and have not received marketing approval, patients in expanded access programs may exhibit adverse drug reactions from using these products. If we participate in expanded access programs, we may be subject to the risk of enrolled patients exhibiting adverse drug reactions or serious adverse events arising from the use of our products. These occurrences can potentially lead to clinical holds of our ongoing clinical trials or complicate the determination of the safety profile of a drug candidate under regulatory review for commercial marketing. Changes in government regulations or in practices relating to the pharmaceutical and biopharmaceutical industries, including healthcare reform in China, and compliance with new regulations may result in additional costs.

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If safety, efficacy or other issues arise with any drug or medical product used in combination with or to facilitate the use of our drug candidates, we may be unable to market such drug candidate or may experience significant regulatory delays.

Our strategy to develop combination therapies depends on the safety and efficacy of each component drug within each combination therapy. If the NMPA, FDA, TFDA, EMA, HSA or another comparable regulatory agency revokes or denies its approval of a component therapeutic, in either the clinical design, clinical administration, therapy approval or commercialization stage, we will be forced to terminate or redesign the clinical trials, experience significant regulatory delays or stop our commercialization efforts. In addition, we may fail our commercialization effort because products that facilitate the use of our drug candidates incur safety, efficacy or availability issues. For example, the regulations in China on the companion diagnostic test used in conjunction with our drug candidates for patient identification are still developing and the definition of diagnostic companion in the U.S. may not be the same as that of China. The lack of regulations presents uncertainties to our commercialization efforts and may have an adverse effect on our business and results of operations.

Adverse drug reactions and negative results from off-label use of our products could materially and adversely affect our business reputation, product brand name and financial condition and expose us to liability.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. Even though the NMPA, FDA, TFDA, EMA, HSA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains the risk that our product is subject to off-label drug use and is prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our products less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and materially and adversely our business reputation, product brand name, commercial operations and financial condition, including our Company’s share price. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approval for our drug candidates.

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

The illegal importation of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect our sales and profitability in China and other countries where we commercialize our products. Unapproved foreign imports of prescription drugs are illegal under current laws of China. However, illegal

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imports may continue to occur or even increase as the ability of patients to obtain these lower-priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers’ ability to import lower-priced versions of our future approved products or competing products from outside China or other countries where we operate. Any future legislation or regulations that increase consumer access to lower-priced medicines from outside China or other countries where we operate could have a material adverse effect on our business.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as China, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode the demand for our future approved drug candidates. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaborators’ brand name(s). In addition, thefts of inventory at warehouses or plants or while in transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

We may be restricted from transferring our scientific data abroad.

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

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

International market conditions and the international regulatory environment have historically been affected by competition among countries and geopolitical frictions. Changes to trade policies, treaties and tariffs, or the perception that these changes could occur, could adversely affect the financial and economic conditions in the jurisdictions in which we operate, as well as our overseas expansion, our financial condition and results of operations. The U.S. administration under President Donald J. Trump has advocated greater restrictions on international trade generally and significant increases on tariffs on certain goods imported into the U.S., particularly from China, and has taken steps toward restricting trade in certain goods. For example, in 2018, the United States announced three finalized tariffs that applied exclusively to products imported from China, totaling approximately US\$250 billion, and in May 2019, the U.S. increased the rate of certain tariffs previously levied on Chinese products from 10% to 25%. In addition, in August 2019, President Donald J. Trump threatened to impose additional tariffs on remaining Chinese products, totaling approximately US\$300 billion. Although on January 15, 2020, the U.S. and China signed an agreement on the phase one trade deal, under which both parties made certain concessions and agreed not to proceed with additional tariffs against one another, the 25% tariffs on US\$250 billion of Chinese imports are still in place. These concerns and threats to impose new tariffs or sanction on China, have resulted in increased tensions in China’s international relations. Moreover, the bilateral relationship is an ongoing matter, evolving sometimes from day to day, and we cannot predict how the relationship will further evolve or what impact any subsequent developments in the relationship may have on our business.

In addition, China and other countries have retaliated, and may further retaliate, in response to new trade policies, treaties and tariffs implemented by the U.S. government. Such retaliation measures may further escalate the tensions between the countries or even lead to a trade war. Any escalation in trade tensions or a trade war, or the perception that such escalation or trade war could occur, may have negative impact on the economies of not merely the two countries concerned, but the global economy as a whole. In addition, if China were to increase the tariff on any of the items imported by our suppliers and contract manufacturers from the U.S., we might not be able to find substitutes with the same quality and price in China or from other countries.

Furthermore, during the Track Record Period, we formed licensing agreements with entities in foreign countries and regions, such as Puma, based in the United States. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. As a result, China’s political relationships with those foreign countries and regions may affect the prospects of maintaining existing or establishing new collaboration partnerships and licensing agreements, and the communication and transfer of know-how.

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There can be no assurance that such licensing partners or potential collaborators or licensing partners in the future will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Any tensions and political concerns between China and the relevant foreign countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. It also remains unclear what actions, if any, the U.S. government will take with respect to other existing international trade agreements. As a result of the above and 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. For further details, please see the section headed “Business – Collaboration and License Arrangements” in this document.

Risks Relating to Manufacturing and Commercialization of Our Drug Candidates

We have limited experience in manufacturing pharmaceutical 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 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;
- 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.

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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 CDMOs that we may engage from time to time. See “– Risks Relating to Our Reliance on Third Parties – We rely on third parties to manufacture and import our clinical drug supplies and expect to rely on third parties to supply raw materials for manufacturing and/or manufacture our drugs when approved, and our business could be harmed if those third parties fail to provide us with sufficient quantities of the raw materials or the drug product or fail to do so at acceptable quality levels or prices.”

Manufacturing methods and formulation are sometimes altered through the development of drug candidates from clinical trials to approval, and further to commercialization, in an effort to optimize manufacturing processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause the drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay the commercialization of drug candidates and require bridging studies or the repetition of one or more clinical trials, which may result in increases in clinical trial costs, 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, TFDA, EMA, HSA or other comparable regulatory agency standards or specifications, 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 equipment. In these cases, we may be required to delay or suspend our manufacturing activities. We may be unable to secure temporary, alternative manufacturers for our drugs with the terms, quality and costs acceptable to us, or at all. Such an event could delay our clinical trials and/or the availability of our 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, jeopardize any GMP certifications we may have and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

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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 and biological products often 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 in the time frame we expect or at all, 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 of our drug candidates, if approved, we will need to increase, or "scale up," the production process by a significant factor over the initial level of production. If we are unable or delayed to do so, 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 establish our manufacturing capacity, mainly through the construction of new manufacturing facilities. However, the timing and success of these plans are subject to significant uncertainty. Moreover, such plans are capital intensive and require significant upfront investment, and there can be no assurance that we will be able to timely obtain such financing, if at all.

Furthermore, given the size of our new facilities, 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 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 facilities. We may also experience various unfavorable events in the course of developing our new manufacturing facilities, 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.

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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.

If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

We successfully received marketing approval from China’s NMPA for Hunterase[®] (CAN101) in September 2020, following the submission of the NDA in July 2019, followed by NDAs of our other drug candidates in the future as their clinical development progress. To obtain regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in pre-clinical studies and well-controlled clinical trials, and, with respect to approval in China, to the satisfaction of the NMPA, that the drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In addition to pre-clinical and clinical data, the NDA or biologics license application must include significant information regarding the chemistry, manufacturing and controls for the drug candidate. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA to the NMPA, the NMPA decides whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the NMPA.

We have limited experience in filing for regulatory approval for our drug candidates, and we have not yet demonstrated the ability to receive regulatory approval for our internally developed drug candidates. As a result, our ability to successfully obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in obtaining regulatory approvals.

We also plan to commercialize our products in other markets such as United States and Taiwan. Regulatory authorities outside of China, such as the NMPA, FDA, TFDA, EMA, HSA, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements and approval processes can vary widely from country to country and could delay or prevent the introduction of our drug candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Seeking foreign regulatory approval could require additional nonclinical studies or clinical trials, which could be costly and time- consuming. The foreign regulatory approval process may include all of the risks associated with obtaining the NMPA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all.

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The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly, and approval is never guaranteed. Following any approval for commercial sale of our drug candidates, certain changes to the drug, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the NMPA and comparable regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target markets will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other drug candidate in the future.

We have limited experience in launching and marketing drug candidates. If we are unable to maintain sufficient marketing and sales capabilities, we may not be able to generate product sales revenue as planned.

Although we launched the first product in 2018, 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 rich experience launching and marketing drug candidates.

We will have to compete with other pharmaceutical and biopharmaceutical 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 drug candidates, we will likely pursue collaborative arrangements regarding the sales and marketing of our drug candidates. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates.

We may fail to effectively manage our network of distributors. Actions taken by our distributors in violation of the relevant agreements or taken by the distributors with whom we have not entered into distribution agreements could materially and adversely affect our business, prospects and reputation.

We have limited control over the operations and actions of our distributors, all of whom, to the best of our Directors’ knowledge, are Independent Third Parties during the Track Record Period. We rely on the distribution agreements and the policies and measures we have in place to manage our distributors, including their compliance with laws, rules, regulations and our policies. See “Business – Sales and Marketing – Our Marketing Model and Sales Arrangements – Distribution and Direct Sale.” We cannot guarantee that we will be able to effectively manage

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our distributors, or that our distributors would not breach our agreements and policies. If our distributors take one or more of the following actions, our business, results of operations, prospects and reputation may be adversely affected:

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

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

Moreover, some of our distributors engage sub-distributors to distribute our products. Historically, we did not require our distributors to seek our approval before engaging such sub-distributors. We do not engage these sub-distributors directly or maintain contractual relationships with them, and mainly rely on our distributors to manage and control their sub-distributors in accordance with regulatory requirements, the terms of the distribution agreements we entered into with our distributors and our policies and measures that our distributors agree to comply with. As a result, we have a more limited control over these sub-distributors. Although we are currently in compliance with the Two-Invoice System, there is no assurance that the sub-distributors will comply with the geographical restrictions we have agreed with our distributors, or comply with other distribution requirements under our distribution agreements and policies. Furthermore, we cannot assure you that we will be able to identify or correct all the sub-distributors' practices that are detrimental to our business in a timely manner or at all, which may adversely affect our results of operations and reputation. As there is no contractual relationship between us and these sub-distributors, we have no direct legal recourse against them if their activities cause harm to our business or reputation.

The market opportunities for our drugs and drug candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

Subsequently, for those drugs that prove to be sufficiently beneficial, if any, we may seek approval as a first-line therapy, but there is no guarantee that our drug candidates, even if approved, would be approved for second-line or first-line therapy.

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Our projections of both the number of people who have the neuromuscular and lysosomal storage or rare disease or cancers we are targeting, as well as the subset of people with these cancers in a position to receive later-stage therapy and who have the potential to benefit from treatment with our drug candidates, are based on our beliefs and estimates and may prove to be inaccurate or based on imprecise data.

Further, new studies may change the estimated incidence or prevalence of these cancers and rare diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our drugs and drug candidates may be limited or may not be amenable to treatment with our drugs and drug candidates. Even if we obtain significant market share for our drug candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first-or second-line therapy.

We intend to manufacture at least a portion of our approved drug candidates ourselves in the future. Delays in completing and receiving regulatory approvals for our manufacturing facilities, or damage to, destruction of or interruption of production at such facilities, could delay our development plans or commercialization efforts.

We do not have manufacturing experience previously, but we plan to build manufacturing facilities in Suzhou, China and Greater Boston, U.S.. 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 facility 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 other sources.

In addition to the similar manufacturing risks described in “– Risks Relating to Our Reliance on Third Parties,” our manufacturing facilities may be subject to ongoing, periodic inspection by the NMPA, FDA, TFDA, EMA, HSA or other comparable regulatory agencies to ensure compliance with cGMP. Our failure to follow and document our adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or the commercialization of our drugs, if approved. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet NMPA, FDA, TFDA, EMA, HSA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the NMPA, FDA, TFDA, EMA, HSA or other comparable regulatory agencies.

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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 drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could materially and adversely our business.

To produce our drugs in the quantities that we believe will be required to meet anticipated market demand of our drug candidates if approved, we will need to increase, or “scale up,” the production process by a significant factor over the initial level of production. If we are unable to do so, are delayed, or 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 drugs in a sufficient quantity to meet future demand.

In addition to the similar manufacturing risks described in “– Risks Relating to Our Reliance on Third Parties,” if our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any drugs 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 or drugs in a timely manner could materially and adversely our business, financial condition and operating results.

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

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain the NMPA or the FDA or other comparable regulatory authorities’ approval for any of our drug candidates and begin commercializing those drugs in China, the U.S., Taiwan, Australia or markets, our operations may be subject to various PRC, U.S. federal and state and other applicable jurisdictions’ fraud and abuse laws, including, without limitation, the PRC Anti-Unfair Competition Law, the PRC Criminal Law, 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 may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business.

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If any of the physicians or 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.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to the anti-bribery laws of various jurisdictions. As our business has expanded, the applicability of the applicable anti-bribery laws to our operations has increased. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

Risks Relating to Our Intellectual Property Rights

Our current or any future patents 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, 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 may diminish the value of our patent rights or narrow the scope of our patent protection. 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 (“USPTO”) challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a

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patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. We 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 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 patent claims being narrowed, invalidated, or held unenforceable, any of 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 do not know 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 measures we take to obtain patent protection with respect to our major drug candidates and technologies, any of our issued patents could be challenged or invalidated. For example, if we 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.

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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. For example, under U.S. law, when new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. 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 fail to meet these 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 conditions, results of operations and prospects.

Our in-licensed patents and intellectual property relating to our self-developed drug candidates may be subject to priority disputes or to inventorship disputes and similar proceedings. If we or our licensing partners are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the development, manufacture and commercialization of one or more of the drug candidates we may develop, which could have a material adverse impact on our business.

We or our licensing partners may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property. If we or our licensing partners are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which our or the in-licensed intellectual properties are subject to, we may lose valuable intellectual property rights through the loss of one or more patents or our patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our licensing partners are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership. If we or our licensing partners are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our drug candidates. The loss of exclusivity or the

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narrowing of our or our licensing partners' patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

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

Competitors or other third parties may challenge the validity and enforceability of our patents and/or those of our licensing partners, infringe, misappropriate or otherwise violate our other intellectual property rights. To counter infringement, misappropriation or any other unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Litigation and other proceedings in connection with any of the foregoing claims can be expensive and time-consuming and, even if resolved in our favor, may cause us to incur significant expenses and could distract management and our scientific and technical personnel from their normal responsibilities. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other violators could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and defend their intellectual property rights than we can.

Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights. An adverse result in any such litigation proceeding could put our and/or in-licensed patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. Moreover, we may not be able to detect infringement against our and/or in-licensed patents. Even if we detect infringement by a third party of any of our or in-licensed patents, we or our licensing partners may choose not to pursue litigation against or settlement with such third party. If we and/or our licensing partners 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.

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Although we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our Collaboration Partners, 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, patent applications and in-licensed patents is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, 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.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the China National Intellectual Property Administration ("CNIPA"), USPTO and other patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and maintenance process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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Changes in patent law 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.

As is the case with other pharmaceutical and biopharmaceutical companies, our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical and biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing pharmaceutical and biopharmaceutical 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, the recent amendment to the Chinese Patent Law, which was promulgated by the SCNPC in October 2020 and became effective in June 2021, introduced patent extensions to eligible innovative drug patents, but lacks operational details. According to the Chinese Patent Law, the patents owned by third parties may be extended, which may in turn affect our ability to commercialize our products (if approved) without facing infringement risks. The adoption of this amendment may enable the patent owner to submit applications for a patent term extension. The extension may not exceed five years, and the total effective term of the patent after the new drug approved for marketing shall not exceed 14 years. 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 products 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

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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 all of which 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 conditions, results of operations and prospects.

FIRMA Pilot Program may restrict our ability to acquire technologies and assets in the U.S. that are material to our commercial success.

The U.S. Congress has passed legislation that will expand the jurisdiction and powers of the Committee on Foreign Investment in the U.S. (“CFIUS”), the U.S. interagency committee that conducts national security reviews of foreign investment. President Trump signed the Foreign Investment Risk Review Modernization Act (“FIRMA”) in August 2018. Pursuant to the FIRMA, investments in companies that deal in “critical technology” are subject to filing requirements and, in some instances, review and approval by the CFIUS. The term “critical technology” includes, among others, technology subject to U.S. export controls and certain “emerging and foundational technology, “a term that is still being defined but that is expected to include a range of U.S. biotechnology. If an investment by a foreign entity in a U.S. business dealing in “critical technology” meets certain thresholds, a filing with the CFIUS is mandatory. While the FIRMA currently grants CFIUS jurisdiction on only controlling and certain non-controlling investments made by foreign persons in U.S. businesses in research and development in biotechnology, the CFIUS’s jurisdiction may be further expanded in the future, which may place additional limitations on strategic collaborations with our current U.S. partners, which could detrimentally affect our capacity to acquire foreign assets in the U.S. that may be material to our commercial success.

The absence of patent linkage, patent term extensions and data and market exclusivity for NMPA-approved pharmaceutical products could increase the risk of early generic competition with 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 patent term restoration that provides a patent term extension of up to five years to reflect patent time period lost during certain portions of product development and the FDA regulatory review process. Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications for a period of up to 30 months if, within 45 days of receiving notice of a follow-on application, we file a patent infringement suit against such applicant.

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Finally, 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 (as defined by the FDCA) 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 United States Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where the FDA designates the drug candidate as an orphan drug and the drug is approved for the designated orphan indication. 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.

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. Hatch-Waxman permits a patent extension term of up to five years as compensation for patent time period lost during clinical trials and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of 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. 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 China, the recent amendment to the Chinese Patent Law, which was promulgated by the SCNPC in October 2020 and took effect in June 2021, describes the general principles of patent term extension and patent linkage, but lacks operational details. The patent term extension provided by the amended Chinese Patent Law is similar to that under the Hatch Waxman Amendments. Since the second half of 2020, several draft measures have been published by NMPA, CNIPA, and Supreme Court (SPC) for public comments, proposing frameworks for patentees to defend their patent exclusivity and apply for patent term extension. As of the date of this document, the final versions of these draft measures have not been published, and uncertainties remain with respect to how the Chinese government will implement the patent term extension or patent linkage system. As a result, the patents we have in-licensed or own in China may not be eligible to be extended for any patent term lost during the regulatory review process. In addition, an extension may not be granted because of, for example, 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. If we are unable to obtain patent term extension, or 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 business, financial condition, results of operations and prospects could be materially harmed.

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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 advisers 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, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisers 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 advisers, including our senior management, may currently be, or were previously employed at other pharmaceutical or biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisers, 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

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intellectual property rights would materially and adversely 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.

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

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If we fail to comply with our obligations in the agreements under which we obtain or in-license intellectual property rights from third parties, we could be required to pay monetary damages or could lose license rights that are important to our business.

We have entered into and may in the future enter into additional license agreements with third parties providing us with rights to various third-party 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. If we fail to comply with our obligations under any of our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. 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 materially and adversely affect 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 licensors that is not subject to the license agreements;
- 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; 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 conditions, results of operations, and prospects.

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

Because our programs may involve additional drug candidates that require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, or other intellectual property rights from third parties that we identify. The licensing and acquisition of third-party

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

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

The registered or unregistered trademarks or trade names that we own or license may be challenged, infringed, circumvented, declared generic, lapsed or determined to be infringing on or dilutive of other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition. In addition, third parties have filed, and may in the future file, for registration of trademarks similar or identical to our trademarks, thereby impeding our ability to build brand identity and possibly leading to market confusion. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such rights, we may not be able to use these trademarks to develop brand recognition of our products. 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.

Claims that our drug candidates or the sale or use of our future products infringes, misappropriates or otherwise violates the patent or other intellectual rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

Our commercial success depends upon our ability to develop, manufacture, market and sell our drug candidates without infringing, misappropriating or otherwise violating the intellectual property rights of others. We cannot guarantee that our drug candidates or any uses of our drug candidates do not and will not in the future infringe third-party patents or other intellectual property rights. It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drug candidates. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

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Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, use or manufacture of the compounds we have developed or are developing. Such third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

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

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated adverse impacts on our business.

Intellectual property rights do not necessarily address all potential threats.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents and trademarks of our tradename. As of the Latest Practicable Date, we own or otherwise have exclusive rights to 17 granted patents and 47 pending patent applications worldwide. See “Business – Intellectual Property” for more details. 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 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 or any future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or may license in the future;

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- we or any future collaborators 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 intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- patents that may be issued from our pending patent applications may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may materially and adversely affect our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Relating to Our Reliance on Third Parties

We have entered into collaborations and may form or seek collaborations or strategic alliances or enter into licensing arrangements in the future, we may not realize the benefits of such alliances or licensing arrangements, and disputes may arise between us and our Collaboration Partners which could harm our business.

We have in the past formed, and may in the future seek and form, strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of 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.

Our strategic collaboration with partners involves numerous risks. 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

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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.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because 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 or biopharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits.

Disputes may arise between us and our 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;
- decisions of our collaborators, especially those in combo therapy trials, to delay any 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 formulation of a drug candidate for clinical testing, or not to pursue development and commercialization of our drugs and drug candidates, continue or renew development or commercialization programs based on clinical trial results or other external factors;
- 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.

We rely on third parties to conduct a certain number of our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates, or experience delay in doing any of the foregoing, and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to generate, monitor or manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on 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 GCPs, which are regulations and guidelines enforced by the NMPA and other comparable regulatory authorities for all of our drugs in clinical development. If we or any of our CROs or clinical investigators fail to comply with applicable GCPs, the clinical

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data generated in our clinical trials may be deemed unreliable and the NMPA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with product produced under GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. In addition, our CROs are not our employees. Except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and non-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, 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 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 obtaining regulatory approval. Our arrangements with collaborators will be critical to successfully bringing products to market and commercializing them. We rely on collaborators in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process and to assist with our commercialization efforts. We do not control our collaborators. Therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If third parties fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. 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 drug which could materially and adversely affect our business, financial condition, cash flows and results of operations.

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We rely on third parties to manufacture and import our clinical drug supplies and expect to rely on third parties to supply raw materials for manufacturing and/or manufacture our drugs when approved, and our business could be harmed if those third parties fail to provide us with sufficient quantities of the raw materials or the drug product or fail to do so at acceptable quality levels or prices.

We currently use third parties for our manufacturing process and for the clinical supply of our drug candidates, some of which are among our five largest suppliers during the Track Record Period. We expect to continue to rely on third-parties to supply raw materials for us to manufacture or manufacture the approved drugs in the future. Reliance on third-party manufacturers 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, TFDA, EMA, HSA 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, TFDA, EMA, HSA or other comparable regulatory authorities;
- our third-party manufacturers 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;
- manufacturers are subject to ongoing periodic unannounced inspection by the regulatory authorities to ensure strict compliance with cGMP and other government regulations. We do not have control over third-party manufacturers' 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 manufacturers in the manufacturing process for our drug candidates;
- manufacturers 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;
- manufacturers 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; and
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or human-made disasters.

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Each of these risks could delay or prevent R&D activities, result in higher costs, or adversely impact commercialization of our future approved drug candidates. In addition, we will rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm, and regulatory authorities could place significant restrictions on our Company until deficiencies are remedied.

Manufacturers of drug and pharmaceutical products often 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, as well as compliance with strictly enforced regulations. Furthermore, if contaminants are discovered in our supply of our drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future, either relating to our third-party CDMOs or on our manufacturing facilities we plan to build in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result 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 drug candidates 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 had a limited number of suppliers during the Track Record Period and the loss of one or more of our key suppliers could disrupt our operations.

In 2019 and 2020 and the six months ended June 30, 2021, our purchases from our five largest suppliers in the aggregate accounted for 63.1% and 83.7% and 69.3% of our total purchases, respectively. During the Track Record Period, we had a small number of suppliers, and the largest purchase amounts related to upfront payments for drug in-licensing and acquisition arrangements, which were not recurring in nature. Our other major purchases were fees paid to CROs we engaged to manage, conduct and support our preclinical research and clinical trials. We expect to continue our purchases from these suppliers as we fund the continuing research and development activities of our Core Products and other drug candidates in our pipeline. We believe that we have long and stable relationships with our existing large third-party suppliers. However, the stability of operations and business strategies of our suppliers are beyond our control, and we cannot assure you that we will be able to secure a stable relationship and high-quality outsourced services with our large suppliers. If any of our large suppliers terminates its business relationship with us, we may encounter difficulty in finding a replacement that can provide services of equal quality at a similar price. If this occurs, our operations may be significantly disrupted.

RISK FACTORS

Our employees, collaborators, service providers, independent contractors, principal investigators, consultants, vendors and CROs may engage in misconduct or other improper activities.

We are exposed to the risk that our employees, collaborators, independent contractors, principal investigators, consultants, vendors and CROs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- NMPA regulations, including those laws requiring the reporting of true, complete and accurate information to the NMPA;
- manufacturing standards; or
- laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. We may not be able to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from the NRDL, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations.

RISK FACTORS

RISKS RELATING TO OUR OPERATIONS

Our future success depends on our ability to retain key executives and to attract, train, retain and motivate qualified and highly skilled personnel especially R&D and clinical related staff.

We are highly dependent on Dr. Xue, our Founder, Chairman and CEO and other principal members of our management and scientific teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain key-person insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Our clinical activities might be delayed if any key member of R&D team leaves. To incentivize valuable employees, especially these R&D and clinical related staff that are key to our R&D efforts, to remain at our Group, in addition to salary and cash incentives, we have provided share incentives that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the market price of our Shares that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, any of our employees could leave our employment at any time, with or without notice.

Recruiting and retaining qualified scientific, technical, clinical, manufacturing, and sales and marketing personnel in the future will also be critical to our success. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

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

RISK FACTORS

Our reputation is key to our business success. Negative publicity may adversely affect our reputation, business and growth prospect.

Any negative publicity concerning us, our affiliates or any entity that shares the “CANbridge Pharmaceuticals” name, even if untrue, could adversely affect our reputation and business prospects. We cannot assure you that negative publicity about us or any of our affiliates or any entity that shares the “CANbridge Pharmaceuticals” name would not damage our brand image or have a material adverse effect on our business, results of operations and financial condition. 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 or any of our affiliates or any entity that shares the “CANbridge Pharmaceuticals” name could adversely affect our ability to maintain our existing collaboration arrangements or attract new partners.

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

We had 173 employees as of the Latest Practicable Date. 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 growth and any future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- 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.

RISK FACTORS

We may be involved in lawsuits, claims, administrative proceedings or other legal proceedings against us, which could be costly and time-consuming to defend and therefore adversely affect our business, financial conditions, results of operations and reputation.

We may be involved in lawsuits claims, administrative proceedings or other legal proceedings arising in the ordinary course of business or pursuant to governmental or regulatory enforcement activity from time to time. Litigation and governmental proceedings can be expensive, lengthy and disruptive to normal business operations, and can require extensive management attention and resources, regardless of their merit. While we do not believe that the resolution of any lawsuits against us will, individually or in the aggregate, have a material adverse effect on our business, financial condition and results of operations, litigation to which we subsequently become a party might result in substantial costs and divert management’s attention and resources. Furthermore, any litigations, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate and become important to us due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake, and the parties involved. In July 2020, Puma Biotechnology, Inc. (Nasdaq: PBYI) (“Puma”) initiated an arbitration proceeding against us in connection with the license agreement between Puma and us signed in 2018. We have reached a settlement with Puma in February 2021 to settle such arbitration. For details, please see “Business – Legal Proceedings and Compliance”. We have implemented heightened measures to monitor our other license agreements, including but not limited to periodic check of performance under the agreements by our business development team and enhanced compliance review by our internal counsel.

Although we maintained various insurances including the product liability insurance, our insurance might not cover claims brought against us, might not provide sufficient payments to cover all of the costs to resolve one or more such claims, and might not continue to be available on terms acceptable to us. In particular, any claim could result in unanticipated liability to us if the claim is outside the scope of the indemnification arrangement we have with our collaborators, our collaborators do not abide by the indemnification arrangement as required, or the liability exceeds the amount of any applicable indemnification limits or available insurance coverage. While we intend to defend the aforementioned matters vigorously, we cannot predict the results of complex legal proceedings and an unfavorable resolution of a lawsuit or proceeding could materially adversely affect our business, results of operations, financial conditions and reputation.

RISK FACTORS

If we engage in acquisitions, joint ventures or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, may have a material adverse effect on our ability to manage our business and may not be successful.

From time to time, to pursue our growth strategy, we may evaluate various acquisitions, joint ventures 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;
- 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.

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

RISK FACTORS

recruit key employees away from companies during the integration phase of an acquisition. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense.

PRC regulations and rules concerning mergers and acquisitions, including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors, or 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. Moreover, according to the Anti-Monopoly Law of PRC and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings, or 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 anti-monopoly enforcement agency of the State Council 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, or 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. 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. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

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

Our growth strategies aim to develop potential therapies for rare oncology and rare diseases in china and globally. For more information, see “Business – Our Strategies.” Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. In addition, managing our growth and executing on our growth strategies will require, among other things, our ability to continue to innovate and develop advanced technology in the highly competitive global and Chinese biopharmaceutical market, effective coordination and integration of our facilities and teams across different sites, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, effective quality control, and management of our suppliers to leverage our purchasing power. Any failure to execute on our growth strategies or realize our anticipated growth could adversely affect our business, financial condition, results of operations and prospects.

RISK FACTORS

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

We are subject to numerous environmental, health and safety laws and regulations, 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 construction projects 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 relevant facilities in certain jurisdictions. 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 pipeline products 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 facilities during the process of research, testing, development and manufacturing of biopharmaceuticals. 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 materially and adversely our business. Other adverse effects could result from such liability, including reputational damage. We may also be forced to close or suspend operations at certain of our affected facilities temporarily, or permanently. As a result, any accidental contamination, biological or chemical hazards or personal injury could have a material 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.

RISK FACTORS

We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control. Natural disasters, epidemics, pandemics, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business.

Our operations may be under the threat of natural disasters such as floods, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, 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.

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, since the end of December 2019, the outbreak of COVID-19 has affected many people in and outside of China, caused temporary suspension of productions and shortage of labor and raw materials in affected regions, and disrupted local and international travel and economy generally. The exacerbation, continuance or reoccurrence of COVID-19 has already caused and may continue to cause an adverse and prolonged impact on the economic, geopolitical and social conditions in China and other affected countries, which may potentially delay our progress in the expected commercialization of CAN008. Although, the existing clinical trials and the commencement of new clinical trials have not been obviously affected by the COVID-19 pandemic, it could 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 or other outbreaks and relevant vaccination schedule. 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.

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

Despite the implementation of security measures, our internal computer systems and those of our partners and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

RISK FACTORS

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 increased 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 an adverse impact on us and our business, including loss of data and damage to equipment and data. 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. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss of information maintained in the information systems and networks of our Company and our vendors, including personal information of our employees and patients, and company and vendor 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 and/or systems. 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 cyberattacks. The number and complexity of these threats continue to increase over time. 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 damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes are costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

RISK FACTORS

We are subject to the risks of doing business globally.

Because we operate in China and other countries, 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; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in certain countries; 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; the effects of applicable local tax regimes and potentially adverse tax consequences; and significant adverse changes in local currency exchange rates.

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.

In the past, local governments in China granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. We recorded government grants of RMB0.2 million, RMB0.4 million and RMB0.2 million for the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, respectively. The local governments have the discretion in deciding the timing, amount and criteria of government financial incentives and thus we cannot predict with certainty whether or how much financial incentive will be granted to us even if we apply for such funding. We generally do not have the ability to influence local governments in making these decisions. Government authorities may also decide to reduce or eliminate incentives or may amend or terminate the relevant financial incentive policies at any time. In addition, some of the government financial incentives are granted to us on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to satisfy any such conditions, we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

Fluctuations in exchange rates could result in foreign currency exchange losses and could materially reduce the value of your [REDACTED].

The change in the value of RMB against the Hong Kong dollar and other currencies may fluctuate and is affected by, among other things, changes in China’s political and economic conditions and China’s foreign exchange policies. Substantially all of our costs are denominated in RMB and US dollars, most of our assets are cash and bank balances primarily denominated in US 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 US dollars against RMB may materially and adversely affect the value of and any dividends payable on, our Shares in Hong Kong dollars.

RISK FACTORS

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, including insurance for our new facilities. Although we have maintained clinical trial insurance, product liability insurance, property loss insurance, business interruption insurance and public liability insurance. We expect our employer liability insurance to be effective upon [REDACTED], our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may negatively impact our drug development and overall operations.

We do not own the real property for our current major operation sites and may be subject to risks relating to leased properties.

We do not own any real property for our operations. As of the Latest Practicable Date, we lease an aggregate area of over 4,000 sq.m. in Greater China and Greater Boston area. Upon expiration of the leases, we will need to negotiate for renewal of the leases and may have to pay increased rent. We cannot assure you that we will be able to renew our leases on terms which are favorable or otherwise acceptable to us, or at all. If we fail to renew any of our leases or if any of our leases are terminated or if we cannot continue to use any of our leased property, we may need to seek an alternative location and incur expenses related to such relocation, and our operation and businesses may also be disrupted or even suspended if we are not able to complete the relocation, including the reconstruction of relevant facilities in the new location, in a timely manner.

We are subject to other risks related to our leased properties. For example, our landlords failed to provide valid title certificates with respect to some of our leased properties to us. If our landlords are not the owners or not authorized by the real owners to sign the lease agreements, the validity and enforceability of the lease agreements may be adversely affected. Since we only use these leased properties for registration purposes, such risk will not have a material adverse impact on our business in the PRC as confirmed by our PRC Legal Advisor.

Pursuant to the applicable PRC laws and regulations, property lease agreements must be registered with the local branch of the Ministry of Housing and Urban-Rural Development of the PRC. As of the Latest Practicable Date, we had not completed the relevant property leasing registrations for some of our leased properties. According to our PRC Legal Advisers, the failure to complete the registration process does not affect the validity of the property lease agreements but a maximum penalty of RMB10,000 may be imposed on us for the non-registration of each lease. We cannot assure we will not be subject to any penalties arising from the non-registration of lease agreements in the future. As advised by our PRC Legal Advisor, such non-compliance does not affect the validity of the property lease agreement according to PRC Civil Code and will not have a material adverse effect on the [REDACTED].

RISK FACTORS

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 currently conduct most of our operations in China. 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. 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 benefits we believe are available to us from developing and manufacturing drugs in China.

Changes in the political and economic policies of the PRC government may materially and adversely affect our business, financial condition and results of operations 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 amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While the PRC economy has experienced significant growth over the past 30 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC 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 PRC laws, rules and regulations.

A large portion of our operations are conducted in China through our PRC subsidiaries, and are governed by PRC laws, rules and regulations. Our PRC subsidiaries are subject to laws, rules and regulations applicable to foreign investment in China. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

RISK FACTORS

In 1979, the PRC 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 PRC 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 nonbinding 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 PRC 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 and clinical trial 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.

On July 2, 2021, the NMPA released the Draft of 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)), or the Draft Guiding Principles. The Draft Guiding Principles emphasize the clinical value-oriented and patient-centered research and development concept and encourage Best Support Care to be utilized as a control in randomized controlled trials. Although we believe our trial design of ongoing and planned clinical trials are in compliance with the current version of Draft Guiding Principles, as the CDE is collecting opinions towards the Draft Guiding Principles, there exists uncertainties as to the enactment, interpretation and application thereof. We will pay close attention to the development of the Draft Guiding Principles and if necessary, make adjustments to our oncology drugs clinical trials according to the latest development of this Draft Guiding Principles to ensure our compliance when they are promulgated and come into force in the future. We do not expect any potential material adverse impact of the Draft Guiding Principles on our business operations. However, as the laws and regulations regarding clinical trials are generally evolving, we cannot assure you that if we will at all times fully comply with the relevant laws and regulations in the future. Failure to comply with such laws and regulations could adversely affect our business and results of operation.

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC 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 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.

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

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or to service any debt we may incur. If any of our PRC subsidiaries incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated after-tax profits as determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiaries are required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. At its discretion, our PRC subsidiaries may allocate a portion of its after-tax profits based on PRC accounting standards to an enterprise expansion fund. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in China, up to the amount of net assets held in each operating subsidiary.

In response to the persistent capital outflow in China and RMB’s depreciation against the U.S. dollar, People’s Bank of China, or PBOC, and the SAFE promulgated a series of capital control measures, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments. The PRC government may continue to strengthen its capital controls, and more restrictions and substantial vetting process may be put forward by the SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends to our investors or other obligations to our suppliers, or otherwise fund and conduct our business.

Our dividend income from our PRC subsidiaries may be subject to a higher rate of withholding tax than that which we currently anticipate.

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

Pursuant to the Arrangement Between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), the withholding tax rate on dividends paid by our PRC subsidiary to our

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Hong Kong subsidiary would generally be reduced to 5%, provided that our Hong Kong subsidiary is a Hong Kong tax resident as well as the beneficial owner of the PRC-sourced income and we have obtained the approval of the competent tax authority. On February 3, 2018, the State Taxation Administration, or the SAT issued the Announcement on Certain Issues Concerning the Beneficial Owners in a Tax Agreement (《關於稅收協定中“受益所有人”有關問題的公告》), also known as Circular 9, which provides guidance for determining whether a resident of a contracting state is the “beneficial owner” of an item of income under China’s tax treaties and similar arrangements. According to Circular 9, a beneficial owner generally must be engaged in substantive business activities and an agent will not be regarded as a beneficial owner.

If our Hong Kong subsidiary holds any equity interest in a PRC subsidiary and does not engage in any substantive business activity in the future, based on the abovementioned principles, PRC tax authorities would not consider our Hong Kong subsidiary as the “beneficial owner” of any dividends paid from our PRC subsidiaries and would deny the claim for the reduced rate of withholding tax. Under the current PRC tax law, if our Hong Kong subsidiary is not considered as a “beneficial owner,” dividends from our PRC subsidiaries to our Hong Kong subsidiary being subject to PRC withholding tax at a 10% rate instead of a 5% rate. This would negatively impact us and it would impact our ability to pay dividends in the future.

Uncertainties exist with respect to the interpretation and implementation of the PRC Foreign Investment Law, which may impose new burdens on us.

The PRC Foreign Investment Law, or the FIL, was enacted by the NPC on March 15, 2019 and became effective on January 1, 2020, which replaces a trio of previous laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law, the Sino-foreign Cooperative Joint Venture Enterprise Law and the Wholly Foreign-invested Enterprise Law, together with their implementation rules and ancillary regulations. This law has become the legal foundation for foreign investment in the PRC. The FIL embodies an expected PRC regulatory trend to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. The Implementation Rules to the Foreign Investment Law were promulgated by the State Council on December 26, 2019 and became effective on January 1, 2020. However, uncertainties exist with respect to interpretation and implementation of the FIL and its Implementation Rules, which may adversely impact our corporate governance practice and increase our compliance costs. For instance, we might be required by government interpretations or implementing rules of the FIL to adjust the corporate governance of certain of our PRC subsidiaries in a five-year transition period. In addition, the FIL imposes information reporting requirements on foreign investors or foreign-invested enterprises. Failure to take timely and appropriate measures to cope with any of these or other regulatory compliance requirements under the FIL may lead to rectification obligations, penalties or other regulatory sanctions on us.

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Restrictions on currency exchange may limit our ability to utilize our revenue effectively.

The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. A portion of our revenue is denominated in RMB. Shortages in availability of foreign currency may then restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to 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, including loans we may secure for our onshore subsidiaries. Currently, our PRC subsidiaries may purchase foreign currency for settlement of “current account transactions,” including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Since a portion of our revenue is denominated in RMB, any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

Our business benefits from certain financial incentives and preferential policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our results of operations.

In the past, local governments in China granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. We recorded government grants of RMB0.2 million, RMB0.4 million and RMB0.2 million for the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, respectively. The local governments have the discretion in deciding the timing, amount and criteria of government financial incentives and thus we cannot predict with certainty whether or how much financial incentive will be granted to us even if we apply for such funding. We generally do not have the ability to influence local governments in making these decisions. Government authorities may also decide to reduce or eliminate incentives or may amend or terminate the relevant financial incentive policies at any time. In addition, some of the government financial incentives are granted to us on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to satisfy any such conditions, we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

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We are subject to PRC tax laws and regulations.

We are subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities. Although we believe that in the past we had acted in compliance with the requirements under the relevant PRC tax laws and regulations in all material aspects and had established effective internal control measures in relation to accounting regularities, we cannot assure you that future examinations by PRC tax authorities would not result in fines, other penalties or actions that could adversely affect our business, financial condition and results of operations, as well as our reputation. Furthermore, the PRC government from time to time adjusts or changes its tax laws and regulations. Such adjustments or changes, together with any uncertainty resulting therefrom, could have an adverse effect on our business, financial condition and results of operations.

It may be difficult to effect service of process upon us or our management that reside in China or to enforce against them or us in China any judgments obtained from foreign courts.

Most of our operating subsidiaries are incorporated in China. Some of our management reside in China. Almost all of our assets are located in China. Therefore, it may not be possible for investors to effect service of process upon us or our management inside China. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions. On July 14, 2006, Hong Kong and China entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排) (the “Arrangement”), pursuant to which a party with an enforceable final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with an enforceable final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. 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 Chinese court is expressly designated as the court having sole jurisdiction for the dispute.

On January 18, 2019, the Supreme People’s Court and the government of the 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 the China. The New Arrangement discontinued the requirements for a choice of

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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 and the completion of the relevant legislative procedures in the 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 China 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 does not have treaties or agreements providing for the reciprocal recognition and enforcement of judgments awarded by courts of the U.S., the United Kingdom, or most other western countries. Hence, the recognition and enforcement in China of judgments of a court in any of these jurisdictions in relation to any matter not subject to a binding arbitration provision may be difficult or even impossible.

On January 9, 2021 the MOFCOM promulgated the Measures for Blocking Improper Extraterritorial Application of Foreign Laws and Measures (阻斷外國法律與措施不當域外適用辦法), or Order No.1, pursuant to which, where a citizen, legal person or other organization of China is prohibited or restricted by foreign legislation and other measures from engaging in normal economic, trade and related activities with a third State (or region) or its citizens, legal persons or other organizations, he/it shall truthfully report such matters to the MOFCOM within 30 days. Upon assessment and being confirmed that there exists unjustified extra-territorial application of foreign legislation and other measures, the MOFCOM could issue a prohibition order to the effect that, the relevant foreign legislation and other measures are not accepted, executed, or observed, but such a citizen, legal person or other organization of China may apply to the MOFCOM for an exemption from compliance with such prohibition order. However, since the Order No.1 is relatively new, the enforcement of it involves uncertainty in practice.

Any failure by the Shareholders or beneficial owners of our Shares to comply with PRC foreign exchange or other regulations relating to offshore investment activities could restrict our ability to distribute profits, restrict our overseas and cross-border investment activities and subject us to liability under PRC laws.

The SAFE has promulgated several regulations requiring PRC residents to register with local qualified banks before engaging in direct or indirect offshore investment activities, including Circular of the State Administration of Foreign Exchange on Issues Relating to the Administration of Foreign Exchange Involved in Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles Conducted by Domestic Residents (國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通告), or SAFE Circular 37, issued and effective on July 4, 2014. SAFE Circular 37 requires PRC residents to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment

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and financing, with assets or equity interests of onshore companies or offshore assets or interests held by the PRC residents, referred to in SAFE Circular 37 as a “special purpose vehicle.” SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. If a shareholder who is a PRC citizen or resident does not complete the registration with the local SAFE branches, the PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the special purpose vehicle, and the special purpose vehicle may be restricted to contribute additional capital to its PRC subsidiaries. Moreover, failure to comply with the various SAFE registration requirements described above may result in liabilities for the PRC subsidiaries of the special purpose vehicle under PRC laws for evasion of applicable foreign exchange restrictions, including but not limited to (1) the requirement by the SAFE to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas and deemed to have been evasive, and (2) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive.

According to the Notice of the State Administration of Foreign Exchange on Issuing the Provisions on the Foreign Exchange Administration of the Overseas Direct Investments by Domestic Institutions (國家外匯管理局關於發佈<境內機構境外直接投資外匯管理規定>的通知) (SAFE Circular 30) and other regulations, if our shareholders who are PRC entities do not complete their registration with the competent SAFE, NDRC or MOFCOM branches, our PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to us, and we may be restricted in our ability to contribute additional capital to our PRC subsidiaries. In addition, our shareholders may be required to suspend or stop the investment and complete the registration within a specified time, and may be warned or prosecuted for relevant liability. Moreover, failure to comply with the SAFE registration described above could result in liability under PRC laws for evasion of applicable foreign exchange restriction.

On February 13, 2015, SAFE promulgated the Notice on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知), or SAFE Circular 13, which came into effect on June 1, 2015, pursuant to which local banks shall review and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration under SAFE Circular 37 and SAFE Circular 30, while the application for remedial registrations shall still be submitted to, reviewed and handled by the relevant local branches of SAFE.

There remains uncertainty as to the interpretation and implementation of the latest SAFE rules at practice level. We are committed to complying with and to ensuring that our Shareholders who are subject to the regulations will comply with the relevant SAFE rules and other regulations; however, due to the inherent uncertainty in the implementation of the regulatory requirements by PRC authorities, such registration might not be always practically available in all circumstances as prescribed in those regulations. In addition, we may not

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

We face uncertainty relating to PRC laws and regulations relating to transfers by a non-resident enterprise of assets of a PRC resident enterprise.

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 (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), or Circular 7, which supersedes certain provisions in the Notice on Strengthening the Administration of Enterprise Income Tax on non-Resident Enterprises (關於加強非居民企業股權轉讓企業所得稅管理的通知), or Circular 698, 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 heightened the PRC tax authorities’ scrutiny over, indirect transfers by a non-resident enterprise of assets (including equity interests) of a PRC resident enterprise, or 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 the 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

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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.

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. 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.

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,” or 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 the Several Issues Relating to the Administration of Income Tax on Non-resident Enterprises (關於非居民企業所得稅管理若干問題的公告). 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 obligations imposed under the Circular 7 if the transfers fall under the Public Market Safe Harbor. As stated in “Information about this Document and the [REDACTED]” in this document, potential [REDACTED] should consult their professional advisors if they are in any doubt as to the tax implications of subscribing for, purchasing, holding, disposing of and dealing in the Shares.

Under China’s Enterprise Income Tax Law, we may be classified as a “resident enterprise” of China. This classification could result in unfavorable tax consequences to us and our non-PRC shareholders.

Under China’s Enterprise Income Tax Law, or the “EIT Law,” an enterprise established outside of China with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it can be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. Notice on Issues about the Determination of Chinese-Controlled Enterprises Registered Abroad as Resident Enterprises on the Basis of Their Body of Actual Management (關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知), which was issued by the SAT on April 22, 2009, or Circular 82, regarding the standards used to classify resident enterprises clarified that dividends and other distributions

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paid by such resident enterprises which are considered to be PRC source income will be subject to PRC withholding tax, currently at a rate of 10%, when received or recognized by non-PRC resident enterprise shareholders. This circular also subjects such resident enterprises to various reporting requirements with the PRC tax authorities. The implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting and properties” of the enterprise. In addition, Circular 82 specifies that certain China-invested enterprises controlled by Chinese enterprises or Chinese group enterprises will be classified as resident enterprises if the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal and minutes of board meetings and shareholders’ meetings; and (iv) half or more of senior management or directors having voting rights. On July 27, 2011, the SAT issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial) (境外註冊中資控股居民企業所得稅管理辦法(試行)), or Bulletin 45, which became effective on September 1, 2011, to provide further guidance on the implementation of Circular 82. Bulletin 45 clarifies certain issues related to determining PRC resident enterprise status, including which competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration.

Currently, most of the members of our management team as well as the management team of some of our offshore holding companies are located in China. However, Circular 82 and Bulletin 45 only apply to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreign corporations like us. In the absence of detailed implementing regulations or other guidance determining that offshore companies controlled by PRC individuals or foreign corporations like us are PRC resident enterprises, we do not currently consider our Company or any of our overseas subsidiaries to be a PRC resident enterprise.

Despite the foregoing, the SAT may take the view that the determining criteria set forth in Circular 82 and Bulletin 45 reflect the general position on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises. Additional implementing regulations or guidance may be issued determining that our Cayman Islands holding company is a “resident enterprise” for PRC enterprise income tax purposes. If the PRC tax authorities determine that our Cayman Islands holding company or any of our non-PRC subsidiaries is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. Second, although under the EIT Law and its implementing rules and Bulletin 45 dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by a PRC enterprise or enterprise group would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax, as the PRC foreign-exchange control authorities and tax authorities have not yet issued guidance

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with respect to the processing of outbound remittances to entities that are treated as resident enterprises for PRC enterprise income tax purposes but not controlled by a PRC enterprise or enterprise group like us. Finally, under the EIT Law and its implementing rules issued by PRC tax authorities dividends paid by us to our non-PRC shareholders may be subject to a withholding tax of 10% for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders, and gains recognized by our non-PRC shareholders may be subject to PRC tax of 10% for non-PRC enterprise shareholders and 20% for non-PRC individual shareholders. Any PRC tax liability on dividends or gain described above may be reduced under applicable tax treaties. However, it is unclear whether, if our Cayman Islands holding company is considered a PRC resident enterprise, non-PRC shareholders might be able to claim the benefit of income tax treaties entered into between PRC and their countries. Similarly, these unfavorable consequences could apply to our other offshore companies if they are classified as a PRC resident enterprise.

Government control of currency conversion of and regulations on loans to, and direct investment in, PRC entities by offshore holding companies may delay or prevent us from making loans or additional contributions to our PRC subsidiaries, which could restrict our ability to utilize the [REDACTED] from the [REDACTED] effectively and affect our ability to fund and expand our business.

The PRC government imposes controls on the convertibility of foreign currencies into Renminbi. Under China’s existing foreign-exchange regulations, foreign-exchange transactions under capital accounts continue to be subject to significant foreign-exchange controls and require the registration with, and approval of, PRC governmental authorities. In particular, if one subsidiary receives foreign-currency loans from us or other foreign lenders, these loans must be registered with SAFE or its local counterparts. If we finance such subsidiary by means of additional capital contributions, these capital contributions must be filed with or approved by certain government authorities, including the MOFCOM or its local counterparts.

In August 2018, the SAFE promulgated the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Exchange Capital Funds of Foreign Invested Enterprises (國家外匯管理局綜合司關於完善外商投資企業外匯資本金支付結算管理有關業務操作問題的通知), or SAFE Circular 142, providing that the Renminbi capital converted from foreign exchange capital funds of a foreign-invested enterprise may only be used for purposes within the business scope approved by the applicable government authority and may not be used for equity investment within the PRC.

On March 30, 2015, SAFE released the Notice on the Reform of the Management Method for 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), or SAFE Circular 19, which came into force from June 1, 2015, and superseded SAFE Circular 142. On June 9, 2016, SAFE further promulgated the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects (關於改革和規範資本項目結匯管理政策的通知), or SAFE Circular 16. SAFE Circular 19 has made certain adjustments to some regulatory requirements

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on the settlement of foreign exchange capital of foreign-invested enterprises. Under SAFE Circular 19 and SAFE Circular 16, the settlement of foreign exchange by foreign invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, SAFE Circular 19 and SAFE Circular 16 also reiterate that the settlement of foreign exchange shall only be used for its own operation purposes within the business scope of the foreign invested enterprises and following the principles of authenticity. Under SAFE Circular 19 and SAFE Circular 16, we may still not be allowed to convert foreign-currency-registered capital of our PRC subsidiaries which are foreign-invested enterprises into RMB capital for securities investments or other finance and investment except for principal-guaranteed bank products. Further, SAFE Circular 19 and SAFE Circular 16 restrict a foreign-invested enterprise from using Renminbi converted from its registered capital to provide loans to a its non-affiliated company.

Violations of SAFE Circular 19 and SAFE Circular 16 could result in severe monetary or other penalties. We cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by us to our PRC subsidiaries, and conversion of such loans or capital contributions into Renminbi. If we fail to complete such registrations or obtain such approvals, our ability to capitalize or otherwise fund our PRC operations may be negatively affected, which could adversely affect our ability to fund and expand our business. On October 23, 2019, the SAFE released the Circular on Further Promoting Cross-border Trade and Investment Facilitation (國家外匯管理局關於進一步促進跨境貿易投資便利化的通知), or SAFE Circular 28, according to which a non-investment foreign-invested enterprise is permitted to make domestic equity investments with its capital funds provided that such investments do not violate the Negative List and the target investments are genuine and in compliance with laws. On April 10, 2020, the SAFE promulgated the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (關於優化外匯管理支持涉外業務發展的通知), or SAFE Circular 8, under which eligible enterprises are allowed to make domestic payments by using their capital funds, foreign loans and the income under capital accounts of overseas listing, without providing the evidentiary materials concerning authenticity of each expenditure in advance, provided that their capital use shall be authentic, and conform to the prevailing administrative regulations on the use of income under capital accounts. Considering that SAFE Circular 28 and SAFE Circular 8 are often principle-oriented and subject to the detailed interpretations by the enforcement bodies to further apply and enforce such laws and regulations in practice, it is unclear how they will be implemented, and there can be high uncertainties with respect to its interpretation and implementation by government authorities and banks.

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The political relationships between China and other countries or regions may affect our business operations.

During the Track Record Period, we have formed partnerships with entities in foreign countries and regions and initiated or plan to initiate clinical trials, in the U.S., Australia, South Korea, Taiwan and certain Asia countries and territories. Establishing new collaboration partnerships globally is key to our future growth. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. As a result, China's political relationships with those foreign countries and regions may affect the prospects of maintaining existing or establishing new collaboration partnerships.

There can be no assurance that such collaborators 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. Since mid-2018, political tension has increased between China and the U.S. and has escalated into a tariff war and deteriorating political and diplomatic relationships. There can be no assurance that potential collaboration partners will not alter their perception of us or their preferences as a result of such adverse changes between China and relevant foreign countries or regions. 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. 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 THE [REDACTED]

No public market currently exists for our Shares; an active trading market for our Shares may not develop and the market price for our Shares may decline or become volatile.

No public market currently exists for our Shares. The initial [REDACTED] for our Shares to the public will be the result of negotiations between our Company and the [REDACTED] (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 deal 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 of the Shares will not decline following the [REDACTED].

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The price and trading volume of our Shares may be volatile, which could lead to substantial losses to investors.

The price and trading volume of our Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and trading volume of our Shares. In addition to market and industry factors, the price and trading volume of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our drug candidates, the results of our applications for approval of our drug candidates, regulatory developments affecting the pharmaceutical industry, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies listed on the Stock Exchange 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 pricing and trading of our Shares, and the price of our Shares when trading begins could be lower than the [REDACTED].

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

Future sales or perceived sales of our Shares in the public market 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 public market 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.

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You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares or other equity securities in the future, including pursuant to the share incentive schemes.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] 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 incentive schemes, which would further dilute Shareholders’ interests in our Company.

We do not expect to pay dividends in the foreseeable future after the [REDACTED].

We currently intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the development and commercialization of our pipeline drug candidates. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an [REDACTED] 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. Accordingly, the return on your [REDACTED] in our Shares will likely depend entirely upon any future price appreciation of our Shares. There is no guarantee that our Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased the Shares. You may not realize a return on your [REDACTED] in our Shares and you may even lose your entire [REDACTED] in our Shares.

We have significant discretion as to how we will use the net [REDACTED] of the [REDACTED], and you may not necessarily agree with how we use them.

Our management may spend the net [REDACTED] from the [REDACTED] in ways you may not agree with or that do not yield a favorable return to our shareholders. We plan to use the net [REDACTED] from the [REDACTED] to conduct clinical trials in China and other APAC regions on our most promising drug candidates and to expand our sales and marketing staff in preparation for the approval and commercialization of those drug candidates. For details, see “Future Plans and Use of [REDACTED] – Use of [REDACTED].” However, our management will have discretion as to the actual application of our net [REDACTED]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the net [REDACTED] from this [REDACTED].

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

Our corporate affairs are governed by our Memorandum and Articles and by the Cayman Companies Act and 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 the jurisdictions where minority Shareholders may be located. See "Appendix III – Summary of the Constitution of Our Company and Cayman Companies Act" in this document.

As a result of all of the above, minority Shareholders may have difficulties in protecting their interests under the laws of the Cayman Islands through actions against our management, Directors or Substantial Shareholders, which may provide different remedies to minority Shareholders when compared to the laws of the jurisdiction in which such shareholders are located.

Facts, forecasts and statistics 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, we cannot guarantee the quality or reliability of these sources. Neither we, the [REDACTED], the Joint Sponsors, the [REDACTED], the [REDACTED], the [REDACTED] nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the statistics in this document relating to the pharmaceutical industry in and outside China may be inaccurate and you should not place undue reliance on them. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various 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 document carefully, and we caution you not to place any reliance on any information contained in press articles or other media regarding us or the [REDACTED].

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

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

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In preparation for the [REDACTED], we have sought the following waivers from strict compliance with the relevant provisions of the Listing Rules and exemptions from strict 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, an issuer must have sufficient management presence in Hong Kong. This normally means that at least two of its executive directors must be ordinarily resident in Hong Kong.

Our Group’s management, business operations and assets are primarily based outside Hong Kong. The headquarters and business operations of our Group are primarily based, managed and conducted outside Hong Kong. We do not have sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 of the Listing Rules.

Since our headquarters and most of the business operations of our Group are managed and conducted outside of Hong Kong, and the executive Director of our Company ordinarily resides outside Hong Kong, our Company considers that it would be practically difficult and commercially unreasonable and undesirable for our Company to arrange for two executive Directors to be ordinarily resident in Hong Kong, either by means of relocation of existing executive Director or appointment of additional executive Directors. Our Company does not have and does not contemplate in the foreseeable future that we will have sufficient management. Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rule 8.12 of the Listing Rules. We will ensure that there is an effective channel of communication between us and the Stock Exchange by way of the following arrangements:

- (a) our Company has appointed Dr. Xue and Mr. Wong Keith Shing Cheung (王承鐸) as authorized representatives of our Company (the “**Authorized Representatives**”) pursuant to Rules 3.05 of the Listing Rules. The Authorized Representatives will act as our Company’s principal channel of communication with the Stock Exchange. They will be readily contactable by phone, facsimile and email to promptly deal with enquiries from the Stock Exchange, and will also be available to meet with the Stock Exchange to discuss any matters within a reasonable period of time upon request of the Stock Exchange;
- (b) when the Stock Exchange wishes to contact our Directors on any matter, each of the Authorized Representatives and the Stock Exchange will have all necessary means to contact all of our Directors (including the independent non-executive Directors) at all times. Our Company will also inform the Stock Exchange promptly in respect of any changes in the Authorized Representatives;

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- (c) furthermore, all Directors who do not ordinarily reside in Hong Kong possess or can apply for valid travel documents to visit Hong Kong and can meet with the Stock Exchange within a reasonable period; and
- (d) we have appointed Somerley Capital Limited as our Company’s Compliance Adviser upon [REDACTED] pursuant to Rule 3A.19 of the Listing Rules for a period commencing on the [REDACTED] and ending on the date on which our Company complies with Rule 13.46 of the Listing Rules in respect of our Company’s financial results for the first full financial year commencing after the [REDACTED]. The Compliance Adviser will have access at all times to our Company’s Authorized Representatives, the Directors and other senior management and act as the additional channel of communication with the Stock Exchange when the Authorized Representatives are not available. Our Company shall ensure that the Compliance Adviser will have access at all times to its Authorized Representatives, Directors and other officers. Our Company shall also ensure that such persons will timely provide such information and assistance as the Compliance Adviser may need or may reasonably request in connection with the performance of the Compliance Adviser’s duties as set forth in Chapter 3A. Our Company shall ensure that there are adequate and efficient means of communication between itself, its Authorized Representatives, Directors and other officers and the Compliance Adviser, and will keep the Compliance Adviser fully informed of all communications and dealings between itself and the Stock Exchange.

WAIVER IN RELATION TO APPOINTMENT 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. Ma Qian (馬倩) (“**Ms. Ma**”) and Mr. Wong Keith Shing Cheung (王承鐸) (“**Mr. Wong**”) as our joint company secretaries. Mr. Wong is a member of the Hong Kong Institute of Certified Public Accountants, 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. Ma has facilitated legal and compliance of the Company since 2017. She has extensive experience in legal and compliance, corporate governance and general corporate matters but presently does not possess any of the qualifications under Rules 3.28 and 8.17 of the Listing Rules. While Ms. Ma 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. Ma as our joint company secretary due to her thorough understanding of the administration and legal and compliance of our Group.

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Accordingly, while Ms. Ma 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. Ma 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 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 Mr. Wong, as a joint company secretary of our Company and a Qualified Person, will work closely with, and provide assistance to, Ms. Ma 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 Mr. Wong’s professional qualifications and experience, he will be able to explain to both Ms. Ma and our Company the relevant requirements under the Listing Rules. Mr. Wong will also assist Ms. Ma 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. He is expected to work closely with Ms. Ma, and will maintain regular contact with Ms. Ma, the Directors and the senior management of our Company. The waiver will be revoked immediately if Mr. Wong ceases to provide assistance to Ms. Ma 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. Ma 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. Ma attended a training seminar 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, Davis Polk & Wardwell, and has been provided with the relevant training materials. Our Company will further ensure that Ms. Ma 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 Mr. Wong and Ms. Ma 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 Somerley Capital 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

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experience of Ms. Ma and the need for ongoing assistance of a Qualified Person will be further evaluated by our Company. We will liaise with the Stock Exchange to enable it to assess whether Ms. Ma, having benefited from the assistance of Mr. Wong and, if applicable, another Qualified Person 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.

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

EXEMPTION IN RELATION TO FINANCIAL STATEMENTS IN THIS DOCUMENT

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 (the “**Third Schedule**”), and set out the reports specified in Part II of the Third Schedule.

Paragraph 27 of Part I of the Third Schedule requires a company to include in its document 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 document, 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 further requires a company to include in its document a report by the auditors of the company with respect to (i) the profits and losses of the company for each of three financial years immediately preceding the issue of the document and (ii) the assets and liabilities of the company of each of the three financial years immediately preceding the issue of the document.

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

Rule 4.04(1) of the Listing Rules requires that the consolidated results of the issuer and its subsidiaries in respect of each of the three financial years immediately preceding the issue of the [REDACTED] document be included in the Accountants’ Report to its document.

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Our Company is a Biotech Company as defined under Chapter 18A of the Listing Rules and is seeking a [REDACTED] under Chapter 18A of the Listing Rules. Rule 18A.03(3) of the Listing Rules requires that a Biotech Company must have been in operation in its current line of business for at least two financial years prior to [REDACTED] under substantially the same management. Rule 18A.06 of the Listing Rules requires that a Biotech Company must comply with Rule 4.04 of the Listing Rules modified so that references to “three financial years” or “three years” in Rule 4.04 shall instead be references to “two financial years” or “two years”, as the case may be. Further, pursuant to Rule 8.06 of the Listing Rules, the latest financial period reported on by the reporting accountants for a new applicant must not have ended more than six months from the date of the [REDACTED] 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 currently prepared to cover the two financial years ended December 31, 2019 and 2020 and the six months ended June 30, 2021.

As such, the Joint Sponsors have applied, on behalf of our Company, 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 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 development, manufacturing and commercialization of biotech products, and falls within the scope of Biotech Company as defined under Chapter 18A of the Listing Rules. Our Company will fulfill the additional conditions for [REDACTED] required under Chapter 18A of the Listing Rules;
- (b) as of the Latest Practicable Date, we have generated limited revenue from product sales. Major financing activities conducted by us since our incorporation include our [REDACTED] Investments, the details of which have been fully disclosed in the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments” in this document;
- (c) given that our Company is only required to disclose its financial results for each of the two financial years ended December 31, 2019 and 2020 under Chapter 18A of the Listing Rules, 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 would be unduly burdensome for our Company;

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- (d) notwithstanding that the financial results set out in this document are only for [the two financial years ended December 31, 2019 and 2020 and the six months ended June 30, 2021 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements; and
- (e) the Accountants' Report covering the two financial years ended December 31, 2019 and 2020 and the six months ended June 30, 2021 (as set out in Appendix I to this document), together with other disclosures in this document, have already provided adequate and reasonable up-to-date information in the circumstances for the potential [REDACTED] to make an informed assessment of the business, assets and liabilities, financial position, management and prospects and to form a view on the track record of our Company. 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 on the condition that particulars of the exemption are set out in this document and that this document will be issued on or before [●], 2021.

WAIVER AND EXEMPTION IN RELATION TO THE [REDACTED] EQUITY INCENTIVE PLAN

Rule 17.02(1)(b) of the Listing Rules requires a listing applicant to, *inter alia*, disclose in the prospectus full details of all outstanding options and their potential dilution effect on the shareholdings upon listing as well as the impact on the earnings per share arising from the exercise of such outstanding options.

Paragraph 27 of Appendix 1A to the Listing Rules requires a listing applicant to disclose, *inter alia*, particulars of any capital of any member of the group which is under option, or agreed conditionally or unconditionally to be put under option, including the consideration for which the option was or will be granted and the price and duration of the option, and the name and address of the grantee, or an appropriate negative statement, provided that where options have been granted or agreed to be granted to all the members or debenture holders or to any class thereof, or to employees under a share option scheme, it shall be sufficient, so far as the names and addresses are concerned, to record that fact without giving the names and addresses of the grantees.

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

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(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

Under paragraph 10 of Part I of the Third Schedule, the number, description and amount of any shares in or debentures of the company which any person has, or is entitled to be given, an option to subscribe for, together with the particulars of the option, that is to say, (a) the period during which it is exercisable; (b) the price to be paid for shares or debentures subscribed for under it; (c) the consideration (if any) given or to be given for it or for the right to it; and (d) the names and addresses of the persons to whom it or the right to it was given or, if given to existing shareholders or debenture holders as such, the relevant shares or debentures must be specified in the prospectus.

As of the Latest Practicable Date, our Company had granted options under the [REDACTED] Equity Incentive Plan to [177] grantees to subscribe for an aggregate of 5,584,800 Shares (or 55,848,000 Shares as adjusted after the Share Subdivision). Share Options to subscribe for 129,877 Shares (or 1,298,770 Shares as adjusted after the Share Subdivision) had lapsed following the resignation of certain grantees and Share Options corresponding to [686,005] Shares (or [6,860,050] Shares as adjusted after the Share Subdivision) had been exercised. As of the Latest Practicable Date, Share Options granted to [177] grantees to subscribe for [4,768,918] Shares (or 47,689,180 Shares as adjusted after the Share Subdivision) were outstanding, representing approximately [REDACTED]% of our Company’s issued share capital immediately after completion of the [REDACTED] (assuming the [REDACTED] is not exercised) for which the grantees include [4] Directors (with respect to [1,133,142] underlying Shares (or [11,331,420] underlying Shares as adjusted after the Share Subdivision)), [3] senior management member (with respect to 816,454 underlying Shares (or 8,164,540 underlying Shares as adjusted after the Share Subdivision)) and [170] other grantees (the “Other Grantees”) (with respect to an aggregate of 2,819,322 underlying Shares (or 28,193,220 underlying Shares as adjusted after the Share Subdivision)). No Share Options were granted to other Connected Persons of the Company. No Shares remain available for grant under the [REDACTED] Equity Incentive Plan.

The principal terms of the [REDACTED] Equity Incentive Plan is set out in the section headed “Appendix IV – Statutory and General Information – D. [REDACTED] Equity Incentive Plan” in this document.

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

We have applied to (i) the Stock Exchange for a waiver from strict compliance with the requirements under Rule 17.02(1)(b) of the Listing Rules and paragraph 27 of Appendix 1A to the Listing Rules and (ii) the SFC for an exemption from strict compliance with paragraph 10(d) of Part I of the Third Schedule pursuant to section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in connection with the disclosure of certain details relating to the Share Options and certain grantees in this document on the ground that the waiver and the exemption will not prejudice the interest of the investing public and strict compliance with the above requirements would be unduly burdensome for our Company for the following reasons:

- (a) our Directors consider that it would be unduly burdensome to disclose in this document full details of all the Share Options granted by us to each of the grantees, which would significantly increase the cost and time required for information compilation and document preparation for strict compliance with such disclosure requirements;
- (b) material information on the Share Options has been disclosed in this document to provide prospective [REDACTED] with sufficient information to make an informed assessment of the potential dilutive effect and impact on earnings per Share of the Share Options in making their investment decision, and such information includes:
 - (i) a summary of the latest terms of the [REDACTED] Equity Incentive Plan;
 - (ii) the aggregate number of Shares subject to the Share Options and the percentage of our Shares of which such number represents;
 - (iii) the dilutive effect and the impact on earnings per Share upon full exercise of the Share Options immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised);
 - (iv) full details of the Share Options granted to our Directors and members of the senior management are disclosed in this document, and such details include all the particulars required under Rule 17.02(1)(b) of the Listing Rules, paragraph 27 of Appendix 1A to the Listing Rules and paragraph 10 of Part I of the Third Schedule;
 - (v) with respect to the Share Options granted by our Company under the [REDACTED] Equity Incentive Plan to grantees, other than those referred to in sub-paragraph (iv) above, the following details are disclosed in this document, including the aggregate number of such grantees and the number of Shares subject to the Share Options, the consideration paid for the grant of the Share Options and the exercise period and the exercise price for the Share Options; and

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

- (vi) the particulars of the waiver and exemption granted by the Stock Exchange and the SFC, respectively;

Our Directors consider that the above disclosure is consistent with the conditions ordinarily expected by the Stock Exchange in similar circumstances as set out in Guidance Letter HKEx- GL11-09 issued in July 2009 and updated in March 2014 by the Stock Exchange.

- (c) the [170] other grantees have been granted Share Options under the [REDACTED] Equity Incentive Plan to acquire an aggregate of 2,819,322 Shares (or 28,193,220 underlying Shares as adjusted after the Share Subdivision), which is not material in the circumstances of our Company, and the exercise in full of such Share Options will not cause any material adverse change in the financial position of our Company;
- (d) our Directors consider that non-compliance with the above disclosure requirements would not prevent our Company from providing potential [REDACTED] with sufficient information for an informed assessment of the activities, assets, liabilities, financial position, management and prospects of our Group; and
- (e) a full list of all the grantees containing all details as required under Rule 17.02(1)(b) of the Listing Rules, paragraph 27 of Appendix 1A to the Listing Rules and paragraph 10 of Part I of the Third Schedule will be made available for inspection in accordance with the section headed “Appendix V – Documents Delivered to the Registrar of Companies and Available on Display – [Documents Available for Inspection]” in this document.

The Stock Exchange [has granted] us a waiver from strict compliance with the relevant requirements under the Listing Rules subject to the conditions that disclosure in respect of the information referred to in paragraph (c) above has been made in this document.

The SFC [has granted] us a certificate of exemption under Section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting our Company from strict compliance with paragraph 10(d) of Part I of the Third Schedule, subject to the conditions that:

- (a) full details of the Share Options granted to our Directors and members of the senior management be disclosed in this document, and such details include all the particulars required under paragraph 10 of Part I of the Third Schedule;

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

- (b) with respect to the Share Options granted by our Company under the [REDACTED] Equity Incentive Plan to the Other Grantees, the following details, including (i) the aggregate number of such grantees and the number of Shares subject to the Share Options; (ii) the consideration paid for the grant of the Share Options; and (iii) the exercise period and the exercise price for the Share Options be disclosed in this document;

- (c) a full list of all the grantees (including the persons referred to in sub-paragraph (a) above) who have been granted Share Options to acquire Shares under the [REDACTED] Equity Incentive Plan, containing all the details as required under paragraph 10 of Part I of the Third Schedule, be made available for inspection in accordance with the section headed “Appendix V – Documents Delivered to the Registrar of Companies and Available on Display – [Documents Available for Inspection]” in this document; and

- (d) the particulars of the exemption be set forth in this document and that this document will be issued on or before [●], 2021.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
<i>Executive Director</i>		
Dr. James Qun Xue	No. 118 Lane 1500 Sizhuan South Rd. Songjiang District Shanghai PRC	American
<i>Non-executive Directors</i>		
Dr. Kan Chen (陳侃)	3842 167th PL NE Apartment K2033 Redmond Washington 98052 United States of America	Chinese
Dr. Derek Paul Di Rocco	17 Salem Street Winchester Massachusetts 01890-1820 United States of America	American
Mr. Xiao Le (樂霄)	No. 288 Fute Zhong Rd. Pudong New Area Shanghai PRC	Chinese
<i>Independent Non-executive Directors</i>		
Dr. Richard James Gregory	166 Tower Road Lincoln Massachusetts 01773 United States of America	American
Mr. James Arthur Geraghty	10 Charlesgate East, Apt 601 Boston Massachusetts 02215 United States of America	American
Mr. Peng Kuan Chan (陳炳鈞)	Flat B8, 14/F, Block B Viking Garden 40-42 Hing Fat Street Tin Hau Hong Kong	Hong Kong

Please refer to the section headed “Directors and Senior Management” in this document for further information with respect to our Directors.

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

Joint Sponsors and [REDACTED]

Morgan Stanley Asia Limited

46/F, International Commerce Centre

1 Austin Road West

Kowloon

Hong Kong

Jefferies Hong Kong Limited

Suite 2201, 22/F Cheung Kong Center

2 Queen's Road Central

Hong Kong

[REDACTED]

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

Legal Advisers to our Company

As to Hong Kong law and United States law:

Davis Polk & Wardwell

Hong Kong Solicitors
18th Floor, The Hong Kong Club Building
3A Chater Road
Hong Kong

As to PRC law:

King & Wood Mallesons

18th Floor, East Tower,
World Financial Center
1 Dongsanhuan Zhonglu
Chaoyang District
Beijing 100020

As to Cayman Islands law:

Harney Westwood & Riegels

3501 The Center
99 Queen's Road Central
Central
Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

Legal Advisers to the Joint Sponsors and the [REDACTED]

As to Hong Kong law and United States law:

Kirkland & Ellis

26th Floor
Gloucester Tower
The Landmark
15 Queen's Road Central
Hong Kong

As to PRC law:

Tian Yuan Law Firm

10/F, Tower B,
China Pacific Insurance Plaza,
28 Fengsheng Hutong
Xicheng District
Beijing
PRC

Auditor and Reporting Accountant

Ernst & Young

*Certified Public Accountants and
Registered Public Interest Entity Auditor*
22/F, CITIC Tower
1 Tim Mei Avenue
Central
Hong Kong

Industry Consultant

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

2504 Wheelock Square
1717 Nanjing West Road
Shanghai
China

[REDACTED]

CORPORATE INFORMATION

Registered Office	89 Nexus Way Camana Bay Grand Cayman KY1-9009 Cayman Islands
Head Office and Principal Place of Business in the PRC	Suite 301 3F, Timeloit No. 17 Rong Chuang Road Chaoyang District Beijing PRC ^(Note)
Principal Place of Business in Hong Kong	Unit A131, 16/F, Tower 5 The Gateway, Harbour City 15 Canton Road, Tsim Sha Tsui Hong Kong
Company’s Website	<u>www.canbridgepharma.com</u> <i>(The information contained in this website does not form part of this document)</i>
Joint Company Secretaries	Ms. Qian Ma (馬倩) Suite 301 3F, Timeloit No. 17 Rong Chuang Road Chaoyang District Beijing PRC Mr. Keith Shing Cheung Wong (王承鐸) <i>(member of the Hong Kong Institute of Certified Public Accountants)</i> 40th Floor, Dah Sing Financial Centre No. 248 Queen’s Road East Wanchai Hong Kong

Note: The Company expects to relocate its China headquarters to Suzhou, Jiangsu Province in the future

CORPORATE INFORMATION

Audit Committee	Mr. Peng Kuan Chan (陳炳鈞) (<i>Chairperson</i>) Dr. Richard James Gregory Dr. Kan Chen (陳侃)
Remuneration Committee	Dr. Richard James Gregory (<i>Chairperson</i>) Mr. James Arthur Geraghty Mr. Xiao Le (樂霄)
Nomination and Corporate Governance Committee	Dr. James Qun Xue (<i>Chairperson</i>) Dr. Derek Paul Di Rocco Dr. Richard James Gregory Mr. James Arthur Geraghty Mr. Peng Kuan Chan (陳炳鈞)
Authorized Representatives	Dr. James Qun Xue No. 118 Lane 1500 Sizhuan South Rd. Songjiang District Shanghai PRC Mr. Keith Shing Cheung Wong (王承鐸) (<i>member of the Hong Kong Institute of Certified Public Accountants</i>) 40th Floor, Dah Sing Financial Centre No. 248 Queen's Road East Wanchai Hong Kong
Compliance Adviser	Somerley Capital Limited 20th Floor, China Building 29 Queen's Road Central Hong Kong
Principal Share Registrar and Transfer Office	Ogier Global (Cayman) Limited 89 Nexus Way Camana Bay Grand Cayman KY1-9009 Cayman Islands

CORPORATE INFORMATION

[REDACTED]

Principal Banks

SPD Silicon Valley Bank

22F, Block B, Baoland Plaza
588 Dalian Rd
Shanghai
PRC

Silicon Valley Bank

3003 Tasman Drive
Santa Clara
CA95054
United States

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from different official government publications, available sources from public market research and other sources from independent suppliers, and from the independent industry report prepared by Frost & Sullivan. We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the [REDACTED]. We have no reason to believe that such information is false or misleading in any material respect or that any fact has been omitted that would render such information false or misleading in any material respect. The information from official government sources has not been independently verified by us, the [REDACTED], Joint Sponsors, [REDACTED], [REDACTED], any of the [REDACTED], any of their respective directors and advisers, or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy. Accordingly, the information from official government sources contained herein may not be accurate and should not be unduly relied upon.

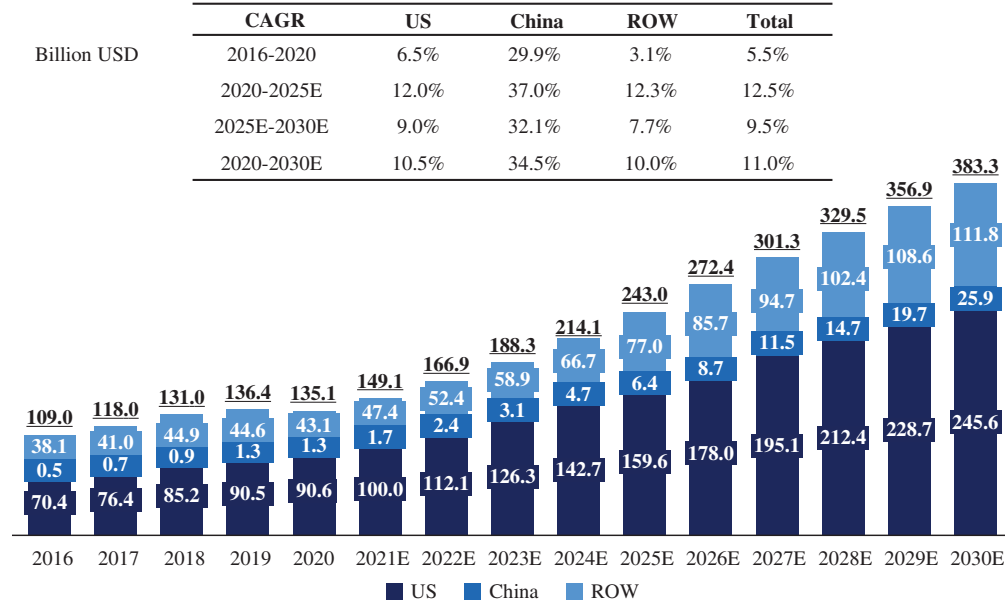
OVERVIEW OF THE GLOBAL RARE DISEASE MARKET

The global rare disease market is a sector of biopharmaceutical market focused on the discovery, development and commercialization of medicines for the treatment of diseases which affect a small number of people, compared with other prevalent diseases in the general population. According to Frost and Sullivan, approximately 80% of rare diseases are genetic, with three out of four cases starting in childhood and a mortality rate of 30% before the age of five. Collectively, rare diseases are estimated to affect 3.5%-5.9% of the world’s population.

The market size of global rare disease drug market grew from US\$135.1 billion in 2020 to US\$383.3 billion in 2030 at a CAGR of 11.0% from 2020 to 2030. Particularly, the rare disease drug market in China is expected to dramatically grow from US\$1.3 billion in 2020 to US\$25.9 billion in 2030 at a CAGR of 34.5%, as compared to the market growth in the U.S. and the rest of the world in the same period at a CAGR of 10.5% and 10.0%, respectively. The China rare disease drug market accounted for 0.4% and 1.0% of the global rare disease market in 2016 and 2020, respectively, and is expected to account for 6.8% in 2030, indicating favorable rare disease market outlook, as China reforms to introduce more innovative medicines to the market and improved access/affordability. The following chart illustrates the historical and forecasted rare disease drug market in the U.S., China and the rest of the world from 2016 to 2030.

INDUSTRY OVERVIEW

Global Rare Disease Drug Market, Breakdown by Regions, 2016-2030E



**Note:* Rare disease drugs in this market include drugs indicated for rare disease only and drugs obtaining orphan drug designation first but their indication expanded later of which generated most of their revenue, such as Humira. However, the part of revenue generated by expanded non-orphan indications was not included in this market.

Frost & Sullivan conducted market researches and interviews on both the demand side and the supply side on the relevant marketed or under-study rare disease drugs via multi-channel sources, including literature researches, secondary industry report, enterprise sales data, expert interview, the overview of the major and other competitors, the overview of major rare disease and relevant market pricing, and the market development trends. Based on these researches, Frost & Sullivan collected the revenue of marketed rare disease drugs with public information and made estimation for the revenue of those without public information to calculate the global market size of rare disease drug. Besides, the market size only includes the revenue of rare disease drugs approved for indicated therapeutic area at ex-factory level. For the therapeutic area that has no approved products, Frost & Sullivan had estimation on when the drug candidates would be approved based on the under-study pipeline circumstances globally.

Source: Frost & Sullivan analysis

Due to the nature of low prevalence, rare diseases were historically an infrequent target for the development of drug treatments by pharmaceutical companies. The term prevalence refers to the total number of people in a community who experience a disease or health condition at a given time, while incidence refers to the number of new cases developed in a population during a given time period. According to Frost & Sullivan, there are about 7,000 rare diseases lacking authorized or satisfactory method of treatment worldwide, reflecting the serious unmet needs for such life-threatening or chronically debilitating diseases. In addition, the majority of rare diseases are chronic and are associated with long term high medical costs and reduced quality of life. The unique nature of rare diseases resulted in a high mortality rate and significant social and economic burden on patients, which renders the development of effective treatments urgent and essential. Small molecules and biologic drug treatments for rare diseases include replacement of deficient gene products, repurposed drugs, newly designed molecular entities, and manipulation of gene expression. Other non-drug treatments involve organ transplantation.

INDUSTRY OVERVIEW

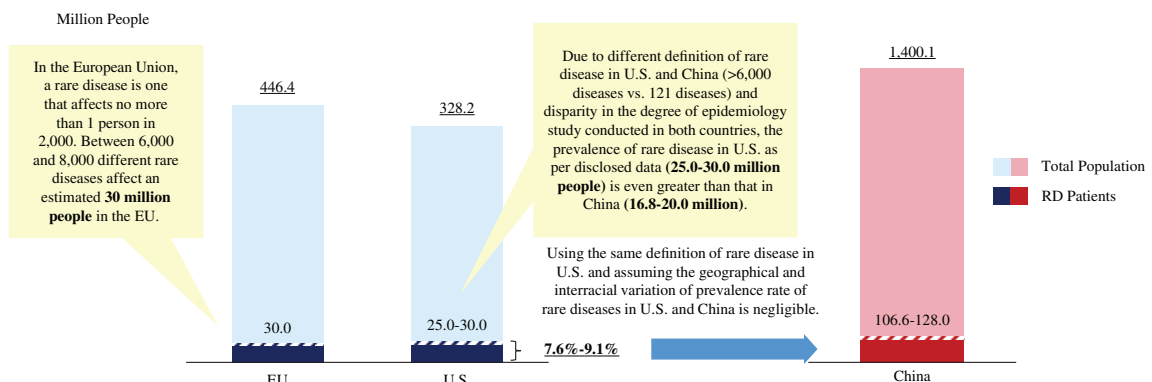
There is currently no harmonized global definition for rare diseases. The definition and classification of rare diseases and the granting of orphan drug designation may differ across regulatory authorities. Governments and respective agencies may establish separate thresholds based on local needs. The table below summarizes the respective definition of rare disease implemented in the U.S., Europe and China.

	The U.S.	Europe	China
Definition	<ul style="list-style-type: none"> Rare diseases that affect fewer than 200,000 people in the United States or are of low prevalence. NIH’s Office of Rare Diseases published a list of over 6,000 rare diseases, ranging from Aegaeas syndrome to Zuska’s disease. 	<ul style="list-style-type: none"> A disease or disorder that affects fewer than 5 in 10,000 citizens is the definition for rare in Europe (Orphan Drug Regulation 141/2000). According to EURORDIS (European Organization for Rare Diseases), the number of rare diseases numbers from about 6,000 to 8,000. 	<ul style="list-style-type: none"> On May 21, 2018, NHFPC and other four departments jointly formulated the first catalogue of rare diseases, include 121 rare diseases. On June 5, 2018, NHFPC published <i>Working Procedure for Rare Diseases Catalogue</i>. Rare disease catalogue will update every two years. According to the “Research Report on The Definition of Rare Diseases in China, 2021” (《中國罕見病定義研究報告2021》), diseases with a new-born incidence less than 1/10,000, prevalence less than 1/10,000 and total number of patients less than 140,000” are defined as rare diseases.

Source: FDA, EMA, CFDA, NHFPC, Frost & Sullivan Analysis

Based on different definitions for rare diseases, the number of rare diseases recognized is far lower in China (121) than the U.S. and Europe (each with over 6,000). The diagram below shows the prevalence of rare diseases in the U.S. and Europe respectively, and in China applying the broader definition of rare disease in the U.S. in 2019, which leads to an implied patient pool potentially over four times larger in China than the U.S. According to a research report published by the Economist Intelligence Unit in 2020, China is believed to be the single largest market with the world’s largest population of rare disease patients. It is estimated that the first list of 121 rare diseases defined in China alone affect more than 3 million patients, therefore it is an appropriately reasonable estimate that China may have a total prevalence base which exceeds 100 million patients suffering from one or more forms of rare diseases, by way of extrapolation adopting the broader definition in the U.S. or Europe.

Prevalence of Rare Disease in U.S. & EU and Estimated Prevalence in China



Source: FDA, EMA, EC, CFDA, NHFPC, Frost & Sullivan Analysis

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Evolution of the Rare Disease Market

The regulatory frameworks within the US and Europe for orphan drug designations for rare diseases are well established. While in China, the first list of rare diseases was published in May 2018, since when many major initiatives and regulatory reforms were announced, which together are expected to significantly develop and grow the Chinese rare diseases drug market and its ecosystem in the next decade.

The global rare disease drug market has grown rapidly since 1983, when the Orphan Drug Act was first promulgated by the FDA, which set standards for regulatory pathways that were followed by other jurisdictions in subsequent years. As rare diseases do not share a harmonized definition across the globe, orphan drug market is used to mirror the growth and potential of rare disease market. According to Frost & Sullivan, orphan drug market includes both targeted therapy drugs indicated for rare disease only and other drugs obtaining orphan drug designation (ODD) which may include those covering additional orphan indications and usage outside of their core prescription label for non-orphan diseases. The part of revenue generated by expanded non-orphan indications was excluded in the market analysis by Frost & Sullivan below. For the purpose of this Industry Overview section, “rare disease drug market” means the total orphan drug market excluding the revenues generated from the non-orphan indication expansions of certain non-targeted ODD drugs, such as Humira or Keytruda.

Unmet Medical Needs and Market Opportunities

There remain urgent and unmet medical needs worldwide for the growing list of rare diseases. It is estimated that, worldwide, less than one-tenth of patients with rare diseases have received disease-specific treatment. The treatment of rare diseases continues to face challenges including lower priority for drug development, limited awareness and availability of targeted treatment options, and unestablished government policies. Unmet medical needs and challenges come along with significant market opportunities and commercial potential. The U.S., followed by Europe, remains as the largest rare diseases market with the most mature ecosystem. The U.S. market alone accounts for 67.1% market share of the global rare diseases market in 2020 and expected remain the world’s largest market in 2030. Owing to the regulatory reforms including simplified application process, flexibility in clinical trial design, and likelihood of trial waiver on the basis of overseas clinical data and post-approval clinical trials, China is experiencing a structural shift for its rare disease market. According to Frost & Sullivan, the rare disease drug market in China is expected to grow at 34.5% CAGR from US\$1.3 billion in 2020 to US\$25.9 billion in 2030. The rapid growing rare disease drug market is primarily driven by the large but untapped patient population, demand for targeted treatment options and favorable regulatory path.

- ***Largely untapped patient population:*** China has a large patient pool with rare diseases compared to the U.S. and Europe but with limited treatment options, diagnosis deficiency and under-developed market and regulations. As compared to the U.S., the market size of rare disease drugs in the U.S. was nearly 70 times larger than that of China in terms of dollar value, while the total number of patients in

INDUSTRY OVERVIEW

China is estimated to be at least four times larger than the US market given overall population size and prevalence rate. The discrepancy between patient population and market size suggests significant room for rare disease drug growth in China. In addition, as China and some other emerging markets including Latin America and Southeast Asia are building up the rare disease ecosystem, the list of rare diseases globally is expected to expand regularly with new types of rare diseases being introduced in medical literatures along with science and technology advancement for their diagnosis and treatments.

- ***Limited awareness and targeted treatment options:*** Delayed diagnosis of rare diseases is common due to lack of knowledge by both patients and doctors, especially in jurisdictions with an immature rare disease ecosystem. After diagnosis, a large number of patients still face the challenge to access effective and targeted treatments that serve as disease-modifying therapies. According to Frost & Sullivan, there are about 7,000 rare diseases lacking authorized or satisfactory method of treatment worldwide. On the other hand, increased disposable income, improved government medical reimbursement coverage and favorable pricing policies have enhanced the accessibility of healthcare services and pharmaceutical medications for patients. As of December 2020, China has approximately 69 drugs approved for the treatment of rare diseases (among which 29 drugs are rare disease-targeted therapies), as compared to approximately 180 approved drugs in more developed markets such as the U.S., Europe and Japan for the 121 rare diseases recognized in the First National Rare Disease List, representing a highly underserved market with massive potential. However, even in established markets such as the U.S., Europe and Japan, there are still 46 diseases that are lacking treatments among the 121 rare diseases.
- ***Favorable government policies under development:*** In recognition of the urgency for effective rare disease treatment and the unique clinical challenges associated with the development of rare disease treatment, regulatory authorities in the U.S., and Europe have provided regulatory incentives and adopted specific regulatory frameworks to encourage development and commercialization of drugs to treat rare diseases. In 1983, the Orphan Drug Act was first enacted in U.S., in order to encourage the development of drugs for rare disease by granting exclusivity for orphan indication, tax credit for qualified clinical trials, and waiver of application fees. The FDA has also adopted post-approval studies in response to the limited size and duration of a pivotal trial before commercialization. Among the major pharmaceutical markets, the EU has enacted orphan drug legislation in 2000. Efforts to establish clearer pathway towards rare disease drug definition and registration are emerging in China, but the ecosystem is still at its infancy compared to those in the U.S. and EU. In 2018, China published the first edition of the Rare Disease List that include 121 rare diseases, including mucopolysaccharidosis, Fabry disease and Gaucher’s disease, hallmarking the transformational debut of the Chinese rare disease market. Currently 29 targeted therapies for the treatment of these 121 diseases have been approved and 16 of them are included in the National

INDUSTRY OVERVIEW

Reimbursement Drug List (NRDL) in 2020. The NMPA is making significant efforts to accelerate approval of rare disease drugs by providing favorable review and approval policies of rare disease in China. Also in 2018, the NMPA and the National Health Commission announced the Guidebook for Review and Approval Procedures of Overseas Imported New Drugs for Chinese Clinical Urgent Demand to provide a dedicated pathway for priority review and approval of overseas drugs imported into the Chinese healthcare market, which allows for an accelerated approval process for drugs with overseas clinical trial data treating serious or life-threatening diseases with clinical advantages and for an exemption of a bridging trial or additional local trial in China. Since 2018, three lists of Clinical Urgently Needed Foreign New Drugs have been announced, with a significant increase in the percentage of rare disease drugs recognized from 42% in first list to 65% in the second list in 2019. The application for marketing of varieties listed in such lists can be submitted directly in accordance with the Work Procedures for Review and Approval of Overseas New Drugs Catering to Clinical Urgent Needs, where a special channel is set up to speed up the review by the NMPA. In April 2021, the initiation of formulation of the second edition of the Rare Disease List was announced by the National Health Commission of the PRC and more rare disease drugs are expected to be included.

- ***Efficient business model and attractive returns:*** The rare disease industry is a highly efficient business model. According to Frost & Sullivan, most rare diseases are caused by genetic mutations with well-defined pathology, which leads to higher probability of technical and regulatory success (“PTRS”)⁽¹⁾ in the research & development (“R&D”) of drugs for the treatment of rare diseases. The R&D effort is also more targeted with smaller clinical trial required. In addition, certain rare disease patients are treated at a limited number of specialized hospitals, resulting in the high pricing power with a focus target patient pool, and small-scale and targeted sales efforts covering key hospitals and clinical centers and KOLs and clinicians. The unique nature of rare diseases has also created a favorable regulatory environment with increasingly well-established regulation and fast track orphan drug pathway, which helps accelerate the development and commercialization of rare disease drugs.
- ***Technology innovation and emergence of gene therapy:*** Propelled by the technology advancement in the rare disease R&D and regulatory approvals across the world, there has been an increasing number of innovative rare disease treatment options to address unmet medical needs, including ERT, designing new molecular entities or manipulation of gene expression. Enabled by new technologies, gene therapies such as CRISPR and RNAi have shown the potential to treat more rare diseases. Approximately 80% of rare diseases result from genetic disorders and thus gene therapies provide hope of a one-time treatment for numerous rare diseases that currently have no specific therapeutic options. Recent advances in genetic

(1) Probability of technical and regulatory success suggests the probability of a product achieving official institutions’ approval from its current phase, based on the individual probabilities of progressing through each stage of development.

INDUSTRY OVERVIEW

engineering and recombinant viral vector development have ignited interest in the field, with several gene therapy products gaining approval. The success of certain marketed pioneering clinical trials of gene and cell therapies has validated their efficacy and safety, such as SPINRAZA developed by Biogen and Zolgensma developed by Novartis and AveXis in treatment of Spinal Muscular Atrophy (SMA). AveXis was a biotechnology company that develops treatments for rare neurological genetic disorders and was acquired by Novartis in 2018.

Rare Disease Therapies Reimbursement and Pricing

Due to the substantial R&D costs and small patient pool associated with the nature of rare diseases, the pricing for orphan drugs is generally higher than that for non-orphan disease drugs. Rare disease therapies are usually life-time chronic treatments. The annual cost for Spinraza, a targeted drug for spinal muscular atrophy (SMA), is approximately US\$0.7 million for the first year and US\$0.4 million in subsequent years in the U.S. New modalities of therapies are offering potential one-time treatment with substantial one-time cost. Zolgensma, an AAV-based gene therapies approved by the FDA, is priced at US\$2.13 million.

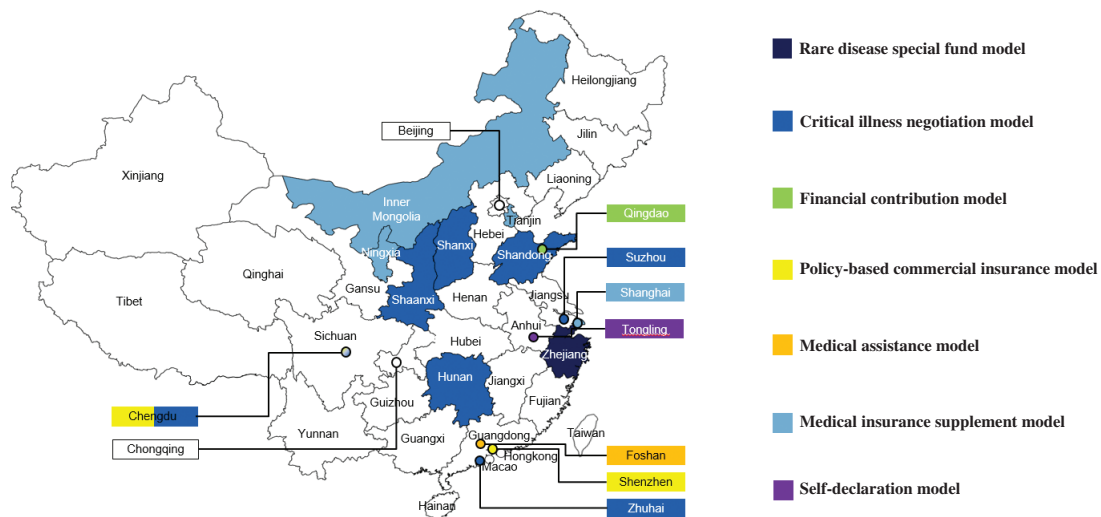
Pricing and reimbursement policies, which dictate the patient access to rare disease drugs, differ greatly between countries, and sometimes even within a single country, due to variations in national policies, healthcare budgets, health insurance, and reimbursement systems. In the U.S., commercial insurance payers cover the majority of the costs of rare disease drugs for insured patients, with many pharmaceutical companies operating patient assistance programs to help offset a portion of the costs for uninsured or underinsured patients. In China, however, national or provincial public medical insurance dominates the healthcare insurance system and commercial medical insurance only plays a supplementary role.

While the Chinese rare disease market is in its infancy, China’s government has rolled out several policies relating to the pricing and medical insurance, as a means to enhance the affordability and accessibility of rare disease drugs. Since rare diseases were covered in The Work Plan for the adjustment of Medicines List for National Medical Insurance in 2019 (Consultation Paper) issued by the National Healthcare Security Administration, certain rare disease drugs such as Bosentan for the treatment of idiopathic pulmonary arterial hypertension (IPAH) has been included in the 2020 National Medical Insurance Drug Catalogue. Pricing benefits are also granted for a batch of 21 orphan drugs and 4 drug substances, where value added tax will be reduced to 3% referring to the anti-cancer drug in import process, and the domestic value added tax may choose the simple method, levied by 3%. Under the National Reimbursement Drug List in 2020, medical insurance included 40 rare disease drugs, albeit most of them are general medicines repurposed for orphan disease indication. A total of 16 medicines for specific targeted treatment of rare diseases are included, accounting for 40% of the list.

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Insurance reimbursement policies significantly increase the affordability and accessibility of treatments to patients. Insurance coverage varies geographically across provinces and tiered cities, with Beijing currently covering up to 80% of the treatment cost for certain rare disease drugs. China is moving towards more established insurance environment for rare disease, where the nationwide insurance coverage will broaden and become more dynamic, providing reimbursement scheme for even ultra-rare disease drugs, along with expansion of patient assistance programs. For example, imiglucerase, a targeted drug for Gaucher disease (GD), is currently not included in the NRDL but has been included in the local reimbursement list of certain provinces and cities such as Zhejiang and Qingdao. According to Frost & Sullivan, the annual out-of-pocket expense of a GD patient in Zhejiang can be as low as approximately RMB30,000 and approximately RMB150,000 in Qingdao under different reimbursement policies, as compared to the estimated annual cost of approximately RMB3 million before reimbursement.

Over the years of China’s exploration in insurance mechanism of rare diseases at the local level, an aggregate of 29 provinces have implemented insurance policies for rare disease with various reimbursement models. The graph below illustrates the coverage of rare disease drug reimbursement policies in China and their respective models:



Source: Frost & Sullivan Analysis

Among all local governments’ offerings of rare disease reimbursement policies, seven major models can be concluded from regions where high level reimbursements for rare diseases are provided, including special fund model, critical illness negotiation model, financial contribution model, policy-based commercial insurance model, medical assistance model, medical insurance supplement model and self-declaration model, as elaborated in the table below. Under the reimbursement model in Zhejiang Province, for example, the total costs incurred for rare disease treatments in a year can be reimbursed by 80% for the portion below RMB300,000, 90% for the portion between RMB300,000 to RMB700,000, and 100% for the portion above RMB700,000.

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Model Category	Reimbursement Policy	Representative Province/Cities
Rare disease special fund model	<ul style="list-style-type: none"> The special fund model is based on the standard of 2 yuan per person per year, one-time transfer from the critical illness insurance fund of this coordinating area to the Zhejiang Province Rare Disease Drug Reimbursement Fund. Drug coverage: Expert argumentation of drug catalogue, price negotiation, dynamic adjustment Reimbursement depth: Cost accumulation, reimbursement in stages, capping of personal burden 	Zhejiang Province
Critical illness negotiation model	<ul style="list-style-type: none"> The funding comes from the basic medical insurance fund and the critical illness insurance fund. Some regions (such as Shanxi Province and Shaanxi Province) also provide a multi-level reimbursement policy supplemented by financial allocations for special assistance and social assistance. Drug coverage: Negotiations to include the scope of medication for critical illness insurance Reimbursement depth: Reimbursement amount: tens of thousand ~ hundreds of thousand RMB/year 	Shanxi Province, Shaanxi Province, Hunan Province, Zhejiang Province, Shandong Province, Sichuan Chengdu, Jiangsu Suzhou, Guangdong Zhuhai
Financial contribution model	<ul style="list-style-type: none"> The financial contribution model is mainly funded by the Ministry of Finance, supplemented by personal payment. Drug coverage: Expert argumentation, special medicine negotiation Reimbursement depth: Less patients' own expenses 	Shandong Qingdao
Policy-based commercial insurance model	<ul style="list-style-type: none"> Drugs are publicly procured by the government, while the fund is operated by a commercial insurance company, with voluntary participation and individual payment (personal account balance, or personal expense). Drug coverage: The Medical Insurance Bureau and the commercial insurance company jointly evaluated the designated drug catalog Reimbursement depth: Higher claims status, processing at different grades 	Guangdong Shenzhen, Sichuan Chengdu
Medical assistance model	<ul style="list-style-type: none"> The sources of medical assistance funds include special medical aid funds allocated by the Ministry of Finance, welfare lottery charity funds, social donations, etc. Drug coverage: Include the diseases in the national rare disease list into the scope of assistance Reimbursement depth: Uncertainty about whether patients can get assistance 	Guangdong Foshan
Medical insurance supplement model	<ul style="list-style-type: none"> The funding comes from basic medical insurance fund. Drug coverage: Limited range of rare disease drugs included Reimbursement depth: Consistent with basic medical insurance reimbursement policy, non-institutionalized, sustainability to be seen 	Ningxia, Tianjin, Inner Mongolia, Fujian Sanming, Yunnan Kunming, Shandong Jining, Guangdong Zhongshan, Fujian Xiamen, Shanghai, etc.
Self-declaration model	<ul style="list-style-type: none"> The sources of funding include basic medical insurance fund and critical illness insurance fund. Drug coverage: No list of specific diseases and drugs established. Patients declare independently. Reimbursement depth: Uncertainty about whether patients can get assistance 	Anhui Tongling

Source: Frost & Sullivan Analysis

Rare disease drug industry offers market potential evidenced by attractive returns. The ten top-selling orphan drugs brought in a combined US\$42.8 billion globally in 2020 among which four are for oncology indications while the other six are targeting rare diseases that require life-long treatments, as shown in the table below.

Global Top 10 Orphan Drug* in Terms of Sales Revenue, 2020

Brand Name	Sales Revenue, 2020	Company	Major Indication	Therapeutic Area	Pricing in US (USD)	Annual Cost (USD)**	Pricing in China (RMB)	Annual Cost (RMB)**	NRDL Date
Revlimid (2005)	12.1	BMS	Multiple Myeloma	Anti-neoplasm	832.52/25mg	227,902.4	1,030.68/25mg (NRDL covered)	282,148.65	2017.07
Ocrevus (2017)	4.6	Roche	Multiple Sclerosis	Autoimmune Disease	17,483.45/300mg/10ml	69,933.8	NA	NA	NA
Darzalex (2015)	4.2	J&J	Multiple Myeloma	Anti-neoplasm	122.07/20mg/ml	123,046.6 ~ 134,765.3	985.5/20mg/ml	993,384 ~ 1,087,992	NA
Soliris (2007)	4.1	Alexion Pharmaceuticals	PNH, aHUS, TMA	Hemoglobinuria, Paroxysmal	6,819.51/300mg/30ml	461,487 ~ 736,560	NA	NA	NA
Tecfidera (2013)	3.8	Biogen, Eisai	Multiple Sclerosis	Autoimmune Disease	144.68/120mg; 144.16/240mg	105,244.1	NA	NA	NA
Jakafi/Jakavi (2011)	3.3	Incyte, Novartis	Myelofibrosis	Myeloproliferative Disorders, Polycythemia Vera	256.88/5mg, 10mg, 15mg, 20mg, 25mg	92,476.8	133.33/5mg	143,996.4 ~ 239,994.0	NA
Pomalyst (2013)	3.1	BMS	Multiple Myeloma	Anti-neoplasm	947.64/1mg, 2mg, 3mg, 4mg	259,416.5	NA	NA	NA
Gilenya (2010)	3.0	Novartis	Multiple Sclerosis	Autoimmune Disease	316.83/0.5mg	115,643.0	228/0.5mg (NRDL covered)	83,220.0	2020.12
Hemlibra (2017)	2.3	Genentech Roche	Hemophilia A	Genetic Disease	16,092.21/150mg/ml	540,698.0	8,100/30mg/ml	1,360,800.0	NA
Aubagio (2012)	2.3	Sanofi	Multiple Sclerosis	Autoimmune Disease	280.78/7mg, 14mg	102,484.7	282/14mg (NRDL covered)	102,930.0	2019.11

Billion USD
■ Chemical Drug
■ Biologics

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Notes:

- * Orphan drug mentioned in this table does not include drugs obtaining orphan drug designation first but their indication expanded later of which generated most of their revenue, such as Humira.
- ** Patient assistance program (PAP) is not taken into consideration when calculating the annual cost, because the eligibility criteria varies among drugs and is usually determined on a case-by-case basis. Assume body weight is 60kg.
- The pricing in EU is not displayed in the table because the regulation of drug prices are different among countries and governments control prices in various ways in the EU.

The revenue is ex-factory price-based, and the downstream medical reimbursement is not taken into consideration.

Source: Annual Reports, Frost & Sullivan Analysis

Expanded Access Programs

Expanded access programs, or compassionate-use programs, are regulatory programs that facilitate access to investigational drugs for the treatment of patients with serious or immediately life-threatening diseases or conditions that lack therapeutic alternatives. The FDA proposed the concept of compassionate-use in 2009, which means that when there is no other effective alternative therapy, clinicians and drug companies can apply to drug regulatory agencies to allow the use of IND by a patient who is incurable or has no drug to be rescued from clinical research, with a purpose of providing possibly the only potential hope for patients who currently have no effective treatment. Although there is no compassionate-use system in China, the new “Drug Administration Law” published in 2019 also incorporated such concept, providing that drugs in clinical trials that are under way for the treatment of diseases that are seriously life-threatening and do not have effective means of treatment may benefit from medical observation and conform to ethical principles and may be used in other patients with the same conditions in institutions conducting clinical trials after examination and informed consent.

RARE ONCOLOGY

Glioblastoma Multiforme (GBM)

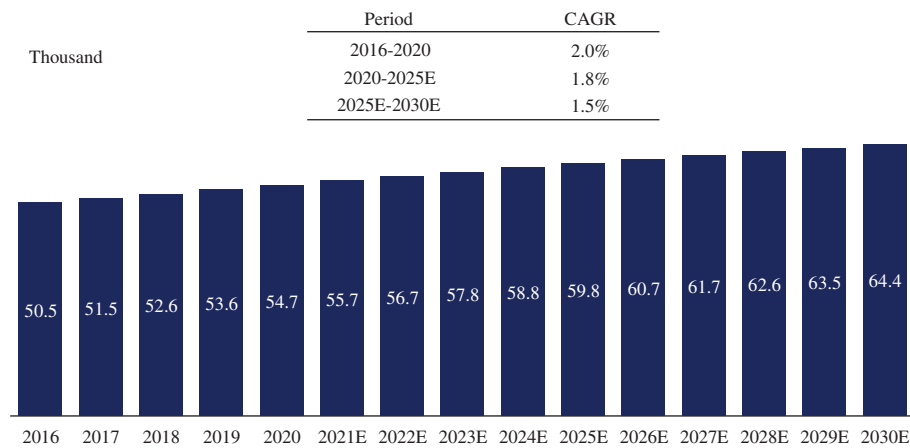
GBM is a fast-growing malignant glioma that develops from glial cells (astrocytes and oligodendrocytes) or their precursors that support the health of the nerve cells within the brain. It is the most common and malignant type of glioma in adults. About 45% of gliomas are glioblastoma multiforme, which is classified as Grade IV (most serious) astrocytoma, is the most common and aggressive brain cancer where a large portion of tumor cells are reproducing and dividing at any given time, with an estimated 5-year survival of 5.5% globally and below 5% in China. The incidence of GBM was approximately 3.9 cases per 100,000 individuals in 2020. The tumor is predominantly made up of abnormal astrocytic cells, but also contain a mix of different cell types (including blood vessels) and areas of dead cells (necrosis). GBM is infiltrative and is the most invasive type of glial tumors, rapidly growing and commonly spreading into nearby brain tissue. It can also sometimes spread to the opposite side of the brain through connection fibers (corpus callosum). GBM is characterized as a disease with one of the highest unmet needs in oncology, with patients having a median overall survival between one and two years.

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Market Overview

According to Heffernan and Sirianni (2018) and Cheng’s Study (2020), substantially all neurological cancers are brain cancers. GBM represents 46.6% of the total incidence of brain cancer in China and has reached 54.7 thousand in 2020 with a CAGR of 2.0% from 2016 to 2020. The incidence represents the addressable market size of CAN008 for GBM, according to Frost & Sullivan. With factors including increasing aging population, ionizing radiation and air pollution, the incidence of GBM in China is expected to steadily 59.8 thousand in 2025 and 64.4 thousand in 2030 at a CAGR of 1.8% and 1.5%, respectively. The prevalence of GBM patients accepting first and second-line treatment in China is estimated to be approximately 50.6 thousand and 36.4 thousand respectively in 2020. The diagnostic rate of GBM in China remains low due to the complicated diagnostic process and lack of accessibility to effective diagnostic methods.

Incidence of Glioblastoma Multiforme in China, 2016-2030E



Source: Frost & Sullivan analysis

Treatment Methods

GBM grows rapidly and is the most invasive type of glioma. There are unmet medical needs for GBM patients in China calling for alternative options as a result of the limitations to the current available treatments.

The standard of care for GBM consists of surgical resection, adjuvant chemotherapy with temozolomide (TMZ). However, radiation and chemotherapy always come with adverse events that greatly undermine the life quality of patients. In addition, tumor cells may develop some resistance to TMZ. Current GBM therapies have limited improvement in progression-free survival (PFS) with an estimated 5-year survival of 5.5% globally and below 5% in China.

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The current targeted therapy treatment options for GBM in China include surgery, radiotherapy combined with TMZ concurrent chemotherapy, tumor treating field (TTF), bevacizumab (Avastin) and a bevacizumab biosimilar. Vascular endothelial growth factor (VEGF) is an important factor in angiogenesis that is highly expressed by the endothelial cells in most human tumors, and bevacizumab biosimilar is a recombinant humanized anti-VEGF monoclonal antibody drug.

TMZ was marketed in 2004 while TTF, bevacizumab (Avastin) and the bevacizumab biosimilar were approved in 2020 in China as new treatments for GBM.

Competitive Landscape

According to Frost & Sullivan, the number of new GBM cases represents the total addressable market size for GBM-targeted drugs. The epidemiology of GBM was estimated by Frost & Sullivan based on the incidence rate reported by literatures and interviews from relevant experts. The expected increase in the incidence of GBM in China is primarily due to the aging of population, ionizing radiation and air pollution in the future ten years. The CAN008 fusion protein has competitive advantages in the treatment of GBM over other treatment options, including a validated novel mechanism of action, improved efficacy and the potential for combination therapy. For details, please refer to “Business – Our Portfolio – Late Stage Drug Products and Candidates – CAN008 CD95-Fc fusion protein for GBM – Market Opportunity and Competition.” CAN008 has been well tolerated with a favorable safety profile and promising efficacy in multiple clinical trials, highlighting its potential to play a significant role in GBM treatment.

The following table illustrates the current status of targeted drugs for GBM marketed in China.

Classification	Generic Name/ Product Code	mOS*	ORR*	mPFS*	Most Common AR*	Company	NMPA Approved Date	Price in China, RMB	Annual Cost in China, RMB
Chemotherapy	temozolomide	15.9 months	22%	4.4 months	Fatigue (13%)	Tasly Diyi Pharmaceutical	2004*	895 (100mg)	101,896
						MSD	2007	3,300 (100mg)	187,853
Chemotherapy	carmustine	/	/	/	Cardiac Disorders	Shandong Ruiying	2006	122 (2g: 0.125g)	2,393
Biological Therapy	bevacizumab	/	19.6%	/	Infection (55%)	Roche	2020	1,934 (100mg)	301,704
						Innovent Bio	2020	1,188 (100mg)	185,328

Notes:

- Generic Temozolomide manufactured by Tasly Diyi Pharmaceutical was approved by NMPA in 2004, which was earlier than the NMPA approval of original drug manufactured by MSD in 2007.
- * Information retrieved from FDA labels.

INDUSTRY OVERVIEW

- Clinical results such as mPFS, ORR, mOS, and AR are for indication of GBM from FDA label. Data is not based on head-to-head comparison between drugs, clinical trials of a drug cannot be directly compared to the clinical trials of another drug and may not be representative of the overall data.
- mOS and mPFS figures for bevacizumab and clinical trial data for carmustine are not available, as such data is not shown on the FDA labels where numbers in this table were retrieved.

Source: Frost & Sullivan Analysis

The following table illustrates the current status of targeted drugs for GBM being developed in China and worldwide.

Classification	Generic Name/ Product Code	Company	China Clinical Status
Chemotherapy	enzastaurin	Xcelience/Denovo Biopharma/ Suoyuan Biopharm	Phase III
	elemene	Second Affiliated Hospital/Zhejiang University	Phase II
	ZSP-1602	Guangdong Zhongsheng Pharma	Phase I
Fusion Protein	asunercept/CAN008	CANbridge	Phase II
	efineptakin alfa/TJ-107	Tianjing Biotech/Binex/ Neoimmunetech	Phase II
Cell and Gene Therapy	ever supreme	Ever Supreme	Phase II
	anti/EGFRvIII-directed CAR-T cell therapy	Shenzhen BinDeBio	Phase II
	B7-H3 CAR-T cell therapy	BoYuan RunSheng Pharma	Phase II
Small Molecular Targeted Drug	ABT-414	AbbVie	Phase II/III
	RX-108	NeuPharma	Phase II
	ACT-001	Accenda	Phase II
	AT-101	Ascentage Pharma	Phase II
	bozitinib	Beijing Borunao Biotech	Phase II
	apatinib	Xijing Hospital	Phase II
	anlotinib	Shandong Cancer Hospital and Institute	Phase I/II
	zotiraciclib	Tragara Pharmaceuticals/ ZHAOKE	Phase I
Vaccine	HSP Gp96 vaccine	Cure & Sure	Phase II
	dendritic and glioma cells fusion vaccine	Hangzhou Medical Biotechnology	Phase II
Oncolytic Adenovirus	T-601	Transgene	Phase I
Antibody	camrelizumab	Jiangsu Hengrui	Phase II
	nimotuzumab	Biotech Pharmaceutical/Sun Yat-sen University	Phase II
	bevacizumab	CTTQ Pharma	Phase I

Source: Frost & Sullivan analysis

INDUSTRY OVERVIEW

RARE DISEASES

Mucopolysaccharidosis Type II (MPS II or Hunter syndrome)

MPS II, also known as Hunter syndrome, is an X-linked recessive lysosomal storage disorder caused by deficient or absent activity of iduronate-2-sulfatase (IDS), an enzyme which cleaves O-linked sulfate moieties from two human glycosaminoglycans (GAG), dermatan sulfate and heparan sulfate. In MPS II, these GAGs accumulate in almost all body organs and tissues including the brain, heart, lung, bone, muscle, intestines, and skin. Accumulation of GAG leads to cellular engorgement, organomegaly, tissue destruction, and organ system dysfunction.

MPS II is a rare, disabling and life-threatening genetic disease. Patients appear healthy at birth, with initial symptoms appearing between 18 months and 4 years of age. Life expectancy of patients with severe MPS II (60%-80% of cases) is significantly reduced, with death occurring generally before the age of 25 as a result of CNS neurodegeneration and cardio-respiratory complications. The remaining patients have attenuated MPS II that may present at any age and is distinguished from the severe form by slower disease progression, lack of CNS neurodegeneration, and long-term survival. The severity of disease is attributed to the amount of residual IDS activity: patients with severe disease have little to no IDS activity, whereas those with the attenuated form have partial IDS activity.

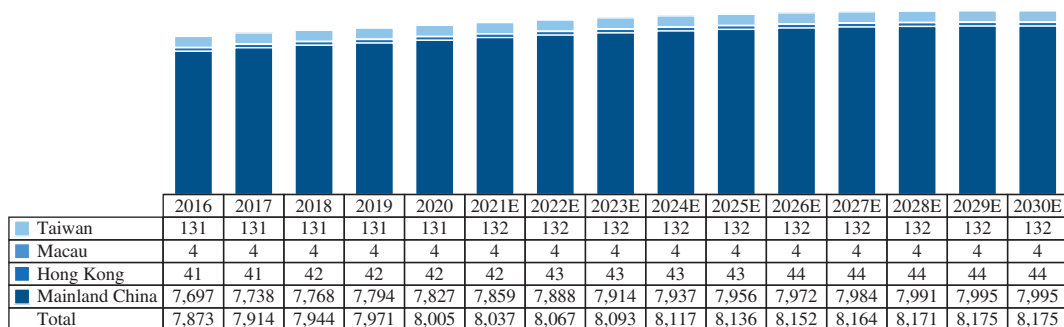
Market Overview

In East Asian countries, MPS II is the most common form of MPS disorders. With Hunterase[®] as the only approved treatment in China and an estimated number of over 8,000 patients countrywide in 2020, there is a high level of unmet need and the Chinese government has included MPS II on the “National Rare Disease List” as a disease group to target. The MPS II market in China remains stable as it is a genetically-related rare disease but with limited treatment options. The prevalence of MPS II in Greater China reached 8,005 in 2020 and is estimated to reach 8,175 in 2030. The prevalence represents the addressable market size of Hunterase[®] (CAN101) in MPS II, according to Frost & Sullivan.

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MPS II Prevalence in Greater China, 2016-2030E

CAGR	Mainland China	Hong Kong	Taiwan	Macau
2016-2020	0.4%	0.6%	0.1%	1.7%
2020-2025E	0.3%	0.6%	0.1%	1.5%
2025E-2030E	0.1%	0.4%	0.0%	-0.1%



Source: Frost & Sullivan Analysis

Treatment Methods

ERT is recommended as the standard of care by worldwide treatment guidelines and expert consensus. ERT provides exogenous IDS enzyme for uptake into cellular lysosomes through the binding of mannose-6-phosphate (M6P) residues on its oligosaccharide chains to M6P receptors on the cell surface, leading to cellular internalization of the enzyme, targeting to intracellular lysosomes, and subsequent catabolism of accumulated GAG. ERT is effective in clearing accumulated GAG with resulting clinical benefits, including improved mobility, slowing disease progression, controlling symptoms and disease manifestations, such as organ enlargement, decreased cardiac, respiratory system and skeleton functions, and has been proven to improve health outcomes of patients with MPS II.

Another current therapy treatment for MPS II in China is hematopoietic stem cell transplantation (HSCT), where stem cells obtained from donor bone marrow, peripheral blood or umbilical cord blood is infused intravenously into a patient. The transplanted stem cells re-populate the patient’s bone marrow with IDS-producing cells which can then migrate into various tissues and organs and then produce sufficient enzyme to alleviate symptoms. The main limitations of HSCT are the difficulty in finding matched donors, the high occurrence of transplant complications such as graft-versus-host disease, and the inability to prevent cognitive decline.

INDUSTRY OVERVIEW

Competitive Landscape

According to Frost & Sullivan, the prevalence of MPS II represents the total addressable market size of MPS II-targeted drugs. The epidemiology of MPS II was estimated by Frost & Sullivan based on the prevalence rate reported by literatures and interviews from relevant experts. MPS II is an inherited genetic disorder, so the expected steady increase in the prevalence of MPS II in Greater China is primarily due to the increasing overall population in the future ten years. ERT is the standard of care based on its ability to reduce GAG storage and improve, slow, or in some instances prevent the progressive tissue and organ damage associated with MPS II. Hunterase[®] (CAN101), as the first and only approved treatment in China, is a purified form of recombinant human iduronate-2-sulfatase (rhIDS) produced in CHO DG44 cells using a serum-free process. The IDS enzyme is specifically taken up by cells and directed into lysosomes, where it degrades stored GAG and prevents further its accumulation. Hunterase[®] is currently the only targeted therapy to MPS II available in China.

The following table illustrates the targeted therapy and drugs approved and in clinical stage for MPS II globally:

Generic Name/ Product Code	Brand Name	Company	Regulatory Approval Date (Country)/US Clinical Status	Price, USD (Region)	Annual Cost, USD (Region)	NMPA Approved Date/China Clinical Status	Price in China, RMB	Annual Cost in China, RMB	Mechanism of Action
idursulfase	Elaprase	Shire (Acquired by Takeda)	2006 (US)*	\$2,249/6mg (South Korea)	\$341,046 (South Korea)	–	–	–	Iduronate sulfatase replacements
idursulfase beta	Hunterase	GC Pharma/ CANBridge	2012 (South Korea)**	\$1,912/6mg (South Korea)	\$289,931 (South Korea)	2020	Unknown	Unknown	Iduronate sulfatase replacements
idursulfase beta	Hunterase ICV	Clinigen/GC Pharma	2021 (Japan)	Unknown	Unknown	–	–	–	Iduronate sulfatase replacements
IR-141	Izcargo	JCR Pharma	2021 (Japan)	Unknown	Unknown	–	–	–	Iduronate sulfatase replacements
RGX-121	–	Regenxbio	Phase I/II	–	–	–	–	–	Gene transference; Iduronate-sulfatase stimulants
DNL-310	–	Denali Therapeutics	Phase I/II	–	–	–	–	–	Iduronate sulfatase replacements
adalimumab	Humira	AbbVie/Eisai/ Lundquist Institute	Phase I/II	–	–	–	–	–	Anti-TNF α monoclonal antibody
SHP-631/AGT-182	–	ArmaGen	Phase I (Completed)	–	–	–	–	–	Iduronate sulfatase replacements
GNR-055	–	AO GENERIUM	Phase I (Completed)	–	–	–	–	–	Iduronate sulfatase replacements

Note: We assume that the average weight of the patient is 35 kg.

* Elaprase was firstly approved in the US in 2006, and now approved in the US, Japan and EU.

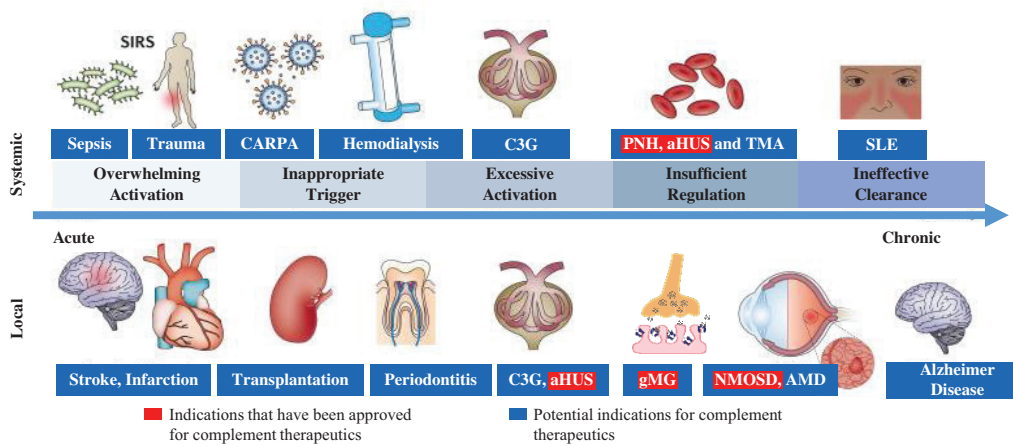
** Hunterase was firstly approved in South Korea in 2012, and now approved in South Korea and China.

Source: FDA, NMPA, Frost & Sullivan analysis

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Complement Mediated Diseases

Disorders with known or suspected complement involvement cover an exceptionally broad range, including tissue-specific, systemic, acute and chronic disorders of the inflammatory, autoimmune, age-related, biomaterial-induced and neurodegenerative spectrum. Dysregulation of the complement system underlies the pathophysiology of a broad spectrum of diseases, such as Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS), generalized Myasthenia Gravis (MG) and Neuromyelitis Optica Spectrum Disorders (NMOSD). The number of potential indications for complement therapeutics, including kidney disorders, is growing owing to new genetic and molecular insights as well as clinical data, and the majority of indications currently are shown in the chart below.



Note for Abbreviations:

(1) aHUS, atypical hemolytic uremic syndrome; (2) AMD, age-related macular degeneration; (3) C3G, C3 glomerulopathy; (4) CARPA, complement activation-related pseudo allergy; (5) gMG, generalized myasthenia gravis; (6) PNH, paroxysmal nocturnal hemoglobinuria; (7) SIRS, systemic inflammatory response syndrome; (8) SLE, systemic lupus erythematosus; (9) TMA, thrombotic microangiopathy.

Source: Frost & Sullivan Analysis

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The following table demonstrates the introduction of major complement mediated diseases and their respective prevalence and current treatment methods.

Indication	Introduction	Prevalence	Treatment Methods
PNH	PNH is a chronic, multi-systemic, progressive and life-threatening disease characterized by intravascular hemolysis, thrombotic events, serious infections and bone marrow failure.	<p>The prevalence of PNH in China has experienced steady growth. From 2016 to 2020, the prevalence of PNH have increased from 23.3 thousand to 23.8 thousand, and is predicted to reach 24.3 thousand in 2025 and 24.5 thousand in 2030.</p> <p>From 2016 to 2020, the prevalence of PNH in the rest of the world have increased from 95.8 thousand to 100.5 thousand, and is predicted to reach 106.2 thousand in 2025 and 111.8 thousand in 2030.</p>	PNH is a disease whose diagnosis may be delayed due to variable clinical findings and this delay increases the risk of mortality and morbidity. PNH treatment can be grouped under three main titles: Supportive Treatments; Treatment changing the course of the disease; Potential Curative Treatment.
aHUS	aHUS is a disease that primarily affects kidney function. This condition, which can occur at any age, causes abnormal blood clots (thrombi) to form in small blood vessels in the kidneys, which can cause serious medical problems if they restrict or block blood flow.	<p>From 2016 to 2020, the prevalence of aHUS in China have increased from 9.7 thousand to 9.9 thousand, and is anticipated to reach 10.1 thousand by 2025 and 10.2 thousand in 2030.</p> <p>From 2016 to 2020, the prevalence of aHUS in the rest of the world has gradually increased from 20.8 thousand to 22.0 thousand. In the next 5 years, the prevalence of aHUS is anticipated to reach 23.4 thousand by 2025, and to reach 24.7 thousand in 2030.</p>	The introduction of eculizumab, the humanized anti-C5 complement monoclonal antibody, has brought about a paradigm shift in the management of aHUS. For children with a clinical diagnosis of aHUS, the physicians propose eculizumab as first-line treatment, to avoid PE and the complications of central venous double line catheters.

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Indication	Introduction	Prevalence	Treatment Methods
gMG	gMG is a rare autoimmune disease caused by antibodies directed against proteins in the postsynaptic membrane of the neuromuscular junction. Targets of antibodies include nicotinic acetylcholine receptor (AChR), muscle-specific tyrosine-kinase (MuSK), lipoprotein receptor-related protein 4 (LRP4) and agrin.	<p>From 2016 to 2020, the prevalence of gMG in China have increased from 229.5 thousand to 233.8 thousand, and is forecasted to reach 239.1 thousand by 2025 and 241.4 thousand by 2030.</p> <p>From 2016 to 2020, the prevalence of gMG in the rest of the world have increased from 1,006 thousand to 1,056 thousand, and is forecasted to reach 1,115 thousand by 2025 and 1,172 thousand by 2030.</p>	All subgroups of MG respond to acetylcholinesterase inhibition. Pyridostigmine is the preferred drug for the treatment of symptoms in all myasthenia gravis subgroups. Studies has shown positive results after early onset or thymoma MG patients conduct thymectomy. Most MG patients need immunosuppressive medication to meet the treatment goals of full or nearly full physical function and high quality of life. Prednisone or prednisolone in combination with azathioprine is used as first-line treatment.
Neuromyelitis optica (NMO)/ NMOSD	NMO/NMOSD is a group of autoimmune conditions characterized by inflammatory involvement of the optic nerve, spinal cord and central nervous system. They have garnered attention due to their high pathogenicity, high risk of relapse, and poor prognosis as an inflammatory central nervous system (CNS) syndrome.	<p>From 2016 to 2020, the prevalence of NMOSD in China have increased from 46.6 thousand to 48.9 thousand. Driven by the increasing prevalence autoimmune disease of China, the prevalence of NMOSD in China is forecasted to reach 51.2 thousand by 2025, and to reach 52.6 thousand.</p> <p>There are an estimated 122.1 thousand people with NMOSD in the rest of the world in 2020. The number is expected to grow to 128.4 thousand people in 2025. From 2025 to 2030, it is expected to be 135.0 thousand people with NMOSD in 2030.</p>	Currently there is no cure for NMOSD. The overall goal of disease management in NMOSD is to reduce the acute attack and prevent the sequential relapse. In the acute phase, current treatment strategy is to alleviate the acute symptoms, shorten the course of the disease and reduce the degree of disability. The purpose of sequential treatment is to prevent recurrence and reduce the accumulation of mental dysfunction. Patients are treated with immunosuppressants, steroids and plasmapheresis in an effort to prevent NMOSD attacks. However, these treatments are known to cause adverse events, such as upper gastrointestinal bleeding (UGIB), femoral head necrosis, progressive multifocal leukoencephalopathy, cardiotoxicity, acute leukemia and etc., which may lead to treatment discontinuation.

C5 is the protease complexes in the complement system that protect against invading organisms. C5 complement inhibitors block the complement cascade at the level of C5, so it can stop the immune responses that cause disease. C5 complement inhibitors also preserve the generation of C3b, which is essential for the clearance of circulating immune complexes and the normal phagocytosis of bacterial and fungal pathogens. Complement C5 inhibitors have massive market potential as they target a broad spectrum of indications that can be addressed as a result of dysregulation of complement system.

INDUSTRY OVERVIEW

Competitive Landscape

The clinical and commercial value of C5 inhibitor has been validated by Alexion through its marketed products ULTOMIRIS and SOLIRIS. SOLIRIS market presented continued growth since its first approval by the FDA in 2007 and by the NMPA in 2018. The 2020 global revenue generated by SOLIRIS were US\$4,064.2 million, reflecting growths of 3.0% compared to the same period in 2019. ULTOMIRIS market recorded annual sales US\$1,076.7 million and US\$338.9 million in 2020 and 2019, respectively, since first approved by the FDA in December 2018, although it has not been approved by the NMPA yet. SOLIRIS is the only approved product in China so far. The comparable annual cost of SOLIRIS is approximately \$500,000 per patient, being one of the most expensive therapies in the world. China remains to be the largest untapped market for complement mediated diseases and more cost-efficient therapies are at urgent needs.

According to Frost & Sullivan, the prevalence of PNH, aHUS, gMG and NMOSD represents the addressable market size of major C5 inhibitors. The epidemiology of these indications was estimated by Frost & Sullivan based on the prevalence rate reported by literatures and interviews from relevant experts. The expected increase in the global prevalence of PNH and NMOSD is primarily due to the aging of population and unhealthy lifestyle in the future ten years, while that of aHUS and gMG may be attributable to the potential increasing number of population with certain medical conditions such as malignant hypertension and thymoma. The following table illustrates the current status of major C5 inhibitors approved or being developed for PNH, aHUS, gMG and NMOSD globally.

Generic Name/ Product Code	Brand Name	Company	FDA Approved Date/US Clinical Status	Indication (FDA)	Price, USD (Region)	Annual Cost, USD (Region)	NMPA Approved Date/China Clinical Status	Indication (China)	Price in China, RMB	Annual Cost in China, RMB
eculizumab	Soliris	Alexion	2007	PNH	\$6,820/ 300mg (US)	\$545,600 (US)	2018	PNH	Unknown	Unknown
			2011	aHUS	\$6,820/ 300mg (US)	\$461,487 (US)		aHUS	Unknown	Unknown
			2017	gMG	\$6,820/ 300mg (US)	\$736,560 (US)	-	-	-	-
			2019	NMOSD	\$6,820/ 300mg (US)	\$736,560 (US)	-	-	-	-
ravulizumab	Ultomiris	Alexion	2018	PNH	\$6,695/ 300mg (US)	\$511,331 (US)	-	-	-	-
			2019	aHUS	\$6,695/ 300mg (US)	\$511,331 (US)	-	-	-	-
			Phase III	NMOSD	-	-	-	-	-	-
			Phase III	gMG	-	-	-	-	-	-
eculizumab biosimilar	Elizaria	AO Generium	2019 (Russia)*	PNH*	-	-	-	-	-	
eculizumab biosimilar/BCD-148	-	Biocad	Phase III (Completed)	PNH	-	-	-	-	-	
eculizumab biosimilar/SB-12	-	Bioepis/ AffaMed Therapeutics	Phase III	PNH	-	-	Phase III Terminated	PNH	-	-
crovalimab	-	Hoffmann-La Roche/Chugai	Phase III	PNH/aHUS	-	-	Phase III	PNH/ aHUS	-	-
eculizumab biosimilar/ABP-959	-	Amgen	Phase III	PNH	-	-	-	-	-	-
zilucoplan	-	Ra Pharmaceuticals	Phase III	gMG	-	-	-	-	-	-
			Phase II (Completed)	PNH	-	-	-	-	-	-
cendisiran	-	Alnylam	Phase II	PNH	-	-	-	-	-	
pozelimab	-	Regeneron	Phase II	PNH	-	-	-	-	-	

Note:

* Elizaria was approved in Russia in 2019 and not yet approved by FDA.

Source: FDA, NMPA, Frost & Sullivan analysis

INDUSTRY OVERVIEW

Other Lysosomal Storage Diseases (LSDs)

LSDs are a group of over 70 diseases that are characterized by lysosomal dysfunction, most of which are inherited as autosomal recessive traits, including Gaucher disease (GD), Fabry disease (FD) and Pompe Disease (PD). For details on FD and PD, please see “– Gene Therapy.” LSDs typically present in infancy and childhood, although adult-onset forms also occur. While clinical trials are in progress on possible treatments for some of these diseases, there is currently no approved treatment for many LSDs.

Gaucher Disease (GD)

GD is a genetic disorder where fat-laden Gaucher cells build up in cells of the reticuloendothelial system, including the spleen, liver, bone marrow, and lungs, and in the most severe cases, the central nervous system. It is one of the most common lysosomal storage disorders. GD is a rare inherited LSD caused by autosomal recessive inheritance of mutations in the GBA gene encoding the lysosomal enzyme, acid β -glucosidase, which converts its major substrate, glucocerebroside (glucosylceramide), into glucose and ceramide, and its minor substrate, lyso-glucocerebroside (lyso-glycosylceramide), into glucose and sphingosine.

Market Overview

The prevalence of GD has experienced steady growth throughout various indications both globally and in China. From 2016 to 2020, the potential diagnosed prevalence of GD in China maintained a steady growth from 2,765 to 2,812, and is expected to reach 2,872 in 2030, representing one of the largest treatment naïve patient pools globally. From 2016 to 2020, the prevalence of GD in the rest of the world also experienced sustainable growth from 68.2 thousand to 71.4 thousand, and is expected to reach 75.1 thousand by 2025 and 78.7 thousand in 2030.

Treatment Methods

GD is a clinically heterogeneous disorder, including neuropathic and non-neuropathic variants. Optimal care may necessitate both palliative and adjunctive therapies. There are currently two specific types of treatment for GD: ERT and substrate reduction therapy (SRT).

ERT is the most accepted form of treatment for GD, and has well-established therapeutic goals (changes in liver and spleen size, improvement in blood parameters, bone pain and bone crises). ERT specifically supplements the lack of enzymes in the patient’s body and reduces the accumulation of glucocerebrosides in the body and shows favorable safety performance.

In SRT a small molecule drug is used to partially inhibit the biosynthesis of the compounds, and accumulate in the absence of a specific lysosomal enzyme. The drug will reduce the number of molecules requiring catabolism within the lysosome, thus contributing to balance the rate of synthesis with the impaired rate of catabolism.

INDUSTRY OVERVIEW

Competitive Landscape

According to Frost & Sullivan, the prevalence of GD represents the total addressable market size of GD-targeted drugs listed below. The epidemiology of GD was estimated by Frost & Sullivan based on the prevalence rate reported by literatures and interviews from relevant experts. GD is an inherited genetic disorder, so the expected steady increase in the global prevalence of GD is primarily due to the increasing overall population in the future ten years. The following table illustrates the current status of targeted drugs for GD marketed in the U.S..

Generic Name/ Product Code	Brand Name	Company	FDA Approved Date	Historical Sales Revenue ¹					Price, USD (Region)	Annual Cost ² , USD (Region)	NMPA Approved Date/China Clinical Status	Price in China, RMB	Annual Cost in China ² , RMB	MoA Category
				2016	2017	2018	2019	2020						
imiglucerase	Cerezyme	Genzyme (Acquired by Sanofi)	1994	827.7	824.9	839.7	792.9	786.9	\$1,784,26/ 400 units (US)	\$278,345 (US)	2017	20,700/ 400 units	3,229,200 ³	ERT
miglustat	Zavesca ⁴	Actelion (Acquired by J&J)	2003	105.6		Undisclosed			\$20,263/ (100 mg*90) (US)	\$246,533 (US)	-	-	-	SRT
velaglucerase alfa	Vpriv	Shire (Acquired by Takeda)	2010	345.7	349.9	361.8	340.4	359.8	\$1,490/ 400 units (US)	\$232,440 (US)	-	-	-	ERT
imiglucerase biosimilar	Abcertin	ISU ABXIS	2012 ⁵			Undisclosed			Unknown	Unknown	-	-	-	ERT
taliglucerase alfa	Eleyso	Protalix	2012			Undisclosed			\$852/200 units (US)	\$265,824 (US)	-	-	-	ERT
eliglustat tartrate	Cerdelga	Genzyme (Acquired by Sanofi)	2014	117.3	142.4	187.8	230.7	266.9	\$7,474/ 84 mg*14 (US)	\$194,858 - \$389,716 (US)	Phase III	-	-	SRT

Notes:

- The sales revenue provided in this table is based on calendar year. The exchange rates used for Euro to USD conversion for the years 2016 to 2020 are 1.10656, 1.130051, 1.181011, 1.119969 and 1.140486 respectively. The exchange rate used for Swiss Franc to USD for 2016 is 1.015257. The exchange rate used for Japanese yen to USD for the years 2019 and 2020 are 0.009176 and 0.00937 respectively.
- Assume patient body weight is 40kg.
- Imiglucerase is currently not included in the NRDL but has been included in the local reimbursement lists of certain cities and provinces including Zhejiang and Qingdao province. The annual cost listed here is the annual cost of adequate medication for an adult patient with GD disease in China. Since the actual dosage amount is usually lower than the theoretical value, RMB2.62 million is used as the calculation standard. According to calculations, annual out-of-pocket expenses for a GD patient in Zhejiang province can be as low as RMB30,000 after reimbursement and medical assistance while annual out-of-pocket expenses for a GD patient in Qingdao province can be approximately RMB150,000.
- Zavesca has been approved for GD and Niemann-Pick type-C disease. The sales revenue in this table indicates its total global sales revenue.
- Abcertin was approved in South Korea in 2012, and not yet approved by FDA.

Source: Frost & Sullivan analysis

INDUSTRY OVERVIEW

The following table illustrates the current status of targeted drugs for GD being developed in China and worldwide.

Generic Name/ Product Code	Company	US Clinical Status	NMPA Approved Date/China Clinical Status	Mechanism of Action (MoA)	MoA Category
venglustat/ ibiglustat	Genzyme (Acquired by Sanofi)	Phase II/III	–	Glucosylceramide synthase (UGCG) inhibitors	SRT
afegostat tartrate/AT-2101	Amicus Therapeutics/ Shire (Acquired by Takeda)	Phase II (Completed)	–	β-glucocerebrosidase (GCase) activity restoration	Molecular chaperone
AVR-RD-02	AVROBIO	Phase I/II	–	Gene therapy	Gene therapy
PR-001	Prevail	Phase I/II	–	Gene therapy	Gene therapy
acetylcysteine	University Of Minnesota	Phase I (Completed)	–	Antioxidant and glutathione inducer	Symptomatic treatment

Source: Frost & Sullivan analysis

Gene Therapy

Approximately 80% of rare diseases result from genetic disorders. Gene therapy seeks to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use, and to achieve durable expression of the therapeutic gene or “transgene” at a level sufficient to ameliorate or cure disease symptoms with minimal adverse events. Aiming to correct or replace dysfunctional genes that are the cause of many rare disease, gene therapy serves as a one-time treatment with the potential to fundamentally address the original source of the disease, and is applicable to a broad spectrum of indications, including monogenic diseases such as muscular dystrophy, spinal muscular atrophy (SMA), hemophilia⁽¹⁾ or severe combined immunodeficiency (SCID), cancer, and LSDs such as Fabry disease (FD) and Pompe Disease (PD).

Ex vivo and in vivo are the two major techniques in gene therapies. For ex vivo gene therapy, cells are extracted from the patient, followed by the transduction with the gene of interest in vitro before their subsequent transplantation back into the patient. For in vivo gene therapy, the vector containing the gene of interest is injected directly into the patient, with adeno-associated virus (AAV) being the most commonly-used vector in current studies.

(1) The current main treatment for hemophilia is replacement therapy. The replacement therapy targeting hemophilia A involves gene recombinant FVIII concentrate virus inactivated hematogenous FVIII concentrate, while the replacement therapy targeting hemophilia B involves gene recombinant FIX concentrate or virus inactivated hematogenousprothrombin complex concentrate.

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Viral Vectors Used in Gene Therapy

Viral transduction has been validated for introducing genetic material into mammalian cells. Viral vectors are highly amenable for many basic research applications, such as protein overexpression, antibody production, and gene knockout, and hold promise for gene therapy. Through viral vectors, therapeutic genes can be effectively delivered to target tissues/cells of patients *in vivo* or *ex vivo*. The currently viral systems for DNA delivery include Retrovirus, Lentivirus, Adenovirus and AAV. Each viral system has its own unique features as shown below:

	Retrovirus	Lentivirus	Adenovirus	AAV
○ Low ● High Definition Type Host Range (Infected Cell Types) No Genome Integration Involved* <i>In vivo</i> Safety Less Immunogenicity Insert size capacity Able to obtain high multiplicity of infection (>25 copies per cell) Stability of inserted gene expression	A retrovirus is a virus that uses RNA as its genetic material. When a retrovirus infects a cell, it makes a DNA copy of its genome that is inserted into the DNA of the host cell. ssRNA Dividing Cells Only X ● ● ~8 kb No (up to 10 copies integrated) ●	Lentiviruses are a subset of retroviruses. Lentiviruses can deliver significant amounts of genetic information into host cells and integrate it into the cellular genome. ssRNA Dividing and Non-dividing Cells X ● ● ~8 kb No (up to 10 copies integrated) ●	Adenovirus (Ad) is a non-enveloped, linear double-stranded DNA virus with 57 identified human Ad serotypes. Adenoviruses are engineered to make them safe and efficient for human use gene therapy vectors. dsDNA Dividing and Non-dividing Cells √ ● ● ~7.5 kb Yes ●	Adeno-associated virus (AAV) is a protein shell surrounding and protecting a small, single-stranded DNA genome, which can be engineered to deliver DNA to target cells. ssDNA Dividing and Non-dividing Cells √** ● ● ~4.5 kb Yes ●

Notes:

- * The integration of a viral vector may result in insertional mutagenesis that can alter the expression of chromosomal genes. Possible genotoxic effects include the inactivation of genes at the integration site and the dysregulation of neighboring genes as a consequence of enhancers and promoters present in the vector.
- ** Although recombinant AAV vector genomes persist within cells as episomes, random integration has been observed.

Source: Frost & Sullivan Analysis

Currently, only two AAV-based gene therapies have been approved by the FDA, including Luxturna in 2017 for a rare inherited retinal dystrophy, and Zolgensma in 2019 for spinal muscular atrophy.

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Gene therapy breakthroughs have been propelled by technological advancement in gene editing tools from Zinc Finger Nucleases (ZFNs) and Transcription Activator-like Effector Nucleases (TALENs) to Clustered Regularly Interspaced Short Palindromic Repeats (CRISPRs) as next-generation gene editing tools. The CRISPR gene editing tool is a ribonucleoprotein complex in which a guide RNA recognizes and binds to a specific nucleotide sequence in the genome, which activates a Cas9 nuclease to create a double-stranded cut of the DNA. Normal cellular machinery repairs the cut strands either through non-homologous end-joining, which adds or removes a few nucleotides to inactivate a gene or splice site, or by replacing a short nucleotide sequence using homology-directed repair with a donor template. A newer adaptation of CRISPR technology called base editing uses a hybrid enzyme to chemically convert a single nucleotide-causing mutation to a non-pathogenic sequence without cutting the DNA. CRISPR is the easiest of the genome editing technologies to design and use because the genome recognition sequence is based on the complementary RNA sequence rather than a protein sequence that needs to undergo iterative designs. CRISPR has the potential for exquisite specificity with no off-target genome effects.

Gene Therapy Application to LSDs

Gene therapy holds the promise to transform treatments for LSDs such as Fabry disease and Pompe disease from chronic to curative. The following table demonstrates the introduction of Fabry disease and Pompe disease, and their respective prevalence and current treatment methods.

Indication	Introduction	Prevalence	Treatment Methods
Fabry disease (FD)	FD is one of the most common LSDs which usually starts in childhood and is much more common in men than women. FD is a rare, inherited disease caused by a mutation in the alpha galactosidase (GLA) gene on the X chromosome. The <i>GLA</i> gene produces the α -GAL enzyme that helps break down a lipid molecule in the cells known as globotriaosylceramide (GL-3). When the <i>GLA</i> gene is mutated, the α -GAL enzyme has reduced or absent activity. As a result, GL-3 builds up in blood vessels and tissues and narrows blood vessels, which can damage the skin, kidneys, heart, brain, and nervous system. Significant medical problems are renal failure, cardiomyopathy, myocardial infarction, arrhythmias, painful peripheral neuropathy, diarrhea, and stroke.	<p>From 2016 to 2020, the prevalence of FD in China maintained a steady growth from 354.0 thousand to 360.3 thousand, and is forecasted to reach 364.6 thousand by 2025 and 368.3 thousand by 2030. China has a relatively large number of patients with FD, accounting for about one fifth of patients in the world.</p> <p>From 2016 to 2020, the prevalence of FD in the rest of the world have increased from 1,359.6 thousand to 1,428.3 thousand, and is forecasted to reach 1,512.1 thousand by 2025 and 1,591.1 thousand by 2030.</p>	<p>There are four main treatment approaches considered for FD, including symptomatic therapy, ERT, substrate reduction therapy and chaperone therapy. Gene therapy is considered an innovative and promising treatment for FD and is currently the clinical development stage.</p> <p><i>Symptomatic Therapy:</i> As Fabry disease damages multiple tissues and organs, various methods are used to alleviate symptoms. Treatment of Fabry disease with supportive care alone is not sufficient because it does not target the underlying Fabry disease pathogenesis. Symptomatic therapy of Fabry disease includes medicine, surgery, lifestyle changes and so on.</p> <p><i>ERT:</i> Exogenous delivery of intravenous recombinant human α-GAL can replace GAL activity in patients with decreased or absent enzyme activity, and thereby reduce GL-3 storage and slowing the progression of renal disease. ERT may cause infusion-related reactions and lead to the formation of anti-ERT antibodies. There are five approved ERTs for FD globally.</p>

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Indication	Introduction	Prevalence	Treatment Methods
			<p><i>Substrate Reduction Therapy (SRT):</i> SRT is intended to lower GL-3 through a different mechanism than ERT by reducing the rate of substrate synthesis to match the lower rate of substrate degradation, thereby restoring metabolic balance. SRT uses small molecule drug which do not induce anti-drug antibody (ADA) development and in some cases may be capable of passing the blood-brain barrier. There are no approved SRTs for FD.</p> <p><i>Chaperones Therapy:</i> Chaperone therapy uses an oral small molecule drug to help α-GAL fold correctly for normal function and increase or restore its activity. Treatment is only applicable to patients with certain missense mutations that produce α-GAL with reduced activity. As a molecular chaperone, migalastat has shown some efficacy in FD and is increasingly being used in patients.</p> <p><i>Gene Therapy:</i> Gene therapy for FD refers to the delivery of the <i>GAL</i> gene into cells, including delivery of DNA and mRNA, in which way the patient's cells can produce α-GAL consistently by DNA delivery while the effect of mRNA is transient and thus requires repeated administration. Gene therapy has the potential to induce immune tolerance in patients with FD. There are currently no approved gene therapies for FD.</p>

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Indication	Introduction	Prevalence	Treatment Methods
Pompe disease (PD)	PD, also known as acid maltase deficiency (AMD), acid alpha-glucosidase (GAA) deficiency and type II glycogen disease storage disease (GSD II), was the first identified LSD. PD is a rare genetic condition resulting from mutations in the acid α -glucosidase (<i>GAA</i>) gene, leading to the deficiency of an enzyme called GAA which breaks down glycogen in lysosomes as part of normal cell turnover. As a result, glycogen builds up inside cells, which damages organs and tissues, especially muscles.	<p>From 2016 to 2020, the prevalence of PD in China have maintained a steady growth from 37.4 thousand to 38.2 thousand, and is forecasted to reach 38.7 thousand by 2025 and 39.3 thousand by 2030.</p> <p>From 2016 to 2020, the prevalence of PD in the rest of the world have increased from 125.8 thousand to 132.2 thousand, and is forecasted to reach 140.1 thousand by 2025 and 147.4 thousand by 2030.</p>	<p>There are two main treatment approaches for Pompe disease, including symptomatic treatment and ERT. Gene therapy is also considered an innovative and promising treatment for Pompe disease and is currently at clinical stages.</p> <p><i>Symptomatic Therapy:</i> Similar to FD, treatment of Pompe disease by symptoms alone can only alleviate the symptoms and does not target the underlying Pompe disease pathogenesis.</p> <p><i>ERT:</i> ERT directly introduces a functional enzyme (recombinant human acid α-glucosidase (rhGAA)) into the body to compensate for deficiency of GAA. ERT can improve respiratory function and muscle weakness by reducing glycogen storage. ERT may cause infusion-related reactions and induce anti-ERT antibodies, particularly in infantile-onset disease with no detectable GAA. The latter requires the use of immunomodulatory drugs like rituximab, mycophenolate mofetil, methotrexate and sirolimus to try to induce immune tolerance. There is one ERT for PD approved globally, and another ERT that has completed clinical development and is awaiting regulatory decisions on approval.</p> <p><i>Gene Therapy:</i> Gene therapy for Pompe disease refers to the delivery of the <i>GAA</i> gene into cells, which can provide a durable source of GAA that addresses a major convenience limitation of ERT being a chronic therapy that requires time-consuming, biweekly infusions. In addition to providing a continuous source of enzyme, gene therapy has the potential to induce immune tolerance in PD patients.</p>

INDUSTRY OVERVIEW

Competitive Landscape

According to Frost & Sullivan, the prevalence of FD represents the addressable market size of FD-targeted drugs listed below. The epidemiology of FD was estimated by Frost & Sullivan based on the prevalence rate reported by literatures and interviews from relevant experts. The expected increase in the global prevalence of FD is primarily due to the increasing overall population and may be associated with the potential increasing number of patients suffering hypertension and left ventricular hypertrophy. The following table illustrates the current status of targeted drugs for Fabry disease marketed globally.

Brand name	Generic Name	Company	Approved Region	First Approved Date	Historical Sales Revenue ¹					Price, (USD) (Region)	Annual Cost ² , (USD) (Region)	China Status	Price in China, RMB	Annual Cost in China ² , RMB	Mechanism of Action
					2016	2017	2018	2019	2020						
Fabrazyme	agalsidase beta	Genzyme (Acquired by Sanofi)	US, China, Japan, EU	2001	745.8	815.9	891.7	910.5	931.8	\$798.3/ 5mg (US)	\$312,186 (US)	Approved	39,900/ 35mg	1,778,400	glycosphingolipid hydrolysis activators; globotriaosylceramide (GL-3) hydrolysis; Alpha-galactosidase replacements
Replagal	agalsidase alfa	Shire (Acquired by Takeda)	China, Japan, EU	2001	452.4	472.1	490.3	458.8	483.5	Unknown	Unknown	Approved	Unknown	Unknown	Alpha-galactosidase replacements
-	agalsidase beta biosimilar	Isu Abxis/ GC Pharma	South Korea	2014	Undisclosed					Unknown	Unknown	-	-	-	glycosphingolipid hydrolysis activators; globotriaosylceramide (GL-3) hydrolysis; Alpha-galactosidase replacements
Galafold	migalastat hydrochloride	Amicus Therapeutics	US, EU, Japan	2016	5.0	36.9	91.2	182.2	260.9	\$1,700.0/ 150mg (US)	\$310,250 (US)	-	-	-	α-Galactosidase stimulants
-	agalsidase beta biosimilar ³	JCR Pharmaceuticals	Japan	2018	-	-	0.4	2.3	4.2	Unknown	Unknown	-	-	-	glycosphingolipid hydrolysis activators; globotriaosylceramide (GL-3) hydrolysis; Alpha-galactosidase replacements

Notes:

- The sales revenue provided in this table is based on calendar year. The exchange rates used for Euro to USD conversion for the years 2016 to 2020 are 1.10656, 1.130051, 1.181011, 1.119969 and 1.140486 respectively. The exchange rates used for Japanese yen to USD for the years 2018 to 2020 are 0.009959, 0.009176 and 0.00937 respectively.
- Assumes 75 kg average patient weight.
- Agalsidase beta biosimilar (JCR Pharmaceuticals) has been approved in Japan only.

Source: Frost & Sullivan Analysis

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The following table illustrates the current status of targeted drugs for Fabry disease being developed in China and worldwide.

Generic Name	Company	US Clinical Stage	Start Date	Mechanism of Action	China Status
pegunigalsidase alfa/ PRX-102	Protalix Biotherapeutics Inc	NDA	2020	Alpha-galactosidase replacements	–
lucerastat	Idorsia Pharmaceuticals/ Actelion (Acquired by J&J)	Phase III	11/2018	Ceramide glucosyltransferase inhibitors	–
ibiglustat/GZ/SAR402671	Genzyme (Acquired by Sanofi)	Phase II	11/2014	Ceramide glucosyltransferase inhibitors	–
AVR-RD-01	Avrobio	Phase I/II	02/2018	Cell replacements; Gene transference; α-Galactosidase stimulants	–
FLT-190	Freeline Therapeutics	Phase I/II	07/2019	Gene transference; α-Galactosidase stimulants	–
ST-920	Sangamo Therapeutics	Phase I/II	07/2019	Gene transference; α-Galactosidase stimulants	–
4D-310	4d Molecular Therapeutics	Phase I/II	09/2020	Gene therapy	–
apabetalone/ RVX000222	Resverlogix	Phase I/II	09/2019	Bromodomain-containing protein 4 inhibitors	–
GC1119	Green Cross Corporation	Phase I (Completed)	11/2012	Recombinant human α-Galactosidase A	–
alpha galactosidase	Greenovation Biotech	Phase I (Completed)	11/2016	Alpha-galactosidase replacements	–
alpha-galactosidase A stem cell therapy	University Health Network	Phase I	07/2016	Autologous stem cell transplantation	–

Source: Frost & Sullivan Analysis

According to Frost & Sullivan, the prevalence of PD represents the addressable market size of PD-targeted drugs listed below. The epidemiology of PD was estimated by Frost & Sullivan based on the prevalence rate reported by literatures and interviews from relevant experts. PD is an inherited genetic disease, so the expected steady increase in the global prevalence of PD is primarily due to the increasing overall population. The following tables illustrate the current status of targeted drugs for Pompe disease in China and worldwide.

Brand name	Generic Name	Company	Approved Region/US Clinical Stage	First Approved Date/ Start Date	Price, USD (Region)	Annual Cost*, USD (Region)	China Status	Price in China RMB	Annual Cost* in China, RMB	Mechanism of Action
Lumizyme	alglucosidase alfa	Genzyme (Acquired by Sanofi)	US, China, Japan, EU	2006	\$905/ 50mg (US)	\$707,839 (US)	Approved	5,480/ 50mg	3,419,520	Alpha glucosidase replacements
–	avalglucosidase alfa	Genzyme (Acquired by Sanofi)	NDA	11/2016	–	–	–	–	–	Glycogen metabolizers Alpha glucosidase replacements
–	cipaglucosidase alfa/ ATB200	Amicus Therapeutics Inc	Phase III	12/2018	–	–	–	–	–	Alpha glucosidase replacements
–	duvoglustat hydrochloride	Amicus Therapeutics Inc	Phase II (Completed)	10/2011	–	–	–	–	–	Maltase-glucoamylase stimulants
–	AAV2/8LSPtGAA	Asklepios Biopharmaceutical, Inc; Duke University; National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)	Phase I/II	11/2018	–	–	–	–	–	GAA gene transference
–	RP-A501	Rocket Pharmaceuticals	Phase I	04/2019	–	–	–	–	–	Gene transference

Note:

* Assumes 75kg average patient weight.

Source: Frost & Sullivan Analysis

INDUSTRY OVERVIEW

Rare Cholestatic Liver Diseases

Cholestatic liver diseases are a group of diseases caused by a primary defect in the flow of bile within the liver or from the liver to the intestines, which results in similar symptoms. Cholestasis can be caused by decreased bile production by dysfunctional hepatic or bile duct cells, inhibition of bile secretion, or blockage of bile excretion, consequently bile flows into the lymphatics and blood circulation instead of the small intestine. Cholestatic liver diseases such as Alagille Syndrome (ALGS) and Progressive Familial Intrahepatic Cholestasis (PFIC) are rare diseases with clear genetic bases, whereas Biliary Atresia (BA) is believed to have a multifactorial cause involving genetic risk factors with immune dysregulation and exposure to environmental factors such as viruses or toxins playing a variable role.

The following table demonstrates the introduction of major rare cholestatic liver diseases, and their respective prevalence, current treatment methods and approved products.

Indication	Introduction	Prevalence	Treatment Methods
ALGS	ALGS is a rare genetic disorder that can affect multiple organ systems of the body including the liver, heart, skeleton, eyes and kidneys. ALGS is an autosomal-dominant multisystem disorder caused by mutations in Jagged 1 (<i>JAG1</i>) or <i>NOTCH2</i> .	From 2016 to 2020, the prevalence of ALGS in China has increased from 7.2 thousand to 7.4 thousand, and is forecasted to reach 7.5 thousand by 2025 and 7.6 thousand by 2030.	There is currently no procedure that can correct the loss of the bile ducts within the liver to cure ALGS syndrome completely. Treatments for ALGS include liver transplantation, diet & lifestyle control and medications.
	Approximately 90% of ALGS patients have liver disease caused by “bile duct paucity,” which means a reduction in the number of bile ducts in the liver. Bile ducts are small tube-like structures that connect the liver, gallbladder and small intestine, while extrahepatic bile ducts refer to the bile ducts outside the liver.	From 2016 to 2020, the prevalence of ALGS in the rest of the world have increased from 65.0 thousand to 68.0 thousand, and is forecasted to reach 71.6 thousand by 2025 and 75.0 thousand by 2030.	The emergence of inhibitors of the apical sodium-dependent bile acid transporter (ASBT) marks an innovative treatment for ALGS with the potential to cure the disease. ASBT inhibitors interrupt the enterohepatic circulation of bile acids, resulting in more bile acids being excreted in the feces and lowering the levels of bile acids systemically, thereby potentially reducing bile acid-mediated liver damage and related effects and complications.

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Indication	Introduction	Prevalence	Treatment Methods
PFIC	<p>PFIC is a liver disorder in which liver cells do not release a digestive fluid, called bile, properly, which results in bile accumulation in the cells, known as cholestasis, which causes liver disease. The condition usually progresses slowly over decades from early life.</p>	<p>From 2016 to 2020, the prevalence of PFIC in China has increased from 9.6 thousand to 9.8 thousand, and is forecasted to reach 10.0 thousand by 2025 and 10.1 thousand by 2030.</p> <p>From 2016 to 2020, the prevalence of PFIC in the rest of the world has increased from 42.7 thousand to 44.8 thousand. In the forecasted next five years, the prevalence of PFIC is forecasted to reach 47.3 thousand by 2025, and reach 49.7 thousand by 2030.</p>	<p>Treatments for PFIC mainly include medical and surgical approaches. Diets, medications, and nasobiliary drainage are used for medical treatment and external or internal biliary diversions are applied for surgical treatment. Surgical approaches have an important role in the relief of symptoms such as pruritus and prevention of development of cirrhosis of the liver. ASBT inhibitor is also a promising investigational medication being evaluated in PFIC.</p>
BA	<p>BA is a rare disease of the liver and bile ducts that occurs in infants. When a baby has biliary atresia, bile flow from the liver to the gallbladder is blocked. This causes the bile to be trapped inside the liver, quickly causing damage and scarring of the liver cells (cirrhosis), and eventually causing liver failure.</p>	<p>From 2016 to 2020, the prevalence of BA in China have increased from 43.7 thousand to 44.6 thousand, and is forecasted to reach 45.3 thousand by 2025 and 45.9 thousand by 2030.</p> <p>The global prevalence rate is comparable to that of China. From 2016 to 2020, the global prevalence of BA increased from 192.6 thousand to 201.0 thousand, and is forecasted to reach 211.0 thousand by 2025 and 220.3 thousand by 2030.</p>	<p>There is currently no cure for BA available. The treatments for BA mainly include liver transplant and the Kasai procedure, an operation to re-establish bile flow from the liver into the intestine. ASBT inhibitor is a potential treatment for BA currently under development.</p>

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Competitive Landscape

According to Frost & Sullivan, the prevalence of ALGS, PFIC and BA represents the addressable market size of the targeted therapies listed below. The epidemiology of these indications was estimated by Frost & Sullivan based on the prevalence rate reported by literatures and interviews from relevant experts. These diseases are inherited genetic conditions, so the expected steady increase in the global prevalence is primarily due to the increasing overall population in the future ten years. Mirum obtained FDA approval for maralixibat for ALGS in September 2021, being the first and only targeted drug for ALGS worldwide. There is currently no approved product in China or worldwide for PFIC or BA. The following tables illustrate the current status of targeted therapies and drugs for ALGS under development in China and worldwide.

Generic Name	Company	Approved Region/ US Clinical Stage	First Approved Date/ Start Date	Mechanism of Action	China Status
maralixibat/ CAN108	Shire (Acquired by Takeda); Mirum; Cambridge	US	09/2021	Ileal bile acid transporter inhibitors	–
odevixibat	Albireo	Phase III	03/2021	Ileal bile acid transporter inhibitors	–

Source: Frost & Sullivan Analysis

The following table illustrates the current status of targeted therapy and drugs for PFIC in China and worldwide.

Generic Name	Company	US Status	Start Date	Mechanism of Action	China Status
odevixibat	Albireo	NDA	2020	Ileal bile acid transporter inhibitors	–
maralixibat/ CAN108	Shire (Acquired by Takeda); Mirum; Cambridge	Phase III	10/2018	Ileal bile acid transporter inhibitors	–

Source: Frost & Sullivan Analysis

The following table illustrates the current status of targeted therapy and drugs for BA in China and worldwide.

Generic Name	Company/ Sponsor	US Status	Start Date	Mechanism of Action	China Status
odevixibat	Albireo	Phase III	07/2020	Ileal bile acid transporter inhibitors	–
maralixibat/ CAN108	Shire (Acquired by Takeda); Mirum; Cambridge	Phase II	05/2021	Ileal bile acid transporter inhibitors	–
n-acetylcysteine	Baylor College of Medicine	Phase II	05/2018	Glutathione synthesis stimulator	–
pentoxifylline	Baylor College of Medicine	Phase II	01/2013	Methylxanthine derivative	–

Source: Frost & Sullivan Analysis

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OVERVIEW OF THE CHINA ONCOLOGY MARKET

The China oncology drug market is a sector focusing on the discovery, development, and commercialization of medicines for the treatment of cancer. The China oncology drug market increased significantly from US\$18.8 billion in 2016 to US\$28.6 billion in 2020, representing a CAGR of 11.1%. It is expected to grow to US\$60.3 billion by 2025, at a CAGR of 16.1% from 2020, and to further grow to US\$99.0 billion by 2030, at a CAGR of 10.4% from 2025.

Breast Cancer

Breast cancer is the most common cancers in women, and the incidence increases year by year. Breast cancer mostly happens in women aged over 50. Human epidermal growth factor receptor (HER2) is a ligand-orphan receptor which is expressed in many human tumors, especially in breast cancers. HER2 inhibitors are either tyrosine kinase inhibitors or monoclonal antibodies that slow down or stop cell growth. The incidence of breast cancer in mainland China reached 331.6 thousand in 2020 at a CAGR of 1.7% from 2016 to 2020 and is estimated to reach 355.6 thousand in 2025 and 372.4 thousand in 2030. In Hong Kong, the incidence of breast cancer reached 5.2 thousand in 2020 and is estimated to reach 6.6 thousand in 2025 and 8.0 thousand in 2030. In Taiwan, the incidence of breast cancer was 15.7 thousand in 2020 and is estimated to reach 19.1 thousand in 2025 and 22.2 thousand in 2030. HER2 positive breast cancer accounts for approximately 25% of breast cancer types in China.

According to Frost & Sullivan, the incidence of breast cancer represents the addressable market size of the targeted therapies listed below. The epidemiology of these indications was estimated by Frost & Sullivan based on the incidence rate reported by literatures and interviews from relevant experts. The expected increase in the incidence of breast cancer in China is primarily due to the increasing aging population and unhealthy lifestyle such as smoking and drinking alcohol in the future ten years. The table below illustrates the current marketed small molecular anti-HER2 drugs in China and worldwide.

Brand name	Generic Name	Company	FDA Approval	Price, USD (US)	Annual Cost, USD (US)	NMPA Approval	Price, RMB (China)	Annual Cost, RMB (China)	Indication	Combination	Treatment Line
Tykerb	lapatinib	Novartis	2007	\$58/250mg	\$6,090 (21 days/ course)	2013	70/ 250mg	7350 (21 days/ course)	Advanced or metastatic breast cancer whose tumors overexpress HER2	Capecitabine	2L
					348 (daily cost)			420 (daily cost)		Letrozole	1L
Ai Rui Ni (艾瑞妮)	pyrotinib	Hengrui	-	-	-	2018	4093.6/ 160mg	12,708	Advanced or metastatic breast cancer whose tumors overexpress HER2	Capecitabine	1L/2L
Nerlynx	neratinib	Puma Biotech/ Cambridge	2017	\$102/ 40mg	\$223,380	2020	Unknown	Unknown	Adjuvant treatment for early stage HER2-positive breast cancer, to follow adjuvant trastuzumab based therapy	Na	2L
					\$12,852 (21 days/ course)					Advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting	Capecitabine
Tukysa	tucatinib	Seattle Genetics	2020	\$172/ 150mg	\$125,560	-	-	-	Advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting	Trastuzumab/ Capecitabine	2L

Notes:

- We assume that the average weight of the patient is 60 kg.
- The course of treatment for lapatinib is mainly determined according to the actual situation of the patient. Currently, there is no unified statement on how long and how many courses of treatment are needed.

Source: FDA, Frost & Sullivan analysis

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The table below illustrates the current status of small molecular anti-HER2 drugs being developed in China.

Product Name/Code	Company	US Clinical Status	Indication (US)	China Clinical Status	Indication (China)
selatinib	Qilu Pharmaceutical Co Ltd	–	–	Phase II	Recurrent or metastatic breast cancer whose tumors overexpress HER2
allitinib	Allist Pharmaceuticals Co.,Ltd	–	–	Phase II	Recurrent or metastatic breast cancer whose tumors overexpress HER2
AMX3009	Arromax Pharmatech Co., Ltd	–	–	Phase I	Solid tumor with HER2+
Hemay-022	Tianjin Hemay Pharmaceutical Co Ltd	–	–	Phase I	HER2 positive breast cancer

Source: FDA, Frost & Sullivan analysis

Oral Mucositis

Oral mucositis is a frequent complication in patients receiving radiation therapy to the head and neck and chemotherapy. The incidence of oral mucositis varies between chemotherapeutic agents, the frequency and dosage of chemotherapy, as well as individual patient. Oral mucositis is a severely debilitating condition that could cause pain and restrict oral intake. It is reported that oral mucositis occurs in up to 20% to 40% of adult cancer patients receiving conventional chemotherapy for solid tumors, about 80% of patients receiving high-dose chemotherapy before hematopoietic stem cell transplantation, and almost all patients receiving radiotherapy for head and neck cancer. Drugs or medical devices for the treatment of oral mucositis is often a short-term treatment to manage the symptoms or complications as a result of patients receiving chemotherapy. Key oral mucositis treatments include mouthwash, pain control medications or other drugs.

REPORT COMMISSIONED BY FROST & SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and to prepare an industry report on the worldwide and China oncology drug markets. Frost & Sullivan is an independent global market research and consulting company 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.

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We have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of the rare disease and oncology drug market for potential [REDACTED]. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing the Frost & Sullivan Report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

We have agreed to pay Frost & Sullivan a fee of RMB650,000 for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [REDACTED] or on the content 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 confirm that after taking reasonable care, there has been no adverse change in the market information since the date of the report prepared by Frost & Sullivan which may qualify, contradict or have an impact on the information set forth in this section in any material respect.

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PRC LAWS AND REGULATIONS

Regulations on Company Establishment and Foreign Investment

The PRC Company Law (中華人民共和國公司法), as amended in 2018, applies to the establishment, operation and management of both PRC domestic companies and foreign-invested Enterprises. Investment in the PRC by foreign investors are also regulated by the Foreign-Owned Enterprise Law of the PRC (中華人民共和國外資企業法) promulgated on April 12, 1986 and amended on October 31, 2000 and September 3, 2016, the Implementing Rules for the Foreign-Owned Enterprise Law of the PRC (中華人民共和國外資企業法實施細則) promulgated on December 12, 1990 and amended on April 12, 2001 and February 19, 2014, the Sino-foreign Equity Joint Venture Enterprise Law (中華人民共和國中外合資經營企業法), promulgated on July 1, 1979 and most recently amended on September 3, 2016, and the Interim Administrative Measures for the Record-filing of the Incorporation and Change of Foreign-invested Enterprises (外商投資企業設立及變更備案管理暫行辦法) promulgated on October 8, 2016 and amended on July 30, 2017 and June 29, 2018. Under these laws and regulations, the establishment of a wholly foreign-owned enterprise is subject to the approval of, or the filing with the MOFCOM or its local counterpart, and such wholly foreign-owned enterprises must register and file with the appropriate administrative bureau of industry and commerce. On January 1, 2020, the Interim Administrative Measures for the Record-filing of the Incorporation and Change of Foreign-invested Enterprises was terminated and replaced by the Measures on Reporting of Foreign Investment Information (外商投資信息報告辦法).

The Foreign Investment Law of the People’s Republic of China (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, provides that the “foreign investment” refers to the investment activities in China carried out directly or indirectly by foreign individuals, enterprises or other organisations (“**Foreign Investors**”), 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 or 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 favourable than that granted to domestic investors and their investments; the “negative list” refers to special administrative measures for access of foreign investment in specific fields as stipulated by the State. The State granted national treatment to foreign investments outside the negative list. The negative list will be released by or upon approval of the State Council. After the FIL came into effect, the FIL replaced the Foreign-Owned Enterprise Law of the PRC, the Implementing Rules for the Foreign-Owned Enterprise Law of the PRC and the Sino-foreign Equity Joint Venture Enterprise Law of the PRC.

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Foreign investment in China is subject to the Catalogue for the Guidance of Foreign Investment Industries (2017 Revision) (外商投資產業指導目錄(2017年修訂)) issued on June 28, 2017 and effective from July 28, 2017, the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2018 Version) (外商投資准入特別管理措施(負面清單)(2018年版)) issued on June 28, 2018 and effective from July 28, 2018, the Catalogue of Industries for Encouraging Foreign Investment (2019 Version)(鼓勵外商投資產業目錄(2019年版)), or the 2019 Catalogue, and the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2019 Revision) (外商投資准入特別管理措施(負面清單)(2019年版)), or the 2019 Negative list, issued on June 30, 2019 and effective from July 30, 2019, 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 Interim Administrative Measures for the Record-filing of the Incorporation and Change of Foreign-invested Enterprises, foreign investments that are not subject to special access administrative measures are only required to complete an online filing with the MOFCOM or its local counterpart. The Catalogue for the Guidance of Foreign Investment Industries (2020 Revision) (鼓勵外商投資產業指導目錄(2020年修訂)) issued on December 27, 2020 and effective from January 27, 2021 and the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2020 Version) (外商投資准入特別管理措施(負面清單)(2020年版)), issued on June 22, 2020 and effective from July 23, 2020, further reduced restrictions on the foreign investment and replaced the Catalogue for the Guidance of Foreign Investment Industries (2017 Revision), the Special Administrative Measures for the Access of Foreign Investment (Negative List) (2018 Version), the 2019 Catalogue and the 2019 Negative list.

According to the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (關於外國投資者併購境內企業的規定), or the M&A Rules, jointly promulgated by MOFCOM, the State-Owned Assets Supervision and Administration Commission of the State Council, the State Taxation Administration (SAT), the State Administration for Industry and Commerce, the China Securities Regulatory Commission, and the SAFE on August 8, 2006, which became effective on September 8, 2006 and was amended by MOFCOM on June 22, 2009, a foreign investor (1) acquiring an equity interest in a non-foreign-invested PRC enterprise or subscribing to additional shares in a non-foreign-invested PRC enterprise, (2) purchasing and operating the assets of non-foreign-invested PRC enterprises through establishment of a foreign-invested enterprise, or (3) purchasing the assets of a non-foreign-invested PRC enterprise and operating such assets through establishment of a foreign-invested enterprise with such assets must comply with the PRC laws and regulations and complete registration/filing with relevant departments. Particularly, any PRC company, enterprise or individual who try to acquire any domestic enterprise affiliated with such company, enterprise or individual through an offshore company established or controlled by such company, enterprise or individual shall comply with relevant foreign investment industry policies and be subject to approval of the MOFCOM.

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Laws and regulations of the PRC in relation to Drugs

Drug Regulatory Regime

We operate our business in China under a legal regime consisting of the SCNPC, the State Council and several ministries and agencies under its authority including, among others, the NMPA, and the National Health Commission, or the NHC. The predecessors of the NMPA and NHC are China Food and Drug Administration (CFDA), and the National Health and Family Planning Commission of the PRC, or the NHFPC, respectively, both of which were established in accordance with the Institutional Reform Program of the State Council (國務院機構改革方案) promulgated by the NPC on March 17, 2018. The NMPA is a regulatory authority responsible for registration and supervision of pharmaceutical products, cosmetics and medical equipment under the supervision of State Administration for Market Regulation, an institution for supervising and administrating the market in China.

The NMPA has set up the Center for Drug Evaluation, or the CDE and other institutions. According to the Decision of the CFDA on Adjusting the Approval Procedures under the Administrative Approval Items for Certain Drugs (國家食品藥品監督管理總局關於調整部分藥品行政審批事項審批程序的決定) issued by the NMPA on March 17, 2017 and effective as from May 1, 2017, the approval for an investigational new drug application, or the IND, should be issued by the CDE in the name of the NMPA.

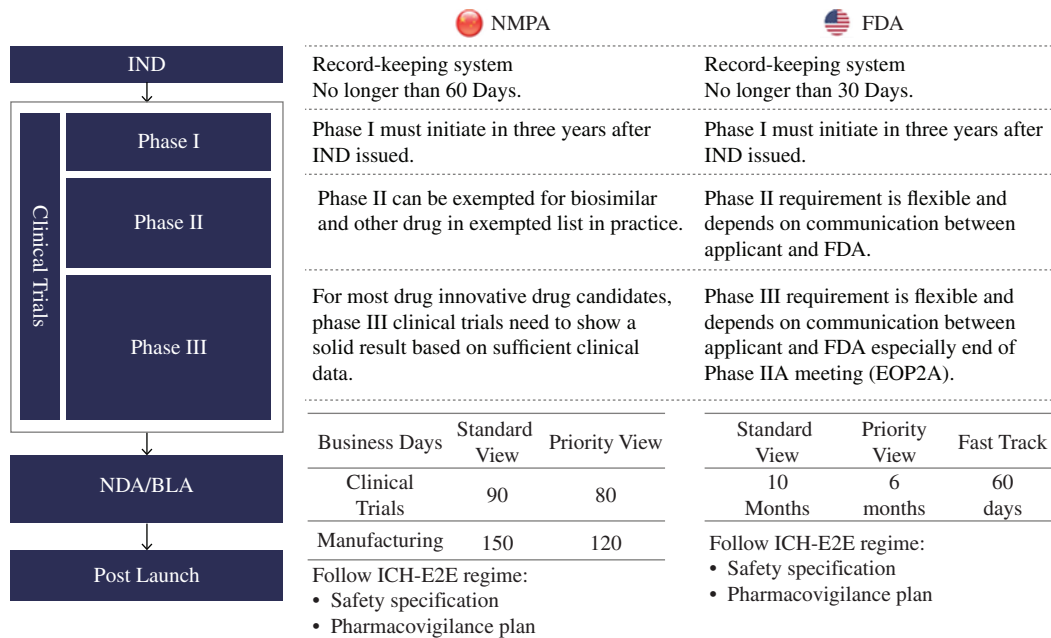
In addition, according to the Administration of Quality of Drug Clinical Practice (GCP Administration) (藥物臨床試驗質量管理規範) issued by the NMPA on April 23, 2020 and effective as from July 1, 2020, which replaced the Administration of Quality of Drug Clinical Practice (GCP Administration)(藥物臨床試驗質量管理規範) issued on August 6, 2003 and effective as from September 1, 2003, and the Opinions on Deepening the Reform of the Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices (關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見) issued by the General Office of the CPC Central Committee and the General Office of the State Council on and effective as from October 8, 2017, the institutions for drug clinical trials should establish an independent ethics committee and the clinical trial schemes are subject to examination, approval and signing with approval opinions by the ethics committee before implementation, in order to protect the rights and interests of human subjects in clinical trials. For a multi-centre clinical trial conducted in the PRC, after ethical review by the leader unit of clinical trial, other member units should recognise the review results of the leader unit and should not conduct repeated review.

The CDE recently announced three batches of List of Overseas Drugs in Urgent Need, which include the List of the First Batch of Oversea New Drugs in Urgent Need for Clinical Purposes, the Second Batch of Oversea New Drugs in Urgent Need for Clinical Purposes and the Third Batch of Oversea New Drugs in Urgent Need for Clinical Purposes (the “**Priority Drug Lists**” (臨床急需境外新藥名單)). According to the Announcement on Matters Relating to the Evaluation and Approval of Overseas Drugs in Urgent Need (關於臨床急需境外新藥審評審批相關事宜的公告) issued by the NMPA and National Health Commission, with regard to a new drug included in Priority Drug Lists, the applicant may directly submit its NDA

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application as well as relevant materials. The CDE will set up a special channel to expedite the evaluation process. With respect to the drug varieties that have not been ascertained and officially declared, the applicants may communicate with the CDE at any time and make an NDA submission as soon as possible.

The following flow chart summarizes and compares the registration procedures in China and the U.S.:



Note: The Procedure is a general approval pathway. In reality, approval pathway may vary case by case.

Source: Frost & Sullivan analysis.

Pharmaceutical Product Development

In the PRC, the NMPA monitors and supervises the administration of pharmaceutical products, as well as medical devices and equipment. The local provincial medical products administrative authorities are responsible for supervision and administration of drugs within their respective administrative regions. The PRC Drug Administration Law (中華人民共和國藥品管理法) promulgated by the SCNPC in 1984, as amended in 2001, 2013, 2015 and 2019, and the Implement Measures of the PRC Drug Administration Law (中華人民共和國藥品管理法實施條例) promulgated by the State Council effective in September 2002 and amended on February 6, 2016 and March 2, 2019, have laid down the legal framework for the administration of pharmaceutical products, including the research, development and manufacturing of new drugs. The PRC Drug Administration Law applies to entities and individuals engaged in the research, production, trade, application, supervision and administration of pharmaceutical products. It regulates and prescribes a framework for the administration of pharmaceutical manufactures, pharmaceutical trading companies, and medicinal preparations of medical institutions and the development, research, manufacturing,

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distribution, packaging, pricing and advertisements of pharmaceutical products. The Implementing Measures of the PRC Drug Administration Law serves to provide detailed implementation regulation for the PRC Drug Administration Law.

The 12th session of the standing committee of the 13th NPC approved the amendment to the Drug Administration Law on August 26, 2019. The revised Drug Administration Law (the “Revised Drug Administration Law”) took effect on December 1, 2019 and brought a series of good changes to the drug supervision and administration system, including but not limited to making it clear what kind of drugs shall be encouraged, changing the clinical trial approval to implied license and prescribing a preferential examination and approval system for certain drugs. According to the Revised Drug Administration Law, drugs refer to articles which are used in the prevention, treatment and diagnosis of human diseases and intended for the regulation of the physiological functions of human beings, for which indications or functions, usage and dosage are specified, including traditional Chinese drugs, chemical drugs and biological products.

Nonclinical Research and Animal Testing

The NMPA promulgated the Administrative Measures for Good Laboratories Practice of Nonclinical Laboratory (藥物非臨床研究質量管理規範) on July 27, 2017, and effective as from September 1, 2017, which replaced the Administrative Measures for Good Laboratories Practice of Nonclinical Laboratory issued in 2003 and has conducted the Administrative Measures for Good Laboratories Practice of Nonclinical Laboratory, or GLP Certification since 2003. On April 16, 2007, the NMPA issued the Circular on Measures for Certification of Good Laboratory Practice and for Nonclinical Laboratory (藥物非臨床研究質量管理規範認證管理辦法), or NMPA Circular 214, which provides that the NMPA decides whether an institution is qualified for undertaking pharmaceutical nonclinical research upon the evaluation of the institution’s organisational administration, its research personnel, its equipment and facilities and its operation and management of nonclinical pharmaceutical projects. If all the requirements are met, a GLP Certification will be issued by the NMPA and the result will be published on the NMPA’s website.

The State Science and Technology Commission promulgated the Regulations for the Administration of Affairs Concerning Experimental Animals (實驗動物管理條例) in November, 1988, which were amended by the State Council in January 2011, July 2013 and March 2017. The State Science and Technology Commission and the State Bureau of Quality and Technical Supervision jointly promulgated the Administration Measures on Good Practice of Experimental Animals (實驗動物質量管理辦法) in December 1997. The State Science and Technology Commission 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)) in December 2001. All of these laws and regulations require a Certificate for Use of Laboratory Animals for performing experimentation on animals.

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Approval and Reform for Clinical Trials of New Drugs

According to the Administrative Measures for Drug Registration (藥品註冊管理辦法) promulgated by the NMPA in January 2020 and effective from July 1, 2020, which replaced the Administrative Measures for Drug Registration issued in 2007, the PRC Drug Administration Law and Implementing Measures of the PRC Drug Administration Law, new drug application is subject to clinical trials. Upon completion of nonclinical research, clinical trials must be conducted for the application of a new drug registration, and applicants must apply for approval of IND from the NMPA, or the CDE before conducting clinical trials.

The Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment (關於改革藥品醫療器械審評審批制度的意見), or the Reform Opinions, promulgated by the State Council on August 9, 2015 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 as well as improving the approval of drug clinical trials.

The Circular Concerning Several Policies on Drug Registration Evaluation and Approval (關於藥品註冊審評審批若干政策的公告), or the Several Policies Circular, promulgated by the NMPA on November 11, 2015 further clarified the measures and policies regarding simplifying and accelerating the approval process of drugs on the basis of the Reform Opinions. The circular further provides that the IND of new drugs is subject to one-off umbrella approval, and the declaration review or approval by stages will no longer be adopted.

The Priority Review and Approval Procedures for Drug Marketing Authorizations (for Trial Implementation)(藥品上市許可優先審評審批工作程序(試行)) promulgated by the NMPA on July 7, 2020 further clarified that a fast track IND or drug registration pathway will be available to the innovative drugs.

According to 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) promulgated by the NMPA on July 24, 2018, within 60 days after the acceptance of and the fees paid for the IND, the applicant may conduct the clinical trials for the drug in accordance with the clinical trial protocol submitted, if the applicant has not received any negative or questioning opinion from the CDE.

The Draft of 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)), or the Draft Guiding Principles, issued by the NMPA on July 2, 2021, emphasize the clinical value-oriented and patient-centered research and development concept during the whole research and development process of oncology drugs. The Draft Guiding Principles recommend that Best Support Care be utilized as a control in randomized controlled trials in order to provide optimal treatment to patients.

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Drug Clinical Trial Registration

According to the Administrative Measures for Drug Registration, upon obtaining the approval of its IND and before conducting a clinical trial, an applicant shall file a registration form with the NMPA containing various details, including the clinical study protocol, the name of the principal researcher of the leading institution, names of participating institutions and researchers, an approval letter from the ethics committee, and a sample of the Informed Consent Form, with a copy sent to the competent provincial administration departments where the trial institutions will be located. The Announcement on Drug Clinical Trial Information Platform (關於藥物臨床試驗信息平台的公告) announced by the NMPA on September 6, 2013, provides that, instead of the aforementioned registration field with the NMPA, all clinical trials approved by the NMPA and conducted in China shall complete a clinical trial registration and publish trial information through the Drug Clinical Trial Information Platform. The applicant shall complete the trial pre-registration within one month after obtaining the approval of the IND in order to obtain the trial’s unique registration number and complete registration of certain follow-up information before the first subject’s enrolment in the trial. If the registration is not completed within one year after the approval of the IND, the applicant shall submit an explanation, and if the first submission is not completed within three years, the approval of the IND shall automatically expire.

The Draft of Measures for the Management of Expanded Sympathetic Use of Drugs for Clinical Trials (拓展性同情使用臨床試驗用藥物管理辦法(徵求意見稿), “Draft of Expanded Sympathetic Use”) announced by the NMPA on December 15, 2017, it sets forth the definition, purposes, criteria and application process of compassionate use or expanded access. The sympathetic use is limited to patients with (i) life-threatening diseases or (ii) diseases that have a severe impact on the quality of life that require early intervention and where there is no effective therapies available. An applicant need to apply to the CDE to carry out the expanded access programs, which can be implemented after approval. However, it is currently uncertain when the Draft of Expanded Sympathetic Use will be formally adopted.

Phases of Clinical Trials and the Communication with the CDE

According to the Administrative Measures for Drug Registration, a clinical trial consists of Phases I, II, III, IV and bioequivalence trial, pursuant to the characteristics of a drug and the research purpose, the research contents shall include clinical pharmacological research, exploratory clinical trial, confirmatory clinical trial and post-marketing research.

However, according to the Technical Guiding Principles for Clinical Trials of Anti-tumor Drugs (抗腫瘤藥物臨床試驗技術指導原則) issued by the NMPA on May 15, 2012, the clinical study staging of anti-tumor drugs is not a fixed developmental sequence. The rapid development of anti-tumor drug research theories and technologies is likely to have an impact on future anti-cancer drug development models. Therefore, applicants can actively explore more scientific and rational research methods and promptly seek advice from the drug registration department under the NMPA. According to Opinions of the NMPA on Encouraging Drug Innovation and Implementing Priority Review and Approval, conditional approval of a

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new drug before completion of a confirmatory Phase III trial may be appropriate if clinical data from an early-stage clinical trials reveals predictable clinical benefits or significantly outperforms the current treatments available in the market. For example, in practice if the efficacy of a drug can be verified in a Phase II clinical trial and its according clinical benefits are predictable, then after completion of a Phase II clinical trial and subject to communication with the CDE, an NDA could be submitted for conditional approval with Phase I and II clinical trials as registrational trials. For such submissions, a confirmatory Phase III trial is required to be implemented post-approval to provide additional evidence of efficacy and safety for the drug candidate. If such confirmatory Phase III trial fails to generate satisfactory results, the approval for a new drug could be suspended. Please also see the section headed “Risk Factors – Risks Relating to Extensive Government Regulations” for details on relevant risks.

According to the Circular on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs, where the application for clinical trial of new investigational drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for Communication Session to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol.

Fast Track Approval for Clinical Trial and Registration

According to the Announcement on Several Policies Pertaining to the Review & Approval of Drug Registration (關於藥品註冊審評審批若干政策的公告) issued by the CFDA in November 2015, which further stipulates that for clinically and urgently needed but insufficient drugs, innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases, a fast track drug registration or clinical trial approval pathway for the following applications: clinically and urgently needed but insufficient drugs, innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases, etc.

According to the Announcement on Matters Concerning the Optimisation of Drug Registration Review & Approval (關於優化藥品註冊審評審批有關事宜的公告) jointly issued by the NMPA and the National Health Commission on May 23, 2018 and effective from the same date, it further simplifies and accelerates the clinical trial approval process.

According to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (藥物研發與技術審評溝通交流管理辦法), or the Communication Measures, promulgated by the NMPA on December 10, 2020, during the research and development periods and in the registration applications of, among others, the innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development periods of drugs, mainly including meetings before the IND,

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meetings upon the completion of Phase II trials and before the commencement of Phase III trials, meetings before submitting a marketing application for a new drug, and meetings for risk evaluation and control. Type III meetings refer to meetings not classified as Type I or Type II.

Clinical Trials of Companion Diagnostics

On August 13, 2020, the Center for Medical Device Evaluation under the NMPA, or the CMDE, issued the draft Guidelines on Clinical Trials of Companion Diagnostics Reagents of Marketed Anticancer Drugs (《已上市抗腫瘤藥物的伴隨診斷試劑臨床試驗指導原則(徵求意見稿)》), pursuant to which anticancer drug companion diagnostics reagents are divided into original companion diagnostics reagents and new companion diagnostics reagents. The draft guidelines provide guidance on clinical trials of companion diagnostics reagents of approved anticancer drugs. The Guidance for Package Insert Update and Technical Review of Oncology Companion Diagnostic Reagents Based on Similar Therapeutic Drugs (基於同類治療藥物的腫瘤伴隨診斷試劑說明書更新與技術審查指導原則) was issued by NMPA on April 7, 2021, and this guidance is the general requirements for the update of the technical review of oncology companion diagnostic reagents based on similar therapeutic drugs.

Sampling and Collecting Human Genetic Resources Filing

The Interim Administrative Measures on Human Genetic Resources (人類遺傳資源管理暫行辦法), promulgated by the Ministry of Science and Technology and the MOH on June 10, 1998, aimed at protecting and fair utilizing human genetic resources in the PRC. On July 2, 2015, the Ministry of Science and Technology issued 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), or the Service Guide, which became effective on October 1, 2015. According to the Service Guide, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organisation of China shall apply for approval of the China Human Genetic Resources Management Office through the online system. On October 26, 2017, the Ministry of Science and Technology 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 listing a drug in the PRC.

The Regulations of the People’s Republic of China on the Administration of Human Genetic Resources (中華人民共和國人類遺傳資源管理條例) promulgated by the State Council on May 28, 2019 and implemented on July 1, 2019, further stipulates that in order to obtain marketing authorisation for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China’s human genetic resources at clinical institutions without export of human genetic resource materials. However, the 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.

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According to the Biosecurity Law of the People’s Republic of China (中華人民共和國生物安全法) promulgated by the SCNPC on October 17, 2020 and implemented on April 15, 2021, the collection, preservation, use, and outbound supply of China’s human genetic resources shall conform to ethical principles and be without harm to public health, national security, or public interest. If China’s human genetic resources are used at a clinical trial institution for international cooperation in clinical trials without the export of human genetic resources, in order to obtain China’s marketing authorization of a relevant drug or medical device, approval is not required; however, the types, quantities, and purposes of the human genetic resources to be used shall be filed with the science and technology department of the State Council before clinical trials.

Sample Manufacturing Practice

According to the Administrative Measures for Drug Registration, all facilities and techniques used in the manufacture of drug samples for clinical trial use in the PRC must conform to GMP guidelines as established by the NMPA.

Regulations on Cross-Strait Medical and Healthcare Cooperation

According to the Cross-Strait Medical and Healthcare Cooperation Agreement (《海峽兩岸醫藥衛生合作協議》) (the “Cooperation Agreement”) entered into by Association for Relations Across the Taiwan Straits (the “ARATS”) and Straits Exchange Foundation (the “SEF”) on December 21, 2010, the two parties agreed to cooperate in regard to the following: (i) prevention and treatment of infectious diseases; (ii) safety management of and research and development for pharmaceuticals; (iii) traditional Chinese medicine research and exchange and safety management of Chinese crude drugs; and (iv) emergency aid and treatment. In regard to clinical trial cooperation, the two parties have agreed to conduct exchanges and cooperation on their systems and regulations relating to clinical trials, management of executive departments and teams, the protection of subjects’ rights and interests, and approval mechanisms for clinical trial plans and trial results. Cooperation in R&D for clinical trials and pharmaceuticals across the strait shall be actively strengthened in accordance with good clinical practice (GCP), with a view towards reducing repetitive trials through the preferential methods of pilot and special projects. Methods shall then be tested to accept the implementation results of the two parties on this basis.

Regulations on International Multi-Center Clinical Trials and Acceptance of Overseas Clinical Trial Data

According to 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), or the Multi-Center Clinical Trial Guidelines, promulgated by the NMPA on January 30, 2015 and effective from March 1, 2015, international multi-centre clinical trial applicants may simultaneously perform clinical trials in different centres using the same clinical trial protocol. Where the applicants plan to implement the International Multi-centre clinical trials in the PRC, the applicants shall comply with relevant laws and regulations, such as the PRC Drug Administration Law, the

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Implementing Regulations of the PRC Drug Administration Law and the Administrative Measures for Drug Registration, execute the GCP, make reference to universal international principles such as the ICH-GCP, and comply with the laws and regulations of the countries involved in the International Multi-Center clinical trials. Where the applicants plan to use the data derived from the International Multi-Center clinical trials for approval of a drug registration in the PRC, it shall involve at least two countries, including China, and shall satisfy the requirements for clinical trials set forth in the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial) and Administrative Measures for Drug Registration and other related laws and regulations.

According to the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) issued by the General Office of CCCPC and the State Council in October 2017, clinical trial data obtained in international multi-center that conforms to China’s requirements for registration of drugs and medical devices can be used for the application for registration in China.

On 10 October 2017, the CFDA issued the Decision on Adjustment of Matters Relating to Registration and Administration of Imported Drugs (《關於調整進口藥品註冊管理有關事項的決定》), pursuant to which, (i) for drugs subject to international multi-center clinical trials carried out in China, Phase I clinical trial shall be allowed to be carried out simultaneously, and the requirement that the clinical trial drug should be registered overseas or that the drug has entered into Phase II or Phase III clinical trial shall be removed, except for biological products for preventive purposes, (ii) following the completion of international multi-center clinical trials carried out in China, the applicant may directly apply for registration of market launch of the drugs according to the Administrative Measures for Drug Registration and other relevant regulations, (iii) with respect to applications for clinical trials or market launch of imported innovative chemical drugs and therapeutic biological products, the marketing authorization in the country or region where the foreign drug manufacturer is located will not be required, and (iv) with respect to drug applications that have been accepted before the release of this Decision, if relevant requirements are met, importation permission can be granted if such applications request exemption of clinical trials for the imported drugs based on the data generated from international multi-center clinical trial.

According to the Technical Guiding Principles for the Acceptance of 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) promulgated by the NMPA on July 6, 2018, the basic principles for accepting overseas clinical trial data include: (1) applicants shall ensure the authenticity, integrity, accuracy and traceability of overseas clinical trial data; (2) the process of generating overseas clinical trial data shall comply with the relevant requirements of the Good Clinical Practice (GCP) of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH); (3) applicants shall ensure the scientific design of overseas clinical trials, the compliance of clinical trial quality management system with the requirements, and the accuracy and integrity of statistical analysis of data; and (4) to ensure that the clinical trial design and statistical analysis of the data are scientific and reasonable, for the drugs with simultaneous R&D at home

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and abroad and forthcoming clinical trials in China, the applicants may, prior to implementing pivotal clinical trials, contact the CDE to ensure the compliance of pivotal clinical trial’s design with the essential technical requirements for drug registration in China. According to the Guiding Principles, the integrity of clinical trial data is the basic requirement for accepting registration applications. For overseas clinical trials used for drug registration applications in China, all overseas clinical trial data shall be fully provided but not selectively. For the subsequent clinical trials carried out in China after the clinical trials being carried out overseas, the drug registration applicants shall evaluate the existing overseas data first before the communication with the CDE. Only those overseas data that can satisfy the following requirements will be fully accepted: (i) the data is authentic and reliable, and is in line with ICH GCP and drug registration requirements; (ii) the data can be adopted in the effectiveness and safety evaluation of target indications; and (iii) there are no ethnic sensitive factors that affect the effectiveness and safety. The data that are not met with all the requirements above will be only accepted partially or not accepted. For the drugs under domestic and overseas R&D, various domestic and overseas clinical trials shall be sorted and summarized to form an integrated data package in accordance with the requirements of the Administrative Measures for Drug Registration before such data can be used for the drug registration application in China.

New Drug Application

According to the Administrative Measures for Drug Registration, drug registration applications include domestic new drug application, domestic generic drug application and imported drug application. Drugs are classified as chemical drugs, biological products and traditional Chinese medicine. When Phases I, II and III of clinical trials have been completed, the applicant may apply to the NMPA for approval of a new drug application. The NMPA then determines whether to approve the application according to the comprehensive evaluation opinion provided by the CDE of the NMPA.

Drug Registration and Marketing Authorization

An applicant shall complete studies in pharmacy, pharmacology, and toxicology, as well as clinical trials of pharmaceuticals, according to the Administrative Measures for Drug Registration promulgated by the NMPA in January 2020 and became effective from July 1, 2020. The applicant shall submit an application for drug marketing authorization and the relevant research materials in accordance with the submission requirements after determining quality standards, verifying commercial scale manufacturing process, and preparing to undergo examination and inspection for drug registration. CDE shall assemble pharmacists, medical professionals, and other technical specialists to analyze the application thoroughly, examining the drug’s safety, effectiveness, and quality control. After the comprehensive review, the drug shall be approved for marketing and a drug registration certificate shall be issued.

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Special Examination and Fast Track Approval for Antineoplastic Drugs under Current Reform Frame

According to the Provisions on the Administration of Special Examination and Approval of Registration of New Drugs (新藥註冊特殊審批管理規定) promulgated by the NMPA on January 7, 2009, special examination and approval for new drugs registration applications applies when (1) the effective constituent of a drug extracted from plants, animals, and minerals, as well as the preparations thereof, have never been marketed in China, and the material medicines and the preparations thereof are newly discovered; (2) the chemical raw materials for medicines as well as the preparations thereof and the biological product have not been approved for marketing, either in China or abroad; (3) new drugs with distinctive clinical treatment advantages for diseases such as AIDS, malignant tumor or other rare diseases; or (4) new drugs for diseases that currently lacking effective treatment. Under the circumstances set out in (1) and (2), drug registration applicants may make special approval applications in submitting applications for clinical trials of new drugs; under the circumstances set out in (3) and (4), drug registration applicants may make special approval applications only in applying for production.

According to the Opinions on Reform of the Review & Approval System of Drugs and Medical Devices (關於改革藥品醫療器械審評審批制度的意見), a special review & approval system shall be adopted for innovative drugs to accelerate the review & approval of innovative drugs for prevention and treatment of AIDS, cancer, major infectious diseases, rare diseases and other diseases.

Announcement on Several Policies Pertaining to the Review & Approval of Drug Registration (關於藥品註冊審評審批若干政策的公告) further specifies that efforts shall be made to accelerate the review & approval of registration application for several categories of innovative drugs including those for prevention and treatment of cancer and other diseases. From December 1, 2015 onwards, applicants may apply to the CDE for accelerated review.

According to the Priority Review and Approval Procedures for Drug Marketing Authorizations (for Trial Implementation) (藥品上市許可優先審評審批工作程序(試行)), an applicant for drug marketing authorization may apply for priority review and approval procedures for the following drugs with obvious clinical value: (I) drugs in urgent clinical demand and in shortage, innovative drugs and modified new drugs for prevention and treatment of serious infectious diseases, rare diseases and other diseases; (II) new varieties, dosage forms and specifications of children's drugs that conform to children's physiological characteristics; (III) vaccines and innovative vaccines that are in urgent need for disease prevention and control; (IV) drugs that have been included in the procedures for breakthrough therapy designation; (V) drugs that are subject to conditional approval; and (VI) other circumstances under which priority review and approval shall be provided for by the NMPA.

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According to the Announcement on Matters Concerning the Optimisation of Drug Registration Review & Approval (關於優化藥品註冊審評審批有關事宜的公告) jointly issued by the NMPA and the National Health Commission on May 23, 2018 and effective from the same date, the CDE will prioritise the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of priority review & approval.

Drugs' registration classification

Under the Administrative Measures for Drug Registration, drugs are classified into Chinese medicine, chemical medicine, biological products and others. Biological products are further divided in 3 categories in the Registration Classification and Application Documents Requirements of Biological Products (《生物製品註冊分類及申報資料要求》), or the Registration Category, which was promulgated by the NMPA on June 29, 2020. Pursuant to the Registration Category, Category I therapeutic biological products or vaccines refer to those that have not been marketed in the PRC or abroad. Category II therapeutic biological products or vaccines refer to improved ones which, compared with the existing products marketed in the PRC or abroad, could improve the safety, effectiveness and quality controllability, and have obvious advantages. Category III therapeutic biological products or vaccines refer to those that have been marketed in the PRC or abroad, including biosimilar drugs.

According to the Notice of the NMPA about the Issuing of the Reform Plan for the Registration Classification of the Chemical Drugs (國家食品藥品監督管理總局關於發布<化學藥品註冊分類改革工作方案>的公告), which was issued and effected on March 4, 2016, the registration classification of the chemical drugs are adjusted to five categories. Category 1 drugs refer to innovative chemical drugs that have not been marketed anywhere in the world. Improved new chemical drugs that are not marketed anywhere in the world fall into Category 2 drugs. Generic chemical drugs, that have equivalent quality and efficacy to the originator's drugs have been marketed abroad but not yet in China, can be classified as Category 3 drugs. Generic drugs, that have equivalent quality and efficacy to the originator's drugs and have been marketed in China, fall into Category 4 drugs. Category 5 drugs are drugs which have already been marketed abroad, but are not yet approved in China. Categories 1 and 2 shall follow the registration application procedure for new drugs according to the Administrative Measures for Drug Registration; categories 3 and 4 shall follow the procedure for generic drugs; category 5 shall follow the application and regulation requirements for importing drugs. Where there is a discrepancy between this plan and the Measures for the Administration of Drug Registration, this plan shall be complied for certainty. The Chemical Drug Registration Classification and Application Data Requirements (《化學藥品註冊分類及申報資料要求》) issued by the NMPA in June 2020 and effective in July 2020 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 regulation, 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.

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Pilot Plan for the Marketing Authorisation Holder System

The Reform Opinions provides a pilot plan for the marketing authorisation holder system, or the MAH system.

Under the authorisation of the NPCSC, the General Office of the State Council issued the Pilot Plan for the Drug Marketing Authorisation Holder Mechanism (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 MAH system, for drugs in 10 provinces in China. Under the MAH system, domestic drug research and development institutions and individuals in the pilot regions are eligible to be holders of drug registrations without having to become drug manufacturers. The marketing authorisation holders may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and GMP-certified, and are also located within the pilot regions. Drugs that qualify for the MAH System are: (1) new drugs (including biological products approved as category I and VII drugs and biosimilars under the Administrative Measures for Drug Registration) approved after the implementation of the MAH System; (2) generic drugs approved as category III or IV drugs under the Reform Plan for Registration Category of Chemical Medicine (化學藥品註冊分類改革工作方案) issued by the NMPA on March 4, 2016; (3) previously approved generics that have passed equivalence assessments against original drugs; and (4) previously approved drugs whose licenses were held by drug manufacturers originally located within the pilot regions, but which have moved out of the pilot regions due to corporate mergers or other reasons.

The Circular on the Matters Relating to Promotion of the Pilot Program for the Drug Marketing Authorisation Holder System (關於推進藥品上市許可持有人制度試點工作有關事項的通知), or the MAH Circular, promulgated by the NMPA on August 15, 2017, clarified the legal liability of the marketing authorisation holder, who is responsible for managing the whole manufacturing and marketing chain and the whole life cycle of drugs and assumes the full legal liability for nonclinical drug study, clinical trials, manufacturing, marketing and distribution and adverse drug reaction monitoring. According to the MAH Circular, the marketing authorisation holder shall submit a report of drug manufacturing, marketing, prescription, techniques, pharmacovigilance, quality control measures and other situations to the NMPA within 20 working days after the end of each year.

The Decision of Extending the Pilot Period of Authorizing the State Council to Carry out the Pilot Plan for the Drug Marketing Authorisation Holder Mechanism in Certain Places (關於延長授權國務院在部分地方開展藥品上市許可持有人制度試點期限的決定), promulgated by SCNPC on October 26, 2018, extended the term of the MAH system to November 4, 2019.

The PRC Drug Administration Law was revised by the NPCSC on August 26, 2019 and came into effect on December 1, 2019, provides that (1) the MAH system will be applicable throughout the country; (2) the legal representative and the key person-in-charge of a drug marketing authorisation holder shall be fully responsible for the quality of drugs.

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Monitoring Periods for New Drugs

According to the Implementing Regulations of the Drug Administration Law and the Administrative Measures for Drug Registration, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of not more than five years for new drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of such new drugs. During the monitoring period of a new drug, no approval shall be granted to any other manufacturer to produce or import the said drug. The only exception is that if, prior to the commencement of the monitoring period, the NMPA has already approved any other IND of the same drug may proceed along drug registration application, review and approval procedures. Where regulations are conformed to, the NMPA shall approve the production or import of the same drug, and the monitoring of such drug produced by the domestic manufacturers should be conducted together with the drug already in the monitoring period.

Packaging of Pharmaceutical Products

According to the Measures for The Administration of Pharmaceutical Packaging (藥品包裝管理辦法) promulgated on February 12, 1988 and effective from September 1, 1988, pharmaceutical packaging must comply with national and professional standards. If there is no national or professional standard available, an applicant can formulate and implement its own standards after obtaining the approval of the provincial administration or bureau of standards. The applicant must reapply if it needs to change its own packaging standards. Drugs that have not been developed and approved for packaging standards must not be sold or marketed in the PRC (except for drugs for the military). According to the GCP Administration, the applicant shall be responsible for the proper packaging and labelling of drugs for clinical trials and in double-blinded clinical trials, the test drug shall be consistent with the control drug or placebo in appearance, odour, packaging, labelling, and other features.

Pharmaceutical Distribution Permit and Good Supply Practice Requirements

According to the newly amended PRC Drug Administration Law and the Implementing Measures of the PRC Drug Administration Law, to be engaged in the wholesale distribution and retailing of drugs, a company must obtain a Drug Distribution License with an appropriate "scope of distribution" from the local drug regulatory authority. According to Measures for the Administration of Drug Distribution License, this license shall be renewed every five years.

The GSP certification for drugs has been cancelled, and the application for GSP certification for drugs will no longer be accepted, since December 1, 2019, pursuant to the Announcement of the NMPA on Implementation of the PRC Drug Administration Law (《國家藥監局關於貫徹實施〈中華人民共和國藥品管理法〉有關事項的公告》). But the competent regulatory authorities conduct the supervision and regulation through changing to the inspection of the implementation of the GSP from time to time and supervising the compliance of enterprises.

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According to Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》) promulgated by the NMPA on April 30, 2000 and last amended on July 13, 2016, which is a set of basic rules for drug distribution management and quality control, drug distributors shall take effective quality control measures in drug purchase, storage, sale, transportation and other links, so as to ensure the quality of drugs, and establish the drug traceability system in accordance with the relevant requirements. 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.

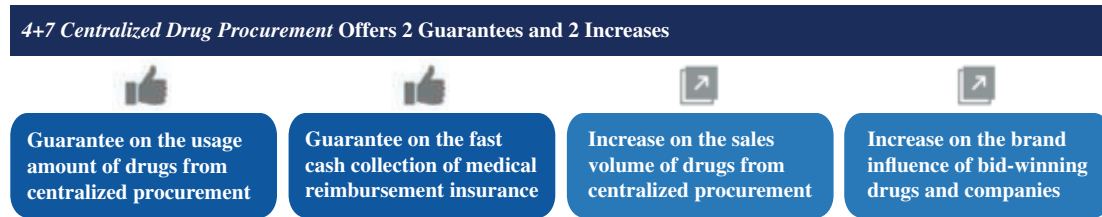
Centralized Drug Procurement and Use

According to the Opinions on Deepening the Reform of Medical Insurance System (中共中央、國務院關於深化醫療保障制度改革的意見) issued by the CPC Central Committee and the State Council on February 25, 2020, a market-oriented price-setting mechanism for drugs and medical consumables shall be created, and the policy of combination of bidding and procurement and quantity-based pricing shall be followed. According to the Notice of Issuing the Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State issued by the General Office of the State Council (關於印發國家組織藥品集中採購和使用試點方案的通知) on January 1, 2019, and the Opinions on the Medical Insurance Supporting Measures for the Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State issued by the State Medical Insurance Administration (關於國家組織藥品集中採購和使用試點醫保配套措施的意見) (“**4+7 Centralized Drug Procurement**”) on February 28, 2019, eleven pilot cities including Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi’an, are selected as the pilot cities for the centralized procurement and use of drugs under the organization of the State. The scope of drugs to be procured in a centralized manner includes selected varieties from the generic names corresponding to generic drugs passing consistency evaluation of quality and efficacy. On the basis of the procurement submitted by public medical institutions in the pilot regions, the total procurement shall be estimated at 60%-70% of total annual drug consumption of all public medical institutions in the pilot regions, and the centralized drug purchasing prices shall be formed by conducting quantity-specific procurement, pegging procurement to prices and trading procurement for prices. After completing the purchases by the public medical institutions in the pilot regions, the public medical institutions shall use the selected drugs as the priority, and the quantity of the selected drugs used during the pilot procurement period shall be no less than that of the non-selected drugs.

According to the Implementation Opinions on Expanding the Regional Scope in the Pilot Program of Centralized Drug Procurement and Use Organized by the State (關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見) issued by several authorities including the National Healthcare Security Administration and NMPA, among others, on September 25, 2019, mode of centralized procurement of drugs with quantity for centralized procurement and use of drugs organized by the State is being promoted throughout the country and such mode is applicable to 25 designated generic drugs in the pilot program of centralized drug procurement and use of drugs organized by the State.

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The following diagram illustrates the advantages and goals of 4+7 Centralized Drug Procurement:



Under 4+7 Centralized Drug Procurement, the healthcare institutions procure the bid-winning drugs with priority, and the doctors have to prescribe the bid-winning drugs so as to satisfy the required quantity commitment. As a result, the sales volume of the bid-winning drugs will significantly increase in the short run, which enables the drugs to gain a substantial market share. Despite of the erosion effect of the average selling price, in the medium run, winning bidders are expected to continue obtaining a higher market share. Given that winning bidders are awarded with the guaranteed procurement, such pharmaceutical companies may be able to reduce their sales and marketing expenses.

Healthcare System Reform

The PRC government recently promulgated several healthcare reform policies and regulations. On March 17, 2009, the Central Committee of the PRC Communist Party and the State Council jointly issued the Guidelines on Strengthening the Reform of Healthcare System (關於深化醫藥衛生體制改革的意見), On December 27, 2016, the State Council issued the Notice on the Issuance of the 13th Five-year Plan on Strengthening the Reform of Healthcare System (關於印發“十三五”深化醫藥衛生體制改革規劃的通知), On April 25, 2017, the General Office of the State Council issued the Main Tasks of Healthcare System Reform in 2017 (深化醫藥衛生體制改革2017年重點工作任務), Highlights of these healthcare reform policies and regulations include (1) establishing a basic healthcare system to cover both urban and rural residents and providing the Chinese people with safe, effective, convenient and affordable healthcare services, (2) improving the healthcare system through the reform and development of a graded hierarchical healthcare system, modern hospital management, basic medical insurance, drug supply support and comprehensive supervision, and (3) improving the efficiency and quality of the healthcare system to meet the various medical needs of the Chinese population. On May 23, 2019, the General Office of the State Council issued the Main Tasks of Healthcare System Reform in 2019 (深化醫藥衛生體制改革2019年重點工作任務), highlighting the following policies and regulations (1) reinforcing the degree of cancer prevention and treatment, accelerating the registration and approval of anti-cancer new drugs at home and abroad and remaining the temporary channel of imperative anti-cancer drugs importation open, (2) consolidating and improving the basic medicine system and establishing an inventive and restrictive mechanism for preferential use. Improving the dynamic adjusting mechanism of the NRDL and incorporating the eligible therapeutic drugs listing in the National Essential Drug List into the NRDL first in accordance with the procedure.

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According to the Notice of the National Healthcare Security Administration and Ministry of Human Resources and Social Security on Issuing the National Drug Catalogue for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (關於印發國家基本醫療保險、工傷保險和生育保險藥品目錄的通知), which came into effect on March 1, 2021 (the “Notice”), all places shall implement the NRDL in a strict manner, and shall not have the discretion to formulate the catalogue or increase the drugs in any form, or adjust the scope of limited payment. Priority shall be given to adjusting the scope of payment for the drugs that were listed in the First Batch of National Key Monitored Drugs for Rational Use (chemical and biological products) (第一批國家重點監控合理用藥藥品目錄(化藥及生物製品)), which was issued and implemented on June 11, 2019.

Pursuant to the Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (城鎮職工基本醫療保險用藥範圍管理暫行辦法), jointly issued by several authorities including the Ministry of Labor and Social Security and the Ministry of Finance on May 12, 1999, among others, the NRDL shall be adjusted every two years in principle, and the provincial reimbursement drug list (“PRDL”) shall be adjusted accordingly. The NRDL is permitted to be expanded to include new drugs once per year, while provincial governments are not entitled to expand their PRDLs on their own. The 5th NRDL was published in August 2019 to remove 150 drugs and add 148 drugs. Consideration was given to the scope of reimbursement and the ratio of traditional Chinese medicine to western medicine to meet current medical demands. The 5th NRDL was then adjusted in the negotiation that occurred in November 2019 to add 70 drugs with an average price cut of 60.7%, which mainly consist of oncology, chronic disease, and rare disease drugs. Moreover, the contracts of 27 existing drugs were successfully extended with an average price cut of 26.4%.

Chronic Diseases Prevention and Treatment

According to the Guiding Opinion of the General Office of the State Council on Promoting the Construction of the Hierarchical Healthcare System (國務院辦公廳關於推進分級診療制度建設的指導意見), or the Hierarchical Healthcare System Opinion, issued by the General Office of the State Council on September 8, 2015, and the Notice on Promoting Pilot Work for Hierarchical Healthcare System (關於推進分級診療試點工作的通知) jointly promulgated by the NHFPC and the State Administration of Traditional Chinese Medicine on August 19, 2016, the hierarchical healthcare system is expected to be gradually improved. The Hierarchical Healthcare System Opinion further clarified that several chronic diseases, including hypertension, diabetes, cancer and cardiovascular and cerebrovascular diseases, are pilot diseases under the hierarchical healthcare system. Primary health institutions, rehabilitation hospitals, and nursing institutions can provide treatments, rehabilitation and nursing services to patients with chronic diseases, patients in rehabilitation, elderly patients and advanced tumor patients who have clear diagnosis and stable disease conditions.

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On January 22, 2017, the General Office of the State Council promulgated the Mid and Long-Term Plan for Chronic Disease Prevention and Treatment in China (2017-2025) (中國防治慢性病中長期規劃(2017-2025)), or the Chronic Disease Plan. One of its objectives is to raise up the overall 5-year survival rate in cancer patients by 5% by 2020 and 10% by 2025. It also points out that the hierarchical healthcare system of chronic diseases, such as tumor, shall be promoted. The social participation in regional medical services, as well as social investments in the field of chronic disease prevention and treatment is also encouraged.

Rare Disease Scope

On May 11, 2018, the NHC, along with the NMPA and three other national ministries and agencies jointly issued the Notice of the First Edition of the Rare Disease List (《關於公佈第一批罕見病目錄的通知》) which includes 121 kinds of rare diseases. Pursuant to the Notice on Publishing the Procedures of Developing the Rare Disease List (《關於印發罕見病目錄製訂工作程序的通知》) issued by the NHC on May 28, 2018, the following four criteria should be met at the same time for rare disease designation: (i) the disease has a low incidence or prevalence in PRC and abroad; (ii) the disease significantly impacts the patient and his or her family; (iii) there is a clear diagnosis method; and (iv) the disease can be treated or intervened in an economically feasible way, or it has been included in a national scientific research project if there is no effective treatment or intervention for such disease. In principle, the catalog update time shall not be shorter than 2 years.

With certain drugs targeting rare diseases being listed in National Rare Disease List, a company may be eligible for the priority review and approval of new drugs for these disease from the NMPA.

PRC Coverage and Reimbursement

Coverage of the National Medical Insurance Program

The national medical insurance program was first adopted according to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (國務院關於建立城鎮職工基本醫療保險制度的決定) issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enrol their employees in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees. On July 10, 2007, the State Council issued the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (國務院關於開展城鎮居民基本醫療保險試點的指導意見), further enlarged the coverage of the basic medical insurance program, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. In addition, on January 3, 2016, the Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (國務院關於整合城鄉居民基本醫療保險制度的意見) issued by the State Council required the integration of the urban resident basic medical insurance and the new rural cooperative medical care system and the establishment of a unified basic medical insurance system, which will cover all urban and rural residents other than rural migrant workers and persons in flexible employment arrangements who participate in the basic medical insurance for urban employees.

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Medical Insurance Catalogue

Program participants are eligible for full or partial reimbursement of the cost of medicines included in the medical insurance catalogue. The Notice Regarding the Tentative Measures for the Administration of the Scope of Basic Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (關於印發城鎮職工基本醫療保險用藥範圍管理暫行辦法的通知), or the Medical Insurance Coverage Notice, jointly issued on May 12, 1999 by several authorities including, among others, the Ministry of Labour and Social Security and the Ministry of Finance, provides that a pharmaceutical product listed in the medical insurance catalogue must be clinically necessary, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements: (1) be set forth in the pharmacopoeia of the PRC, (2) satisfy the standards promulgated by the NMPA, and (3) be approved by the NMPA for imported pharmaceutical products.

The 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, or the NRDL, sets forth the payment standard for pharmaceutical products under the basic medical insurance, work-related injury insurance and maternity insurance funds. The MOHRSS (According to the above institutional reform, the functions with respect to change the NRDL have been transferred to the PRC National Health Insurance Bureau), together with other government authorities, has the power to determine which medicines are listed in the NRDL. Medicines listed in the NRDL are divided into two parts, List A and List B. List A drugs are widely used clinical treatments with good efficacy and lower prices compared to similar drugs, while List B drugs are clinical treatments with good efficacy and slightly higher prices compared to List A drugs.

On July 13, 2017, the MOHRSS announced that the 2017 NRDL would be expanded to include an additional 36 drugs classified as List B medicines, 18 of which are anti-cancer drugs. On September 30, 2018, the PRC National Health Insurance Bureau announced that another 17 anti-cancer drugs were included into the 2017 NRDL classified as List B Medicines. Since 2017, the NRDL has reflected an emphasis on drugs that treat cancer. The 5th NRDL was promulgated in August 2019 to remove 150 drugs and add 148 new drugs, and was adjusted in November 2019 to add 70 drugs.

According to the Medical Insurance Coverage Notice, a PRDL must be made by the labour administration departments of the provincial governments in the PRC. Provincial evaluation institutions and expert groups select the drugs to be listed in the PRDL. Provincial governments are required to include all List A drugs listed in the NRDL in their PRDL, but have discretion to adjust upwards or downwards by no more than 15% the number of List B drugs listed in the NRDL to be listed in the PRDL based on local economic levels, medical demands, and medication practices.

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According to the Medical Insurance Coverage Notice, patients purchasing List A drugs listed in the NRDL are entitled to reimbursement of the entire amount of the purchase price through the basic medical insurance program. Patients purchasing List B drugs listed in the NRDL are required to pay a certain percentage of the purchase price and obtain reimbursement for the remainder of the purchase price through the basic medical insurance program.

The NRDL must be adjusted every two years in principle, and the PRDL must be adjusted based on the adjustment of the NRDL. The PRDL can only be adjusted according to the respective adjustment of the NRDL, and all adjustments to the List A drugs in the NRDL are required to be made in the PRDL. The NRDL is permitted to be expanded for new drugs once every year, while provincial governments are not permitted to expand the PRDL for new drugs.

The Opinions on Promoting Drug Pricing Reform (推進藥品價格改革的意見), which was promulgated by the NDRC, the NHFPC, the NMPA, the MOFCOM and certain other departments on May 4, 2015, and came into effect on June 1, 2015, set forth that from June 1, 2015, except for narcotic drugs and Class I psychotropic drugs, the restrictions on the prices of the drugs that were subject to government pricing will be cancelled. The medical insurance regulatory authority shall, along with other competent departments, draw up provisions in relation to the standards, procedures, basis and methods of the payment of drugs paid by medical insurance funds. The prices of patent drugs and exclusively produced drugs are set through transparent and public negotiation among multiple parties. The prices for blood products not listed in the Medical Insurance Drugs List, immunity and prevention drugs that are purchased by the government in a centralised manner, and AIDS antiviral drugs and contraceptives provided by the government for free, shall be set through tendering purchase or negotiation. Except as otherwise mentioned above, the prices for other drugs may be determined by manufacturers and operators on their own on the basis of production or operation costs and market supply and demand. The Opinions on Working Effectively in Current Drug Pricing Management (關於做好當前藥品價格管理工作的意見) promulgated by National Healthcare Security Administration on November 26, 2019 emphasizes market-oriented pricing mechanisms for drugs and the guiding role of medical insurance in drug pricing and promotes drug prices to return to a reasonable level through centralized drug procurement. In addition, the 2017 NRDL proposed to explore the development of a negotiation mechanism for drugs to be listed in the NRDL. The MOHRSS will, in accordance with relevant criteria, negotiate for the drugs proposed to be negotiated as determined by experts upon review. Those eligible drugs will be included in the payment scope of the medical insurance fund.

According to the Opinions on Deepening the Reform of the Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices, to support the clinical application of new drugs, (1) the dynamic adjustment mechanism applicable to the catalogue of drugs by medical insurance will be improved, (2) the establishment of a negotiation mechanism regarding payment standards for drugs covered by medical insurance will be explored, (3) new drugs will be promptly incorporated according to applicable provisions into the payment scope covered by basic medical insurance, and (4) research and development of new drugs will be supported.

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Medical Insurance Reimbursement Standards

According to the Notice of Opinion on the Diagnosis and Treatment Management, Scope and Payment Standards of Medical Service Facilities Covered by the National Urban Employees Basic Medical Insurance Scheme (《關於印發<城鎮職工基本醫療保險診療項目管理、醫療服務設施範圍和支付標準意見>的通知》) promulgated on June 30, 1999, the basic medical insurance scheme would cover a portion of the costs of diagnostic and treatment devices, as well as diagnostic testing. The scope and rate of reimbursement are determined by provincial policies.

According to the Decision on the Establishment of the Urban Employee Basic Medical Insurance Program (《關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998, Opinions on the Establishment of the New Rural Cooperative Medical System (《關於建立新型農村合作醫療制度意見的通知》) issued by the General Office of the State Council on January 16, 2003, the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》) issued by the State Council on July 10, 2007, and the Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》) promulgated on January 3, 2016, medical insurance would be available to all employees and residents in both rural and urban areas.

The Guidance On Further Deepening the Reform of the Payment Method of Basic Medical Insurance (《關於進一步深化基本醫療保險支付方式改革的指導意見》) is further released by the General Office of the State Council in June 2017. The major aim is to develop a diverse reimbursement mechanism that includes diagnosis-related groups, per-capita caps, and per-bed-day caps. By 2020, these new reimbursement systems will be implemented across the country, replacing the current reimbursement method, which is based on service category and product price. Local healthcare security administrations will implement total budget control for their jurisdictions and determine the amount of reimbursement to public hospitals based on hospital performance and individual basic medical insurance funds' expenditure targets.

Price Controls

The PRC Drug Administration Law (2019 Revision) (中華人民共和國藥品管理法(2019修訂)), which being revised on August 26, 2019 and came into effect on December 1, 2019, regulates that for drugs with their prices determined by the market, marketing authorization holders, manufacturers and distributors of drugs, and medical institutions shall conduct pricing under the principles of fairness, rationality, good faith, and consistency between quality and prices. Marketing authorization holders, manufacturers and distributors of drugs, and medical institutions shall comply with the price management rules for drugs of the medicinal product price department of the State Council to determine the prices of drugs, and shall be prohibited from making exorbitant profits, price monopoly, and price fraud, among others.

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The Notice on Issuing the Opinion on Promoting Pharmaceutical Price Reform (關於印發推進藥品價格改革意見的通知) which was promulgated by the NDRC, the NHFPC, the NMPA, the MOFCOM and certain other departments on May 4, 2015, and came into effect on June 1, 2015, regulates that government price controls on pharmaceutical products (other than narcotic drugs and certain psychiatric drugs) were lifted on June 1, 2015. After price controls were lifted, prices of pharmaceutical products are mainly determined by market competition. Instead of direct governmental price controls, the government will regulate prices mainly by establishing a centralized procurement mechanism, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices.

The Opinions on Working Effectively in Current Drug Pricing Management (關於做好當前藥品價格管理工作的意見) promulgated by National Healthcare Security Administration on November 26, 2019 further improves the drug pricing formation mechanism and emphasizes the market-oriented drug pricing mechanism. Except that narcotic drugs and Class I psychotropic drugs are subject to government pricing, other drugs shall be reasonably priced by drug operators according to the market. Meanwhile, the national and provincial medical security departments may implement or commission price cost investigation on drug suppliers, and the results can be used as the basis for determining whether the drugs sold at unfair prices.

Drug Distribution and Two-Invoice System

According to the Implementing Opinions on Promoting the “Two-Invoice System” for Drug Procurement By Public Medical Institutions (For Trial Implementation) (“Two-Invoice System Notice”) (《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)》) which was issued on December 26, 2016, the Two-Invoice System is a system that mandates pharmaceutical manufacturers to issue one invoice to pharmaceutical distributors and pharmaceutical distributors to provide another invoice to public medical institutions. Sale of products invoiced from the manufacturer to its wholly owned or controlled distributors, or for imported drugs, to their exclusive distributor, or from a distributor to its wholly owned or controlled subsidiary is excluded.

According to the Two-Invoice System Notice and the Several Opinions of the General Office of the State Council on Further Reform and Improvement in Policies of Drug Production, Circulation and Use (《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》), which was issued on January 24, 2017, on a priority basis, the Two-Invoice System would be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) and pilot cities for public hospital reform, with the goal of having it implemented nationwide by 2018. Pharmaceutical companies must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

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Intellectual Property Rights

In terms of international conventions, China has entered into (including but not limited to) the Agreement on Trade-Related Aspects of Intellectual Property Rights (與貿易有關的知識產權協議), the Paris Convention for the Protection of Industrial Property (保護工業產權巴黎公約), the Madrid Agreement Concerning the International Registration of Marks (商標國際註冊馬德里協議) and the Patent Cooperation Treaty (專利合作條約).

Patents

According to the Patent Law of the PRC (中華人民共和國專利法) promulgated by the SCNPC on March 12, 1984, as amended on September 4, 1992, August 25, 2000, December 27, 2008 and October 17, 2020, and effective from June 1, 2021 and the Implementation Rules of the Patent Law of the PRC (中華人民共和國專利法實施細則), promulgated by the State Council on June 15, 2001 and as amended on December 28, 2002 and January 9, 2010, there are three types of patents in the PRC: invention patents, utility model patents and design patents. The protection period is 20 years for an invention patent and 10 years for a utility model patent and 15 years for a design patent, commencing from their respective application dates. Any individual or entity that utilises a patent or conducts any other activity in infringement of a patent without prior authorisation of the patent holder shall pay compensation to the patent holder and is subject to a fine imposed by relevant administrative authorities and, if constituting a crime, shall be held criminally liable in accordance with the law. According to the PRC Patent Law, for public health purposes, the State Intellectual Property Office of the PRC may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which PRC has acceded. In addition, according to the Patent Law, any organisation or individual that applies for a patent in a foreign country for an invention or utility model patent established in China is required to report to the State Intellectual Property Office for confidentiality examination.

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 SCNPC in September 1993, as amended in November 4, 2017 and April 23, 2019 respectively, the term “trade secrets” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others’ trade secrets by: (1) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; or (3) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; (4) instigate, induce or assist others to violate confidentiality obligation or to violate a rights holder’s requirements on keeping confidentiality of commercial

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secrets, so as to disclose, use or allow others to use the commercial secrets of the rights holder. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties.

Trademarks

According to the Trademark Law of the PRC (中華人民共和國商標法), promulgated by the SCNPC on August 23, 1982, amended on February 22, 1993, October 27, 2001, August 30, 2013 and April 23, 2019 and effective from 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, if intending to continue to use the trademark. Where the registrant fails to do so, a grace period of six months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be cancelled. Industrial and commercial administrative authorities have the authority to investigate any behaviour in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided according to law.

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, or the MIIT, on August 24, 2017 and effective from 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 China Internet Network Information Center on June 18, 2019, which became effective on the same day. The MIIT is the main regulatory body 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.

Product Liability

The Product Quality Law of the PRC (中華人民共和國產品質量法) promulgated by the SCNPC on February 22, 1993 and amended on July 8, 2000, August 27, 2009 and 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

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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 Civil Code of the PRC (中華人民共和國民法典), promulgated by the NPC on May 28, 2020 and effective from January 1, 2021 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.

Environmental Protection

Construction Project Environment Protection

According to the Environmental Protection Law of the PRC (中華人民共和國環境保護法), promulgated by the SCNPC on December 26, 1989 and amended on April 24, 2014, the Environmental Impact Assessment Law of the PRC (中華人民共和國環境影響評價法), promulgated by the SCNPC on October 28, 2002 and amended on July 2, 2016 and December 29, 2018 respectively, the Administrative Regulations on the Environmental Protection of Construction Project (建設項目環境保護管理條例), promulgated by the State Council on November 29, 1998 and amended on July 16, 2017, and other relevant environmental laws and regulations, enterprises which plan to construct projects shall provide the assessment reports, assessment form, or registration form on the environmental impact of such projects with relevant environmental protection administrative authority for approval or filing. Enterprises may entrust a technical entity to conduct an environment impact assessment of its construction projects, and prepare environment impact reports and environment impact statements on construction projects; if a construction entity has the technical capability of environment impact assessment, it may carry out the above activities itself.

Water Pollution and Pollutant Discharge

According to the Law of the PRC on the Prevention and Control of Water Pollution (中華人民共和國水污染防治法) promulgated by the SCNPC on May 11, 1984 and amended on May 15, 1996, February 28, 2008 and June 27, 2017, and effective from January 1, 2018, the Law of the PRC on the Prevention and Control of Atmospheric Pollution (中華人民共和國大氣污染防治法) promulgated by the SCNPC on September 5, 1987 and amended on August 29, 1995, April 29, 2000, August 29, 2015 and October 26, 2018 respectively, the Law of the PRC on the Prevention and Control of Pollution from Environmental Noise (中華人民共和國環境噪聲污染防治法) promulgated by the SCNPC on October 29, 1996 and amended on December 29, 2018, and the Law of the PRC on the Prevention and Control of Environmental Pollution of Solid Waste (中華人民共和國固體廢物污染環境防治法), promulgated by the SCNPC on October 30, 1995 and amended on December 29, 2004, June 29, 2013, April 24, 2015,

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November 7, 2016 and April 29, 2020, all the enterprises that may cause environmental pollution in the course of their production and business operation shall introduce environmental protection measures in their plants and establish a reliable system for environmental protection.

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 under relevant laws and regulations, including the Regulations on Urban Drainage and Sewage Disposal (城鎮排水與污水處理條例), which was promulgated on October 2, 2013 and came into force on January 1, 2014, and the Measures for the Administration of Permits for the Discharge of Urban Sewage into the Drainage Network (城鎮污水排入排水管網許可管理辦法), which was promulgated on January 22, 2015 and came into force on March 1, 2015. 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.

Hazardous Chemicals

Regulation on Safety Administration of Hazardous Chemicals (危險化學品安全管理條例) (the "Hazardous Chemicals Regulation") was promulgated by the State Council on January 26, 2002 and amended on March 2, 2011 and December 7, 2013. The Hazardous Chemicals Regulation provides regulatory requirements on the safe production, storage, use, operation and transportation of hazardous chemicals. The PRC government exerts strict control over, and adopts an examination and approval system of, the manufacture and storage of hazardous chemicals.

An enterprise that stores and uses hazardous chemicals is required to appoint a qualified institution to conduct safety evaluation of its safety production conditions once every three years and to prepare the safety evaluation report accordingly. Such report shall set out the rectification measures and plans for problem solution as to the safety production. The safety evaluation report and the implementation of the rectification measure shall be filed with the safety supervision regulatory authority.

According to the Administrative Regulations on Precursor Chemicals (易制毒化學品管理條例), effected on November 1, 2005 and amended on July 29, 2014 and February 6, 2016 and September 18, 2018, the state applies the classified administration and licensing system to the production, distribution, purchase, transportation and import and export of precursor chemicals. An entity that is to purchase any precursor chemical in Category II or III shall, prior to the purchase, report the type and quantity in demand for record, with the public security authority of the local people's government at the county level.

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Fire Prevention

The Fire Prevention Law of the PRC (中華人民共和國消防法) (the “Fire Prevention Law”) was adopted on April 29, 1998, amended on October 28, 2008, April 23, 2019 and April 29, 2021. According to the Fire Prevention Law and other relevant laws and regulations of the PRC, the emergency management authority of the State Council and its local counterparts at or above county level shall monitor and administer the fire prevention affairs. The fire and rescue department of such a people’s government is responsible for implementation. The Fire Prevention Law provides that the fire prevention design or construction of a construction project must conform to the national fire prevention technical standards.

Foreign Exchange Control

According to the PRC Regulation for the Foreign Exchange (中華人民共和國外匯管理條例), or the Foreign Exchange Regulations promulgated by the PRC State Council on January 29, 1996, which was amended on January 14, 1997 and August 5, 2008, and the Regulation on the Administration of the Foreign Exchange Settlement, Sales and Payment (結匯、售匯及付匯管理規定), or the Settlement Regulations promulgated by the People’s Bank of China on June 20, 1996 and effective from July 1, 1996, foreign exchanges required for distribution of profits and payment of dividends may be purchased from designated foreign exchange banks in the PRC upon presentation of a board resolution authorizing distribution of profits or payment of dividends.

According to the Circular of SAFE on Further Improving and Adjusting the Foreign Exchange Policies on Direct Investment (國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知) and its appendix, the Operating Rules for Foreign Exchange Issues with Regard to Direct Investment under Capital Account (資本項目直接投資外匯業務操作規程), promulgated on November 19, 2012 and amended on May 4, 2015 by the State Administration of Exchange Control, or the SAFE, (1) the opening of and payment into foreign exchange accounts under direct investment accounts are no longer subject to approval by the SAFE; (2) reinvestment with legal income of foreign investors in China is no longer subject to approval by SAFE; (3) the procedures for capital verification and confirmation that foreign-funded enterprises need to go through are simplified; (4) purchase and external payment of foreign exchange under direct investment accounts are no longer subject to approval by SAFE; (5) domestic transfer of foreign exchange under direct investment account is no longer subject to approval by SAFE; and (6) the administration over the conversion of foreign exchange capital of foreign-invested enterprises is improved. Later, on February 13, 2015, the SAFE issued the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (關於進一步簡化和改進直接投資外匯管理政策的通知), effective from June 1, 2015, which prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

REGULATORY ENVIRONMENT

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), or the FDI Provisions, which were promulgated by the SAFE on May 11, 2013 and became effective on May 13, 2013, and as amended on October 10, 2018 and December 30, 2019, regulate and clarify the administration over foreign exchange administration in foreign direct investments.

According to the Circular on the Reform of the Management Method for 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金結匯管理方式的通知) promulgated by the SAFE on March 30, 2015 and effective from June 1, 2015, and the Circular on the Reform and Standardisation of the Management Policy of the Settlement of Capital Projects (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) promulgated by the SAFE on June 9, 2016, the settlement of foreign exchange by foreign invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, the settlement of foreign exchange shall only be used for its own operation purposes within the business scope of the foreign invested enterprises and following the principles of authenticity.

The SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles (國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知), or the SAFE Circular 37, on July 4, 2014. The SAFE Circular 37 requires PRC residents to register with the local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such PRC residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests. Failure to comply with the SAFE registration requirements could result in liability under PRC law for evasion of foreign exchange controls. The Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment provides that the bank instead of SAFE can directly handle the initial foreign exchange registration and amendment registration under SAFE Circular 37.

According to the Measures for the Administration of Overseas Investment (境外投資管理辦法) promulgated by the MOFCOM on September 6, 2014 which became effective on October 6, 2014, overseas investment means the enterprises legally incorporated in the PRC which own the non-financial enterprises or obtain the ownership, control, operation management rights and other interests of the existing non-financial enterprises in foreign countries through incorporation, merger and acquisition and other means. MOFCOM and the provincial commercial administration authorities are responsible for the management and supervision of the overseas investments. MOFCOM and the provincial commercial administration authorities will implement filing administration and approval respectively according to the different types of overseas investments.

REGULATORY ENVIRONMENT

According to the Administrative Measures for Overseas Investment by Enterprises (企業境外投資管理辦法) promulgated by the National Development and Reform Commission on December 26, 2017, which became effective on March 1, 2018, overseas investment means any investment activity in which a domestic enterprise of the PRC obtains overseas ownership, control, operation and management rights and other relevant interests directly or through its controlled overseas enterprise by way of contributing asset, interest or providing financing and guarantee. To conduct overseas investment, certain procedures (such as approval and record-filing of overseas investment project) shall be complied with according to the relevant circumstances of the overseas investment project.

Labour and Social Insurance

According to the PRC Labour Law (中華人民共和國勞動法), which was promulgated by the SCNPC on July 5, 1994 and effective from January 1, 1995, and amended on August 27, 2009 and December 29, 2018 respectively, the PRC Labour Contract Law (中華人民共和國勞動合同法), which was promulgated by the SCNPC on June 29, 2007 and effective from January 1, 2008, and amended on December 28, 2012 and effective from July 1, 2013, and the Implementing Regulations of the Employment Contracts Law of the PRC (中華人民共和國勞動合同法實施條例), which was promulgated by the State Council on September 18, 2008, labour contracts in written form shall be executed to establish labour relationships between employers and employees. In addition, wages cannot be lower than local minimum wage. The employers must establish a system for labour safety and sanitation, strictly abide by State rules and standards, provide education regarding labour safety and sanitation to its employees, provide employees with labour safety and sanitation conditions and necessary protection materials in compliance with State rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

According to the Social Insurance Law of PRC (中華人民共和國社會保險法), which was promulgated by the SCNPC on October 28, 2010 and effective from July 1, 2011, and amended on December 29, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds (社會保險費徵繳暫行條例), which was promulgated by the State Council on January 22, 1999 and amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Funds (住房公積金管理條例), which was promulgated by the State Council on April 3, 1999 and amended on March 24, 2002 and March 24, 2019, employers are required to open social insurance account and housing provident fund account within 30 days from the date of establishment, and employers are also required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance, maternity insurance and to housing provident funds. Any employer who fails to contribute may be fined and ordered to make good the deficit within a stipulated time limit.

REGULATORY ENVIRONMENT

Dividend Distribution

According to the FIL and its Implementation Rules (中華人民共和國外商投資法實施條例), which issued on December 26, 2019 and effective on January 1, 2020, foreign-invested enterprises in the PRC may pay dividends only out of their accumulated profits as determined in accordance with PRC accounting standards and regulations. Under the current regulatory regime in China, a foreign-invested enterprise is required to set aside at least 10% of its respective accumulated profits each year to fund certain reserve funds, until the accumulative amount of such fund reaches 50% of its registered capital. These wholly foreign-owned companies may also allocate a portion of their after-tax profits based on PRC accounting standards to staff welfare and bonus funds. Amounts allocated to these reserve funds and staff welfare and bonus funds reduce the amount distributable as cash dividends. Upon approval of the competent governmental authorities, foreign investors may utilise RMB dividends to invest or re-invest in enterprises established in China.

According to the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Control (國家外匯管理局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) promulgated by the SAFE on January 18, 2017, (1) 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 (2) 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 utilisation arrangements, and provide board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

Employee Stock Incentive Plan

On February 15, 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知), or the Stock Option Rules, which prescribed that PRC citizens or non-PRC citizens residing in China for a continuous period of no less than one year (except for foreign diplomatic personnel in China and representatives of international organisations in China) who participate in any stock incentive plan of an overseas publicly listed company shall, through the domestic company to which the said company is affiliated, collectively entrust a domestic agency (may be the Chinese affiliate of the overseas publicly listed company which participates in stock incentive plan, or other domestic institutions qualified for asset trust business lawfully designated by such company) to handle foreign exchange registration, and entrust an overseas institution to handle issues like exercise of options, purchase and sale of corresponding stocks or equity, and transfer of corresponding funds. In addition, the domestic agency is required to amend the SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan. Moreover, the SAFE Circular 37 provides that PRC residents who participate in a share incentive plan of an overseas unlisted special purpose company may register with local branches of SAFE before exercising rights.

REGULATORY ENVIRONMENT

Enterprise Income Tax

According to the EIT Law promulgated by the National People’s Congress on March 16, 2007, which became effective on January 1, 2008 and was amended on February 24, 2017 and December 29, 2018, and the Implementation Rules of the Enterprise Income Tax Law of the PRC (中華人民共和國企業所得稅法實施條例) promulgated by the State Council on December 6, 2007, which became effective on January 1, 2008, and amended on April 23, 2019, other than a few exceptions, the income tax rate for both domestic enterprises and foreign-invested enterprises is 25%. Enterprises are classified as either “resident enterprises” or “non-resident enterprises”. Besides enterprises established within the PRC, enterprises established outside China whose “de facto management bodies” are located in China are considered “resident enterprises” and subject to the uniform 25% enterprise income tax rate for their global income. A non-resident enterprise refers to an entity established under foreign law whose “de facto management bodies” are not within the PRC but which have an establishment or place of business in the PRC, or which do not have an establishment or place of business in the PRC but have income sourced within the PRC. An income tax rate of 10% will normally be applicable to dividends declared to non-PRC resident enterprise investors that do not have an establishment or place of business in the PRC, or that have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC.

According to an Arrangement Between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income (內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排), or the Double Tax Avoidance Arrangement, and other applicable PRC laws, if a Hong Kong resident enterprise is determined by the competent PRC tax authority to have satisfied the relevant conditions and requirements under such Double Tax Avoidance Arrangement and other applicable laws, the 10% withholding tax on the dividends the Hong Kong resident enterprise receives from a PRC resident enterprise may be reduced to 5%. However, based on the Circular on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties (關於執行稅收協定股息條款有關問題的通知) issued on February 20, 2009 by the SAT, if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment; and based on the Announcement on Certain Issues with Respect to the “Beneficial Owner” in Tax Treaties (國家稅務總局關於稅收協議中“受益所有人”有關問題的公告) issued by the SAT on February 3, 2018 and effective from April 1, 2018, if an applicant’s business activities do not constitute substantive business activities, it could result in the negative determination of the applicant’s status as a “beneficial owner”, and consequently, the applicant could be precluded from enjoying the above-mentioned reduced income tax rate of 5% under the Double Tax Avoidance Arrangement.

REGULATORY ENVIRONMENT

TAIWAN LAWS AND REGULATIONS

Regulatory Authorities of Pharmaceutical Products

In Taiwan, the Taiwan Food and Drug Administration (the “TFDA”; 食品藥物管理署) of the Ministry of Health and Welfare (衛生福利部) is the regulatory authority of pharmaceutical products, medical devices, cosmetics, and food-related matters. The TFDA governs the main regulations of pharmaceutical products under the Pharmaceutical Affairs Act (the “PAA”; 藥事法) and its sub-laws or implementation regulations, such as the Regulations for Registration of Medicinal Products (the “RRMP”; 藥品查驗登記審查準則) and the Regulations for Good Clinical Practice (the “RGCP”; 藥品優良臨床試驗作業準則).

According to the PAA and its enforcement rules, new drugs refer to drugs of new compositions, new therapeutic compounds or new methods of administration. Before a new drug is lawfully distributed in Taiwan, a market approval/marketing authorization (the “MA”) must be obtained from the TFDA.

The procedure of initiating a clinical trial and obtaining an MA for a new drug generally proceeds as follows:

- Pre-investigational new drug (the “IND”) activities;
- Application for IND;
- Clinical trial;
- the NDA;
- Market approval; and
- Post-marketing surveillance.

Clinical Trials

A human clinical trial is required for an NDA under the RRMP. The RGCP further states that a human clinical trial must be conducted in a medical institution (“Site”). According to the Medical Care Act (the “MCA”; 醫療法), only teaching hospitals and non-teaching hospitals with specific expertise and having TFDA approval can conduct human clinical trials. Without approvals from both of the TFDA and the Institutional Review Board (the “IRB”; 人體試驗委員會) of the Site, no clinical trial can be conducted. All clinical trials must comply with the following regulations: the RGCP, the Good Clinical Practices (藥品優良臨床試驗規範), the MCA, the Human Subjects Research Act (人體研究法), the Regulations on Human Trials (the “RHT”; 人體試驗管理辦法), the Human Biobank Management Act (人體生物資料庫管理條例), the Principles of Recruiting Subjects for Clinical Trial (臨床試驗受試者招募原則), various criteria for conducting clinical trials (including General Criteria for Drug Clinical Trial (藥品臨床試驗一般基準) and Criteria for Drug Clinical Trial for Cancer Treatment Medicines (癌症治療藥品臨床試驗基準), the Personal Data Protection Act (個人資料保護法) and other related regulations issued by the TFDA.

REGULATORY ENVIRONMENT

TFDA Review Process for NDA

All NDAs are subject to TFDA’s dossier assessment. An applicant should follow the notice issued by the TFDA and collect the drug permit if the dossiers pass the TFDA assessment. According to the RRMP, a drug permit should be obtained within three (3) months of the notice date. In addition to the general review process, the TFDA also announced three expedited review and approval systems for the NDAs, as summarized below: (1) fast track (精簡審查) for an NCE drug that has been approved by the US, Japan, and/or the EU; (2) priority review (優先審查) for a new drug intended for the treatment of severe disease in Taiwan, and has major advantages in terms of medical care; and (3) accelerated approval (加速核准機制) for a new drug (i) that can fulfill Taiwan’s unmet medical need, (ii) that has received the orphan drug designation from one of the A-10 countries, or (iii) that is not for a rare disease and the manufacturing or importation thereof would be difficult.

Pharmaceutical Manufacturing and Distribution

The TFDA promulgated to implement the international GMP standards (PIC/S:Guide to Good Manufacturing Practice for Medicinal Products; “PIC/S GMP”; 西藥藥品優良製造規範) in 2007 to ensure that the standard of pharmaceutical manufacturing in Taiwan is in line with international standard. All drug manufacturing factories must comply with the PIC/S GMP, which includes the Good Distribution Practice (the “GDP”; 西藥優良運銷準則). According to the Regulations for the Issuance of Medicinal Products and Medical Devices Manufacturing Licenses and Evidentiary Documents for Good Manufacturing Practices (藥物製造許可及優良製造證明文件核發辦法), the license validation period of local drug manufacturing or foreign manufacturing of imported drug is two (2) years and needs to be extended six (6) months before the expiration date. In accordance to the Regulation for the Issuance and Management of Drug Distribution Licenses and Certificates (西藥運銷許可及證明文件核發管理辦法), the validation period of drug distribution license maybe three (3) to five (5) years. Before said license is expiring, an extension of the expiration date needs to be made six (6) months before the expiration date.

HONG KONG LAWS AND REGULATIONS

Pharmaceutical Products and Medicines

The Pharmacy and Poisons Ordinance (Chapter 138 of the Laws of Hong Kong) (the “**Pharmacy and Poisons Ordinance**”) governs the manufacture, labeling, distribution, dispensing, supply, wholesale and retail sale, possession registration and the import and export of pharmaceutical products or medicines in Hong Kong. Pharmaceutical products or medicines are required to conform to the standards on safety, efficacy and quality before they can obtain registration. Further, pharmaceutical products or medicines have to be registered with the Pharmacy and Poisons Board of Hong Kong (the “**Pharmacy and Poisons Board**”) before they can be offered for sale in Hong Kong.

REGULATORY ENVIRONMENT

Registration of Pharmaceutical Product

Under the Pharmacy and Poisons Regulations (Chapter 138A of the Laws of Hong Kong) (the “**Pharmacy and Poisons Regulations**”), pharmaceutical products must be registered with the Pharmacy and Poisons Board before they can be sold, offered for sale, distributed or possessed for the purposes of sale, distribution or other use in Hong Kong. Any person who engages in the sale of unregistered pharmaceutical products commits an offense and is liable to a maximum fine of HK\$100,000 and imprisonment for 2 years.

Licensing of Pharmaceutical Products Wholesaler

The Pharmacy and Poisons Regulations provides that no person other than an authorized seller of poisons or a licensed manufacturer selling pharmaceutical products of his own manufacture only shall, by way of wholesale dealing, sell or supply at or from any premises any substance or article consisting of or containing any poison unless he is holder of a wholesale poisons license issued in respect of those premises.

SINGAPORE LAWS AND REGULATIONS

In Singapore, the Health Sciences Authority regulates the conduct of clinical trials of therapeutic products and medicinal products under the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations, respectively.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

OVERVIEW

We are a China-based, rare disease-focused biopharmaceutical company committed to the research, development and commercialization of biotech therapies. Our Group was founded by Dr. Xue, our founder, Chairman of the Board, executive Director and Chief Executive Officer, who has extensive entrepreneurial and managerial experience in the biotech industry across the PRC and the United States with funds accumulated from prior engagements. For details of Dr. Xue’s biography, please refer to the section headed “Directors and Senior Management” in this document.

Our Group started our business operations in the PRC in 2012. Our Company was incorporated as an exempted company with limited liability in the Cayman Islands on January 30, 2018 and became the holding company of our Group after the reorganization, details of which are set out in the sub-section headed “Reorganization” in this section.

BUSINESS DEVELOPMENT MILESTONES

The following sets forth key business development milestones of our Group:

Year	Milestone
2012	CANbridge Life Sciences was established in the PRC, which has been primarily engaged in the research and development of bio-pharmaceutical products in the PRC including among others, the identification of drug candidates
2013	CANbridge Life Sciences completed its angel round financing in an aggregate amount of approximately RMB7 million
2015	We obtained an exclusive license to develop, manufacture and commercialize CAN008 from Apogenix for the treatment of GBM in Greater China We completed the onshore series A financing in an aggregate amount of approximately US\$13 million We received IND approval from the Taiwan Food and Drug Administration to initiate phase I/II trials for CAN008 on patients with GBM, and subsequently completed phase I first patient dosing in Taiwan for CAN008
2017	We completed the onshore series B-1 financing in an aggregate amount of approximately US\$24 million

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Year	Milestone
	<p>We submitted the IND application for CAN008 Phase II/III trial in GBM in China</p> <p>We completed patient enrollment for Phase I clinical trial of CAN008 in GBM in Taiwan</p>
2018	<p>We completed the series B-2 financing in the form of convertible loan in an aggregate amount of approximately US\$30 million</p> <p>Our Company was incorporated in the Cayman Islands</p> <p>We received IND approval from the NMPA to commence second-line phase II/III trials for CAN008 in China on patients with GBM</p> <p>We entered into strategic partnership with WuXi Biologics for rare disease therapeutics to develop a range of products including CAN103, through which we were granted license for additional products including CAN106</p> <p>We strategically shifted our business focus to rare disease and rare oncology with growing focus of rare disease therapy on the Chinese sociopolitical agenda including the implementation of various measures to encourage the development of rare disease therapy by the PRC state authorities and in view of the promising market opportunities</p>
2019	<p>We obtained exclusive license rights in Hunterase[®] (CAN101) from GC Pharma to commercialize Hunterase[®] (CAN101) in Greater China</p> <p>We submitted NDA for Hunterase[®] (CAN101) for Hunter Syndrome in China and Hunterase[®] (CAN101) was granted priority review by NMPA</p> <p>Our Group completed the offshore series C financing in an aggregate amount of approximately US\$46 million</p>
2020	<p>We received IND approval for CAN106 from the Health Sciences Authority of Singapore</p> <p>We received approval in the PRC for Hunterase[®] (CAN101) as the first mucopolysaccharidosis type II (MPS II) ERT in the PRC</p> <p>We entered into strategic collaboration with the Horae Gene Therapy Center at the UMass Medical School and initiated gene therapy research programs for rare genetic diseases</p>

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Year	Milestone
2021	<p>We entered into a strategic collaboration and licensing agreement with LogicBio and obtained (i) exclusive license to develop, manufacture and commercialize gene therapy candidates for two targets including for the treatment of Fabry and Pompe diseases, (ii) options for the development of AAV sL65-based treatments for two additional targets; and (iii) an option to obtain an exclusive license for LB-001 an investigational in-vivo gene editing technology based on GeneRide™ platform for the potential treatment of methylmalonic acidemia (MMA) in designated areas pursuant to the license agreement</p> <p>We entered into a strategic collaboration and licensing agreement with Mirum for the exclusive right to develop and commercialize maralixibat in Greater China</p> <p>We completed the offshore series D and series E financing in an aggregate amount of approximately US\$98 million and US\$58 million, respectively</p> <p>We obtained CDE clearance from NMPA for an updated Phase 2 clinical first-line trial application for CAN008 in China</p> <p>We began commercialization of Hunterase® (CAN101) in the PRC</p>

OUR MAJOR SUBSIDIARIES AND OPERATING ENTITIES

The principal business activities and the dates of incorporation of our subsidiaries most relevant to the core operations of our Group during the Track Record Period are shown below. In addition, we established CANbridge (Suzhou) Bio-pharma Co., Ltd. (北海康成(蘇州)生物製藥有限公司) on April 15, 2021.

Name of major subsidiary	Place of incorporation/ establishment	Date of incorporation/ establishment	Principal business activities
CANbridge Care Pharma Hongkong Limited	Hong Kong	June 19, 2018	Research and development and commercialization of medical products

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of major subsidiary	Place of incorporation/ establishment	Date of incorporation/ establishment	Principal business activities
CANbridge Life Sciences Ltd. (北海康成(北京)醫藥科技有限公司)	PRC	June 12, 2012	Research and development and commercialization of medical products
CANbridge (Shanghai) Life Sciences Ltd. (北海康成(上海)生物科技有限公司)	PRC	June 22, 2016	Research and development and commercialization of medical products
CARE Pharma Shanghai Ltd. (諾愛藥業(上海)有限公司)	PRC	January 17, 2018	Research and development
CANbridge Pharma Co., Ltd. (北海康成股份有限公司)	Taiwan	October 5, 2019	Research and development and commercialization of medical products

MAJOR ACQUISITIONS, DISPOSALS AND MERGERS

During the Track Record Period and up to the Latest Practicable Date, we had not conducted any acquisitions, disposals or mergers that we consider to be material to us.

ESTABLISHMENT, MAJOR SHAREHOLDING CHANGES AND DEVELOPMENT OF OUR GROUP

1. Establishment of CANbridge Life Sciences

On June 12, 2012, CANbridge Life Sciences, our principal operating entity in the PRC, was established as a limited liability company with an initial registered capital of RMB1,000,000 contributed by Dr. Xue, by himself and through CANbridge Consulting, LLC (康成諮詢有限責任公司) (“CANbridge Consulting”).

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

The shareholding structure of CANbridge Life Sciences upon its establishment was as follows:

Name of Shareholder	Subscribed Registered Capital (RMB)	Percentage Ownership
Dr. Xue	510,000	51.00%
CANbridge Consulting ⁽¹⁾	490,000	49.00%
Total	1,000,000	100.00%

Note:

- (1) CANbridge Consulting is a limited liability company incorporated in the state of Massachusetts, United States and is wholly-owned by Dr. Xue.

2. Angel Financing Capital Injection in 2013

Pursuant to a joint venture agreement entered into among Dr. Xue, CANbridge Consulting, Xu Ying (許瑩) (“**Xu Ying**”), Cao Wei (曹威) (“**Cao Wei**”), Liu Bing (劉兵) (“**Liu Bing**”), Chen Song (陳松) (“**Chen Song**”), Li Mei (李玫) (“**Li Mei**”) and Xu Ping (徐萍) (“**Xu Ping**”), save for CANbridge Consulting, each of the parties to the agreement agreed to subscribe for registered capital of CANbridge Life Sciences in an aggregate amount of RMB7 million. Such subscription was approved by the Bureau of Commerce of Chaoyang District of Beijing Municipality (北京市朝陽區商務委員會) in December 2012. Upon the completion of such capital injection on March 13, 2013, CANbridge Life Sciences was held by Dr. Xue, CANbridge Consulting, Xu Ying, Cao Wei, Liu Bing, Chen Song, Li Mei and Xu Ping as to 44.88%, 6.12%, 3.00%, 11.50%, 11.50%, 11.50%, 6.30% and 5.20%, respectively.

3. Shareholding Transfer in 2013 and Capital Injection in 2014

On October 5, 2013, the then shareholders of CANbridge Life Sciences entered into an equity transfer agreement, pursuant to which Cao Wei, Liu Bing, Chen Song, Li Mei and Xu Ping wholly or partially transferred their equity interests in CANbridge Life Sciences to Dr. Xue for an aggregate consideration of RMB1,608,000, corresponding to a registered capital of RMB1,608,000 on arm’s-length basis. Upon completion of such share transfer, Li Mei, who is an Angel Investor and a friend of Dr. Xue, ceased to be a shareholder of CANbridge Life Sciences.

Pursuant to a joint venture agreement dated March 24, 2014 entered into among Dr. Xue, CANbridge Consulting, Xu Ying, Cao Wei, Liu Bing, Chen Song, Xu Ping, Caroline Ann Merrifield (“**Ms. Merrifield**”) and David Daniel Fleming (“**Mr. Fleming**”), Ms. Merrifield and Mr. Fleming agreed to subscribe for registered capital of CANbridge Life Sciences in an

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

aggregate amount of RMB101,266, for an aggregate subscription price of US\$250,000 based on arm’s length negotiations, taking into account its prospects in the identification and research and development of drug candidates. Upon completion of such capital injection on September 4, 2014, the equity interest in CANbridge Life Sciences was held as follows:

Name of Shareholder	Subscribed Registered Capital (RMB)	Percentage Ownership
Dr. Xue	5,198,000	64.16%
CANbridge Consulting, LLC	490,000	6.05%
Xu Ying	240,000	2.96%
Cao Wei ⁽¹⁾	592,000	7.31%
Liu Bing ⁽²⁾	592,000	7.31%
Chen Song	592,000	7.31%
Xu Ping	296,000	3.65%
Ms. Merrifield	81,013	1.00%
Mr. Fleming	20,253	0.25%
Total:	8,101,266	100.00%

Note:

1. Cao Wei served as a Director of the Company from July 18, 2018 to April 21, 2020.
2. Liu Bing served as Director of the Company from July 18, 2018 to June 11, 2021.

4. Series A-1 Financing in 2014 and Series A-2 Financing in 2015

Pursuant to a capital increase agreement dated September 30, 2014 entered into among (i) CANbridge Life Sciences, (ii) the then existing shareholders of CANbridge Life Sciences and (iii) the new subscribers consisting of QM16 Limited (“**QM16**”), Maxtec Group Limited (“**Maxtec**”), Lu Ning (盧寧) (“**Lu Ning**”) and Lai Chunbao (賴春寶) (“**Lai Chunbao**”), QM16, Maxtec and Lu Ning and Lai Chunbao agreed to subscribe for registered capital of CANbridge Life Sciences in an aggregate amount of RMB1,761,145, for an aggregate subscription consideration of US\$5,000,000, which was determined based on arm’s length negotiations taking into account prospects in the research and development of drug candidates including among others, Caphosol™ (CAN002). For details, see the sub-section headed “[REDACTED] Investments – 7. Principal Terms of the [REDACTED] Investments” in this section. The capital injection was completed on December 16, 2014.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Pursuant to a capital increase and equity transfer agreement dated October 8, 2015 entered into among (i) CANbridge Life Sciences, (ii) the then existing shareholders of CANbridge Life Sciences, (iii) the new subscribers consisting of Xinjiang Taitong Share Investment Partnership L.P. (新疆泰同股權投資合夥企業(有限合夥)) (“**Xinjiang Taitong**”), Hangzhou Tigermed Consulting Co., Ltd. (杭州泰格醫藥科技股份有限公司) (“**Hangzhou Tigermed**”), Qian Hui (錢輝) (“**Qian Hui**”) and Xue Yintong (薛殷彤) (“**Xue Yintong**”) and (iv) the new transferees consisting of Beijing Haicheng Qiyuan Pharmaceutical Technology Centre L.P. (北京海成祁源醫藥科技中心(有限合夥)) (“**Beijing Haicheng**”) and Song Chunsheng (宋春勝) (“**Song Chunsheng**”), QM16, Xinjiang Taitong, Hangzhou Tigermed, Qian Hui, Xue Yintong and Chen Song agreed to subscribe for registered capital of CANbridge Life Sciences in an aggregate amount of RMB2,748,067, for a subscription consideration of US\$8,222,223 (or equivalent in RMB), which was determined based on arm’s length negotiations taking into account prospects in the research and development of drug candidates, including the grant of exclusive right to develop, manufacture and commercialize CAN008 (APG101) in Greater China. For details, see the sub-section headed “– [REDACTED] Investments – 7. Principal Terms of the [REDACTED] Investments” in this section. Such capital injection was completed on December 29, 2015. Under the agreement, Dr. Xue also agreed to transfer registered capital in the amount of RMB1,250,000 to Beijing Haicheng for a transfer price of RMB1,250,000 and to transfer registered capital in the amount of RMB164,500 to an Angel Investor for a transfer price of RMB164,500.

Upon completion of the equity transfer and capital subscriptions described above, the equity interest in CANbridge Life Sciences was held as follows:

Name of Shareholder	Subscribed Registered Capital (RMB)	Percentage Ownership
Dr. Xue	3,783,500	30.00%
CANbridge Consulting	490,000	3.89%
Xu Ying	240,000	1.90%
Cao Wei	592,000	4.69%
Liu Bing ⁽¹⁾	592,000	4.69%
Chen Song	660,064	5.23%
Xu Ping	296,000	2.35%
Ms. Merrifield	81,013	0.64%
Mr. Fleming	20,253	0.16%
QM16	2,113,452	16.76%
Maxtec ⁽²⁾	587,166	4.66%
Lu Ning	97,744	0.78%
Lai Chunbao	254,289	2.02%
Xinjiang Taitong	469,639	3.72%
Hangzhou Tigermed ⁽²⁾	306,286	2.43%
Qian Hui	306,286	2.43%

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of Shareholder	Subscribed Registered Capital (RMB)	Percentage Ownership
Xue Yintong	306,286	2.43%
Beijing Haicheng ⁽³⁾	1,250,000	9.91%
Song Chunsheng	164,500	1.30%
Total	12,610,478	100.00%

Notes:

1. Liu Bing, one of the Angel Investors, served as Director of the Company from July 18, 2018 to June 11, 2021.
2. For further background information about Maxtec and Hangzhou Tigermed, please refer to the sub-section headed “[REDACTED] Investments – 8. Information about the [REDACTED] Investors” in this section.
3. Beijing Haicheng is a limited liability partnership established in the PRC whose general partner is an Angel Investor. Beijing Haicheng was an entity set up to hold shares as part of an employee share option plan of CANbridge Life Sciences Ltd..

5. Series B-1 Financing in 2017

Pursuant to a capital increase agreement dated February 4, 2017 entered into among (i) CANbridge Life Sciences, (ii) the then existing shareholders of CANbridge Life Sciences and (iii) the new subscribers consisting of Beijing Longpan Health Medical Investment Centre L.P. (北京龍磐健康醫療投資中心(有限合夥)) (“**Lapam Fund III**”), Beijing Longpan Life Pharmaceutical Startup Investment Centre L.P. (北京龍磐生物醫藥創業投資中心(有限合夥)) (“**Lapam Fund II**”), Beijing Chongde Yingsheng Startup Investment Co., Limited (北京崇德英盛創業投資有限公司) (“**Chongde Yingsheng**”), Beijing Zhongling Yanyuan Startup Investment Centre L.P. (北京中嶺燕園創業投資中心(有限合夥)) (“**Zhongling Yanyuan**”), WuXi AppTec (Wuhan) Co., Ltd. (武漢藥明康德新藥開發有限公司) (“**WuXi Wuhan**”), Huang Wei (黃衛) (“**Huang Wei**”) and Ma Jikai (馬繼凱) (“**Ma Jikai**”), Lapam Fund III, Lapam Fund II, Chongde Yingsheng, Zhongling Yanyuan, QM16, WuXi Wuhan, Huang Wei and Ma Jikai agreed to subscribe for registered capital of CANbridge Life Sciences in an aggregate amount of RMB3,783,144, for an aggregate subscription price of US\$21,000,000. Such subscription price was determined based on arm’s length negotiations taking into account prospects in the research and development of drug candidates including having received IND approval from the Taiwan Food and Drug Administration to initiate phase I/II trials for CAN008 on patient with GBM and the subsequent completion of phase I first patient dosing for CAN008. For details, see the sub-section headed “– [REDACTED] Investments – 7. Principal Terms of the [REDACTED] Investments” in this section. The capital injection was completed on March 21, 2017.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Pursuant to a capital increase agreement dated May 8, 2017 entered into among (i) CANbridge Life Sciences, (ii) the then existing shareholders of CANbridge Life Sciences and (iii) Shenzhen Qianhai Yuanming Medical Industry Investment Fund L.P. (深圳前海元明醫療產業投資基金(有限合夥)) (“**Shenzhen Yuanming**”), Shenzhen Yuanming agreed to subscribe for registered capital of CANbridge Life Sciences in an amount of RMB522,703, for a consideration of RMB20,000,000, which was determined based on arm’s length negotiations taking into account prospects in the research and development of drug candidates including having received IND approval from the Taiwan Food and Drug Administration to initiate phase I/II trials for CAN008 on patient with GBM and subsequent completion of phase I first patient dosing for CAN008. For details, see the sub-section headed “– [REDACTED] Investments – 7. Principal Terms of the [REDACTED] Investments” in this section. Such capital injection was completed on June 6, 2017.

Upon completion of the capital subscriptions described above, the equity interest in CANbridge Life Sciences was held as follows:

Name of Shareholder	Subscribed Registered Capital (RMB)	Percentage Ownership
Dr. Xue	3,783,500	22.37%
CANbridge Consulting	490,000	2.90%
Xu Ying	240,000	1.42%
Cao Wei	592,000	3.50%
Liu Bing ⁽¹⁾	592,000	3.50%
Chen Song	660,064	3.90%
Xu Ping	296,000	1.75%
Ms. Merrifield	81,013	0.48%
Mr. Fleming	20,253	0.12%
QM16	2,653,901	15.69%
Maxtec	587,166	3.47%
Lu Ning	97,744	0.58%
Lai Chunbao	254,289	1.50%
Beijing Haicheng	1,250,000	7.39%
Hangzhou Tigermed	306,286	1.81%
Song Chunsheng	164,500	0.97%
Xue Yintong	306,286	1.81%
Xinjiang Taitong	469,639	2.78%
Qian Hui	306,286	1.81%
Lapam Fund III ⁽²⁾	1,178,944	6.97%
Lapam Fund II ⁽²⁾	262,253	1.55%
Chongde Yingsheng	720,599	4.26%
Zhongling Yanyuan ⁽²⁾	540,449	3.19%
WuXi Wuhan	180,150	1.06%

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

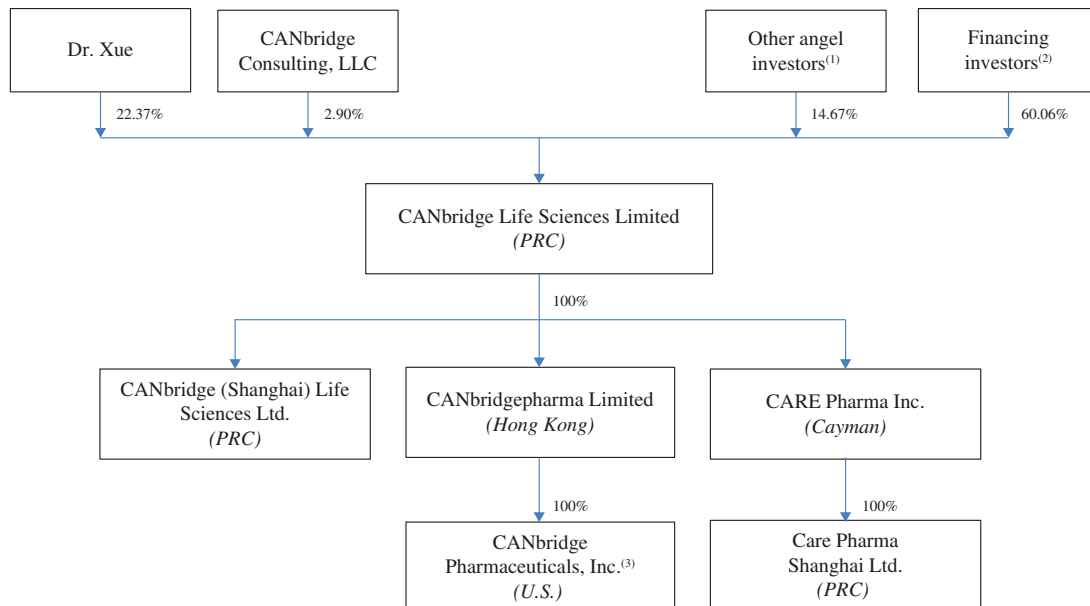
Name of Shareholder	Subscribed Registered Capital (RMB)	Percentage Ownership
Huang Wei	180,150	1.06%
Ma Jikai	180,150	1.06%
Shenzhen Yuanming ⁽²⁾	522,703	3.09%
Total	16,916,325	100.00%

Notes:

1. Liu Bing, one of the Angel Investors, served as Director of the Company from July 18, 2018 to June 11, 2021.
2. For further background information about Lapam Fund III, Lapam Fund II, Zhongling Yanyuan and Shenzhen Yuanming, please refer to the sub-section headed “[REDACTED] Investments – 8. Information about the [REDACTED] Investors” in this section.

REORGANIZATION

The following chart sets forth our Group’s corporate and shareholding structure following completion of the series A and series B financing in CANbridge Life Sciences and immediately prior to the commencement of the reorganization (the “**Reorganization**”).



HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Notes:

1. This includes investors who participated in the angel financing rounds of CANbridge Life Sciences as set out in the sub-sections headed “Establishment, Major Shareholding Changes and Development of our Group – 2. Angel Financing Capital Injection in 2013 and 3. Shareholding Transfer in 2013 and Capital Injection in 2014” in this section.
2. This includes investors who participated in the onshore series A and series B financing of CANbridge Life Sciences as set out in the sub-sections headed “Establishment, Major Shareholding Changes and Development of our Group – 4. Series A-1 Financing in 2014 and Series A-2 Financing in 2015” and “– 5. Series B-1 Financing in 2017” in this section.
3. CANbridge Pharmaceuticals, Inc. was incorporated in the U.S. in 2017 in preparation for potential expansion of our business in research and development of drug candidates to the U.S.

In preparation for the [REDACTED], we underwent the following Reorganization steps:

1. Incorporation of our Company

On January 30, 2018 and as part of the Reorganization, our Company was incorporated in the Cayman Islands as an exempted company with limited liability and as the ultimate holding company of our Group. On the date of incorporation of our Company, 1 subscriber share was allotted and issued at par value to our initial subscriber, Sertus Nominees (Cayman) Limited, which was subsequently transferred at par value to CTX Pharma, a company wholly-owned by Dr. Xue. On the same day, 9,999 ordinary shares were allotted and issued at nominal value to CTX Pharma.

2. Incorporation of CANbridge Pharmaceuticals Limited

On March 12, 2018, CANbridge Pharmaceuticals Limited was incorporated in Hong Kong as a limited liability company wholly-owned by our Company. On the date of incorporation of CANbridge Pharmaceuticals Limited, an aggregate of 10,000 ordinary shares of CANbridge Pharmaceuticals Limited were allotted and issued to our Company.

3. Acquisition of shares in CANbridge Biomed

Pursuant to a bought and sold note dated May 30, 2018 entered into between Value Plus Accounting Limited and CANbridge Pharmaceuticals Limited, CANbridge Pharmaceuticals Limited acquired the entire shareholding interest in CANbridge Biomed consisting of 1 ordinary share from Value Plus Accounting Limited, at a nominal value of HK\$1. Upon completion of such share transfer, CANbridge Biomed became an indirect wholly-owned subsidiary of our Company.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

4. Transfer of Equity Interests in CANbridge Life Sciences and Subscription of Shares of our Company

Through a series of equity transfers since June 2018 with the then shareholders of CANbridge Life Sciences, CANbridge Biomed acquired the entire equity interest in CANbridge Life Sciences from the then shareholders of CANbridge Life Sciences for an aggregate consideration of US\$37,874,400.20, after good faith negotiations with the then shareholders of CANbridge, taking into consideration their respective interests in facilitating the completion of our Reorganization. Upon completion of such equity transfers, CANbridge Life Sciences became an indirect wholly-owned subsidiary of our Company. Our Company then issued corresponding Shares and Preferred Shares to certain former shareholders of CANbridge Life Sciences or their affiliates or nominees pursuant to share subscription agreements. A total of 6,481,266 Shares, 1,761,144 Series A-1 Preferred Shares, 2,748,067 Series A-2 Preferred Shares and 4,305,847 Series B-1 Preferred Shares were issued in full on February 1, 2019 as set forth in the table below:

Name of Shareholder	Number of Shares allotted	Number of Preferred Shares allotted	Consideration (US\$)	Corresponding shareholding interest
CTX Pharma ⁽¹⁾	4,263,500	–	8,125,186.66	27.23%
Xiangyun Holdings Limited ⁽²⁾	592,000	–	59.20	3.78%
	–	68,064 Series A-2 Preferred Shares	6.81	0.43%
Hongweix Holdings Limited ⁽³⁾	592,000	–	59.20	3.78%
Yike Holdings Limited ⁽⁴⁾	592,000	–	59.20	3.78%
Apollo China Holdings Limited ⁽⁵⁾	296,000	–	29.60	1.89%
Clear Stone Holdings Limited ⁽⁶⁾	240,000	–	24.00	1.53%
Sea&Sky Holdings Limited ⁽⁷⁾	164,500	–	16.45	1.05%
Merrifield Holdings Limited ⁽⁸⁾	81,013	–	154,029.66	0.52%
Flemingddf Holdings Limited ⁽⁹⁾	20,253	–	38,506.94	0.13%
Spring Wind Holdings Limited ⁽¹⁰⁾	–	97,743 Series A-1 Preferred Shares	9.77	0.62%
		156,546 Series A-2 Preferred Shares	15.65	1.00%
Grand Path Holdings Limited ⁽¹¹⁾	–	97,743 Series A-1 Preferred Shares	185,840.24	0.62%
Maxtec ⁽¹²⁾	–	587,166 Series A-1 Preferred Shares	1,116,376.12	3.75%
		469,639 Series A-2 Preferred Shares	2,606,893.28	3.00%
Qiming Venture Partners IV, L.P. ⁽¹³⁾	–	948,542 Series A-1 Preferred Shares	1,803,458.71	6.06%
		1,100,221 Series A-2 Preferred Shares	2,091,845.32	7.03%

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Name of Shareholder	Number of Shares allotted	Number of Preferred Shares allotted	Consideration (US\$)	Corresponding shareholding interest
		523,907 Series B-1 Preferred Shares	996,102.06	3.35%
Qiming Managing Directors Fund IV, L.P. ⁽¹³⁾	–	29,950 Series A-1 Preferred Shares	56,943.80	0.19%
		34,739 Series A-2 Preferred Shares	66,049.11	0.22%
		16,542 Series B-1 Preferred Shares	31,451.23	0.11%
Yuhao Holdings Limited ⁽¹⁴⁾	–	306,286 Series A-2 Preferred Shares	30.63	1.96%
Medkelvin Holdings Limited ⁽¹⁵⁾	–	306,286 Series A-2 Preferred Shares	30.63	1.96%
Chengzhang Holdings Limited ⁽¹⁶⁾	–	180,150 Series B-1 Preferred Shares	18.02	1.15%
Dingkai Holdings Limited ⁽¹⁷⁾	–	180,150 Series B-1 Preferred Shares	18.02	1.15%
Hangzhou Tigermed	–	306,286 Series A-2 Preferred Shares	1,700,180.45	1.96%
Lapam Fund III	–	1,178,944 Series B-1 Preferred Shares	6,544,276.82	7.53%
Lapam Fund II	–	262,253 Series B-1 Preferred Shares	1,455,754.86	1.68%
Beijing Shuanglu Lisheng Pharma Technology Co., Ltd. (北京雙鷺立生醫藥科技有限公司) (“Shuanglu Lisheng”) ⁽¹⁸⁾	–	720,599 Series B-1 Preferred Shares	4,000,015.84	4.60%
Zhongling Yanyuan	–	540,449 Series B-1 Preferred Shares	2,999,964.93	3.45%
WuXi PharmaTech Healthcare Fund I L.P. ⁽¹⁹⁾	–	180,150 Series B-1 Preferred Shares	1,000,050.91	1.15%
Shenzhen Yuanming	–	522,703 Series B-1 Preferred Shares	2,901,462.26	3.34%
Total	6,841,266	8,815,058	37,874,766.38	100.00

Notes:

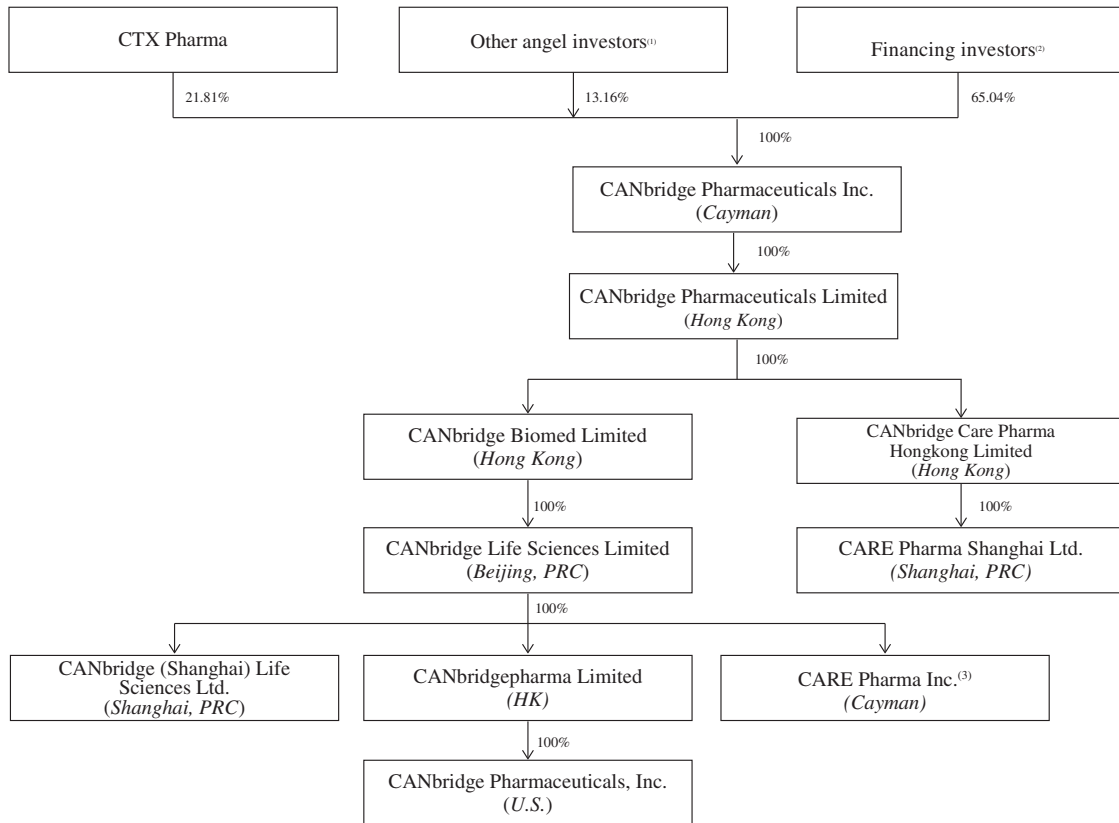
1. CTX Pharma is wholly-owned by Dr. Xue, our founder, executive Director and Chief Executive Officer and held 4,273,500 shares of our Company in total immediately after such share allotment which included 10,000 shares of our Company issued to CTX Pharma at the time of incorporation of our Company.
2. Xiangyun Holdings Limited is wholly-owned by Chen Song, who is a former shareholder of CANbridge Life Sciences, a private investor and a friend of Dr. Xue.
3. Hongweix Holdings Limited is wholly-owned by Cao Wei, who is a former shareholder of CANbridge Life Sciences, a private investor and a friend of Dr. Xue.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

4. Yike Holdings Limited is wholly-owned by Liu Bing, an Angel Investor, a private investor, a friend of Dr. Xue, a former shareholder of CANbridge Life Sciences and a former Director of our Company who resigned on June 11, 2021 due to the restructuring of the board composition and optimization of the governance structure of the Company in preparation for the [REDACTED] which include the reduction in the total number of Directors and the appointment of independent non-executive Directors. There was no dispute between Liu Bing and the Group and/or its shareholders during the Track Record Period and up to the Latest Practicable Date.
5. Apollo China Holdings Limited is wholly-owned by Xu Ping, who is a former shareholder of CANbridge Life Sciences, a private investor and a friend of Dr. Xue.
6. Clear Stone Holdings Limited is wholly-owned by Xu Ying, who is a former shareholder of CANbridge Life Sciences, a private investor and a friend of Dr. Xue.
7. Sea&Sky Holdings Limited is wholly-owned by Song Chunsheng, a private investor, a friend of Dr. Xue, who is a former shareholder of CANbridge Life Sciences.
8. Merrifield Holdings Limited is wholly-owned by Caroline Ann Merrifield, who is a former shareholder of CANbridge Life Sciences, a private investor and a friend of Dr. Xue.
9. Flemingddf Holdings Limited is wholly-owned by David Daniel Fleming, who is a former shareholder of CANbridge Life Sciences, a private investor and a friend of Dr. Xue.
10. Spring Wind Holdings Limited is wholly-owned by Lai Chunbao, who is a former shareholder of CANbridge Life Sciences, a private investor and an individual shareholder of TF Capital.
11. Grand Path Holdings Limited is a BVI limited company ultimately controlled by Ms. Liu Ying, a private investor. Grand Path Holdings Limited subscribed for such number of Series A-1 Preferred Shares that corresponded with the disposal of equity interest held by Lu Ning, a private investor and an individual shareholder of TF Capital, in CANbridge Life Sciences as part of the Reorganization.
12. Maxtec subscribed for such number of Series A-2 Preferred Shares that corresponded with the disposal of equity interest held by Xinjiang Taitong’s in CANbridge Life Sciences as part of the Reorganization.
13. Both Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P. are affiliates of QM16. QM16 is a limited company incorporated in Hong Kong and owned by Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P..
14. Yuhao Holdings Limited is wholly-owned by Qian Hui, who is a former shareholder of CANbridge Life Sciences, a private investor and a friend of Dr. Xue.
15. Medkelvin Holdings Limited is wholly-owned by Xue Yintong, who is a former shareholder of CANbridge Life Sciences, a private investor and a friend of Dr. Xue.
16. Chengzhang Holdings Limited is wholly-owned by Huang Wei, who is a former shareholder of CANbridge Life Sciences, a private investor and a friend of Dr. Xue.
17. Dingkai Holdings Limited is wholly-owned by Ma Jikai, who is a former shareholder of CANbridge Life Sciences, a private investor and a friend of Dr. Xue.
18. Shuanglu Lisheng is a limited liability company established in the PRC and nominated by Chongde Yingsheng to subscribe for Series B-1 Preferred Shares of our Company as part of the Reorganization. On March 10, 2020, Shuanglu Lisheng transferred 720,599 Series B-1 Preferred Shares to Chongde Yingsheng.
19. WuXi PharmaTech Healthcare Fund I L.P. is an affiliate of Wuxi Wuhan.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

The following chart sets forth our Group’s corporate and shareholding structure following completion of the Reorganization as of February 1, 2019 (without taking into account any dilutive effect resulting from the then outstanding Share Options. Details of the Share Options are set out in the subsection headed “– Issue of Shares to [REDACTED] Equity Incentive Plan Optionees).



Notes:

- (1) These other angel investors include holders of 2,577,766 Shares (equivalent to 13.16% of the then total issued capital of Company), who (other than Dr. Xue) are investors having participated in the angel financing rounds of CANbridge Life Sciences as set out in the sub-section headed “Establishment, Major Shareholding Changes and Development of our Group – Angel Financing Capital Injection in 2013 and 3. Shareholding Transfer in 2013 and Capital Injection in 2014” in this section.
- (2) These other investors include holders of 1,761,145 Series A-1 Preferred Shares (equivalent to 8.99% of the then total issued Shares), 2,748,067 Series A-2 Preferred Shares (equivalent to 14.02% of the then total issued Shares), 4,305,847 Series B-1 Preferred Shares (equivalent to 21.98% of the then total issued Shares), 3,283,518 Series C-1 Preferred Shares (equivalent to 16.76% of the then total issued Shares) and 641,940 Series C-2 Preferred Shares (equivalent to 3.28% of the then total issued Shares). The Series C-1 financing and the subscription of additional Series C-2 Preferred Shares by Blue Ridge Mountains Limited were completed while the Company was undergoing Reorganization. No holder of Series B-2 Preferred Shares was included in these investors as the Series B-2 financing was introduced prior to the commencement of the Reorganization in the form of a convertible loan which, was not converted at the completion of the Reorganization.
- (3) CARE Pharma Inc. was later deregistered on December 31, 2020.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

ISSUE OF SHARES TO [REDACTED] EQUITY INCENTIVE PLAN OPTIONEES

In April 2016, the board of directors of CANbridge Life Sciences approved an equity incentive plan (the “CANbridge Beijing Equity Incentive Plan”), which was subsequently inherited and replaced by the 2019 equity incentive plan passed by the Board on July 25, 2019 the “[REDACTED] Equity Incentive Plan”).

Pursuant to the [REDACTED] Equity Incentive Plan and the relevant option award agreements entered into between our Company and, among others, the Directors and members of the senior management, as set out in the table below (the “Optionees”), the Company granted to the Optionees Share Options to purchase Shares. Certain of such Share Options were exercised by the Optionees and an aggregate of 686,005 Shares under the Share Options were issued by the Company to the Optionees by August 30, 2021. The table below sets out the details of the issuance of Shares pursuant to the Share Options in 2020 and 2021:

Name of Optionee	Number of Shares allotted
Dr. Xue	73,305
Mr. James Arthur Geraghty	65,000
Ms. Belinda Termeer ⁽¹⁾	161,667
Mr. Mark Goldberg ⁽²⁾	170,000
Mr. Paul Wagner ⁽³⁾	25,000
Mr. Michael Glynn ⁽⁴⁾	10,000
Mr. Song Chunsheng ⁽⁵⁾	50,000
Ms. Xu Ying ⁽⁶⁾	20,000
Mr. Glenn Hassan ⁽⁷⁾	3,846
Dr. Gerald Cox ⁽⁸⁾	30,000
Mr. Nam Kit Lau ⁽⁹⁾	41,250
Mr. Mark Bamforth ⁽¹⁰⁾	23,958
Dr. Guangping Gao ⁽¹¹⁾	11,979
Total	686,005

Notes:

- (1) Ms. Belinda Termeer is a successor of Mr. Henri Termerr who was an external consultant of our Group and a member of our scientific advisory board.
- (2) Mr. Mark Goldberg is an external consultant of our Group and a member of our scientific advisory board. The shares allotted to him were subsequently transferred to his family trust.
- (3) Mr. Paul Wagner was the former chief business officer of our Group.
- (4) Mr. Michael Joseph Glynn is an external consultant of our Group and one of our [REDACTED] Investors.
- (5) Mr. Song Chunsheng is a consultant of our Group and one of our Angel Investors. Mr. Song Chunsheng exercised his share options through Sea&Sky Holdings Limited, a company wholly-owned by him.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

- (6) Ms. Xu Ying is a former employee of our Group and one of our Angel Investors. Ms. Xu Ying exercised her share options through Clear Stone Holdings Limited, a company wholly-owned by her.
- (7) Mr. Glenn Hassan is the Chief Financial Officer of our Group.
- (8) Dr. Gerald Cox is our Chief Development Strategist and interim CMO.
- (9) Mr. Nam Kit Lau is a Vice President of our Finance Department.
- (10) Mr. Mark Bamforth is a consultant of our Group and a member of our scientific advisory board. Mr. Mark Bamforth exercised his share options through The Mark R. Bamforth Irrevocable Trust, a family trust ultimately controlled by him.
- (11) Dr. Guangping Gao is a consultant of our Group and a member of our scientific advisory board.

For details of the [REDACTED] Equity Incentive Plan, see sub-section headed “Appendix IV – Statutory and General Information – D. [REDACTED] Equity Incentive Plan” in this document.

OTHER SHAREHOLDING CHANGES

1. Transfer of Shares in CANbridge Pharmaceuticals, Inc.

Pursuant to a share transfer agreement dated July 10, 2020 and a letter agreement dated July 10, 2020 entered into between CANbridgepharma Limited (our direct wholly-owned subsidiary incorporated in Hong Kong) and our Company, our Company acquired the entire shareholding interest in CANbridge Pharmaceuticals, Inc. (our indirect wholly-owned subsidiary incorporated in the United States), consisting of 100 ordinary shares from CANbridgepharma Limited, for a consideration of US\$2.29 million which was offset against the same amount owed by CANbridgepharma Limited to our Company. The amount of consideration was determined based on the then outstanding amount of intra-group balances between the parties. Upon completion of such share transfer, CANbridge Pharmaceuticals, Inc. became a direct wholly-owned subsidiary of our Company.

2. Transfer of Shares in 2021

On February 4, 2021, pursuant to share transfer agreements entered into among CTX Pharma (a company wholly-owned by Dr. Xue), Win Yin (HK) Investment Company Limited (a company beneficially owned by Chen Wenbi, Yan Ming and Chen Ningfeng, each a private investor and an independent third party) and Fusion Capital Management Limited (a company ultimately controlled by Wong Yan Ki Angel (黃欣琪), a private investor and an independent third party), CTX Pharma transferred 135,409 Shares to Win Yin (HK) Investment Company Limited and 33,853 Shares to Fusion Capital Management Limited, respectively, at the price of US\$14.77 per share, for an aggregate consideration of approximately US\$2.5 million. The aforesaid share transfers were concluded as the ultimate beneficial owners of Win Yin (HK) Investment Company Limited and Fusion Capital Management Limited became interested in investing in the Company shortly after our Series E (tranche 1) financing was completed but before we began negotiating with the relevant investors on our Series E (tranche 2) financing. The consideration was determined based on arm’s length negotiations taking into account

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prospects in the research and development of drug candidates, including having received IND approval for CAN106 from the Health Sciences Authority of Singapore and approval in the PRC for Hunterase® (CAN101) as the first mucopolysaccharidosis type II (MPS II) ERT in the PRC. For details, see the sub-section headed “– [REDACTED] Investments – 7. Principal Terms of the [REDACTED] Investments” in this section. The amounts of the consideration were determined on arm’s-length basis. The ultimate beneficial owners of Win Yin (HK) Investment Company Limited and Fusion Capital Management Limited were introduced to Dr. Xue through existing investors of the Company. Win Yin (HK) Investment Company Limited and Fusion Capital Management Limited and their ultimate beneficial owners are parties independent of Dr. Xue and of the Company.

[REDACTED] INVESTMENTS

1. Series A-1, Series A-2 and B-1 Financing in CANbridge Life Sciences

For details of the series A-1, series A-2 and series B-1 financing in CANbridge Life Sciences, please refer to the sub-sections headed “Establishment, Major Shareholding Changes and Development of our Group – 4. Series A-1 Financing in 2014 and Series A-2 Financing in 2015” and “– 5. Series B-1 Financing in 2017” in this section. For details of the Series A-1, Series A-2 and Series B-1 Preferred Shares subsequently issued, please refer to the sub-section headed “Reorganization – 5. Transfer of Equity Interests in CANbridge Life Sciences and Subscription of Shares of our Company” in this section.

2. Series B-2 Financing in 2018

On February 21, 2018, our Company entered into an investment agreement with, among others, Jesan Capital Company Limited (“**Jesan**”), Mayfair Holdings Limited (“**Mayfair**”), QM16, Yuanming Healthcare Holdings Limited (“**Yuanming Healthcare**”), pursuant to which Jesan, Mayfair, Qiming Venture Partners IV, L.P., Qiming Managing Directors Fund IV, L.P. and Yuanming Healthcare agreed to subscribe for an aggregate of 3,624,926 Series B-2 Preferred Shares to be issued by our Company at a subscription price of approximately US\$8.28 per Series B-2 Preferred Share, for an aggregate consideration of US\$29,999,963.35. The amounts of consideration were determined based on arm’s length negotiations taking into account prospects in the research and development of drug candidates, including the submission of IND application for CAN008 Phase II/III trial in GBM in China and the completion of patient enrollment for Phase I clinical trial of CAN008 in GBM in Taiwan. For details, see the sub-section headed “– [REDACTED] Investments – 7. Principal Terms of the [REDACTED] Investments” in this section. Such consideration was fully settled on February 27, 2018.

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The Series B-2 Preferred Shares were issued in full on March 29, 2019 as set forth in the table below:

Name of Shareholder	Number of Series B-2 Preferred Shares Subscribed	Consideration (US\$)
Jesan ⁽¹⁾	3,020,772 Series B-2 Preferred Shares	25,000,000
Mayfair	362,493 Series B-2 Preferred Shares	2,999,981.68
Qiming Venture Partners IV, L.P.	117,132 Series B-2 Preferred Shares	999,981.67
Qiming Managing Directors Fund IV, L.P.	3,698 Series B-2 Preferred Shares	1,000,000
Yuanming Healthcare	120,831 Series B-2 Preferred Shares	
Total	3,624,926	30,000,000

Note:

- On April 16, 2019, Jesan transferred 965,286 Series B-2 Preferred Shares to Yuhao HK Limited. On May 28, 2019, Jesan transferred the remaining 2,055,486 Series B Preferred Shares to WuXi AppTec (HongKong) Limited. On April 20, 2020, Yuhao HK Limited transferred 263,260 and 131,630 Series B-2 Preferred Shares to Nanjing BGI-Cowin No.1 Venture Investment Partnership and Shenzhen BGI-USUM Venture Investment Centre (Limited Partnership), respectively. On July 31, 2020, Yuhao HK Limited transferred 110,351 Series B-2 Preferred Shares to Huangpu River Capital SPC.

3. Series C Financing in 2018 and 2019

On August 10, 2018, our Company entered into the series C preferred share subscription agreement with, among others, the Series C Preferred Shareholders set out in the tables under this sub-section, pursuant to which the Series C Preferred Shareholders agreed to subscribe for an aggregate of 2,946,499 Series C-1 Preferred Shares at a subscription price of approximately US\$10.39 per Series C-1 Preferred Share, for an aggregate consideration of US\$30,600,000, which was settled on September 10, 2018. Pursuant to the same share subscription agreement, certain Series C Preferred Shareholders agreed to convert the outstanding amount under certain bridge loan agreements (the “**Bridge Loan Agreements**”) into an aggregate of 288,873 Series C-1 Preferred Shares and 641,940 Series C-2 Preferred Shares at a conversion price of approximately US\$10.39 per Series C-1 Preferred Share or approximately US\$9.35 per Series C-2 Preferred Share (as applicable), at an aggregate conversion price of US\$9,000,000. For details on the Series C Preferred Shares issued, please refer to the tables below.

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On September 30, 2018, our Company entered into a further series C share subscription agreement with Blue Ridge Mountains Limited (“**Blue Ridge**”), pursuant to which Blue Ridge agreed to subscribe for 48,146 Series C-1 Preferred Shares at a subscription price of approximately US\$10.39 per Series C-1 Preferred Share, for a consideration of US\$500,000 which was settled on October 25, 2018.

On January 30, 2019, our Company entered into a further series C share subscription agreement with WuXi Biologics Healthcare Venture (“**WuXi Biologics**”), pursuant to which WuXi Biologics agreed to subscribe for 481,454 Series C-3 Preferred Shares at a subscription price of approximately US\$10.39 per Series C-3 Preferred Share, for a consideration of US\$5,000,000 which was settled on February 1, 2019.

On April 4, 2019, our Company entered into a further series C share subscription agreement with SACF GP I, L.P. (“**SACF**”), pursuant to which SACF agreed to subscribe for 96,291 Series C-3 Preferred Shares at a subscription price of approximately US\$10.39 per Series C-3 Preferred Share, for a consideration of US\$999,975 which was settled on April 19, 2019.

The amount of consideration for each investment under the Series C Financing was determined based on arm’s length negotiations taking into account prospects in the research and development of drug candidates, including having received IND approval from the NMPA to commence second-line phase II/III trials for CAN008 in China on patients with GBM and the entry into strategic partnership with WuXi Biologics for rare disease therapeutics to develop a range of products including CAN103. For details, see the sub-section headed “[REDACTED] Investments – 7. Principal Terms of the [REDACTED] Investments” in this section.

The Series C Preferred Shares described above were issued in full by March 10, 2020 as set forth in the table below:

(i) *Share Purchases*

Name of Series C Shareholder	Number of Series C Preferred Shares Subscribed	Consideration (US\$)
Blue Ridge	1,636,945 Series C-1 Preferred Shares	17,000,000
WuXi Biologics	481,454 Series C-1 Preferred Shares 481,454 Series C-3 Preferred Shares	5,000,000 5,000,000
Fortune Creation Ventures Limited (“ Fortune Creation ”) ⁽¹⁾	577,745 Series C-1 Preferred Shares	6,000,000
SVB Leerink Holdings LLC (formerly known as Leerink Holdings LLC)	28,887 Series C-1 Preferred Shares	300,000

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Name of Series C Shareholder	Number of Series C Preferred Shares Subscribed	Consideration (US\$)
Healthcare Innovation Investment Fund LLC (formerly known as Leerink Partners Co-Investment Fund, LLC)	28,887 Series C-1 Preferred Shares	300,000
Qiming Venture Partners IV, L.P.	233,359 Series C-1 Preferred Shares	2,423,480
Qiming Managing Directors Fund IV, L.P.	7,368 Series C-1 Preferred Shares	76,520
SACF ⁽²⁾	96,291 Series C-3 Preferred Shares	999,975
Total	3,572,390	37,100,000

(ii) *Conversions under the Bridge Loan Agreements*

Name of Series C Shareholder	Number of Series C Preferred Shares Subscribed	Conversion Price (US\$)
SACF	288,873 Series C-1 Preferred Shares	3,000,000
Yuanming Healthcare	267,475 Series C-2 Preferred Shares	2,500,000
Qiming Venture Partners IV, L.P.	259,288 Series C-2 Preferred Shares	2,423,480
Qiming Managing Directors Fund IV, L.P.	8,187 Series C-2 Preferred Shares	76,520
WuXi PharmaTech Healthcare Fund I L.P.	106,990 Series C-2 Preferred Shares	1,000,000
Total	1,412,045	9,000,000

Notes:

- Following the allotment of 577,745 Series C-1 Preferred Shares to Fortune Creation on September 10, 2018, Fortune Creation transferred the 481,454 Series C-1 Preferred Shares to BioTrack BH Limited on March 28, 2019.
- Following the allotment of 96,291 Series C-3 Preferred Shares to SACF on April 24, 2019, SACF transferred the same to Jumbo Hero Limited on July 15, 2019.

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4. Series D Financing

On February 15, 2020, our Company entered into the series D-1 preferred share subscription agreement with, among others, the Series D-1 Preferred Shareholders. Pursuant to the February 15, 2020 agreement above, the Series D-1 Preferred Shareholders set out in the table below agreed to subscribe at a subscription price of approximately US\$11.82 for (i) upon the first completion, an aggregate of 4,754,717 Series D-1 Preferred Shares for an aggregate consideration of US\$56,200,753 which was fully settled on March 10, 2020; and (ii) upon the second completion, an aggregate of 3,113,409 Series D-1 Preferred Shares for an aggregate consideration of US\$36,800,493 which was fully settled on May 24, 2021. The amounts of consideration were determined based on arm’s length negotiations taking into account prospects in the research and development of drug candidates, including having obtained exclusive license rights in Hunterase® (CAN101) from GC Pharma to commercialize Hunterase® (CAN101) in Greater China and having submitted NDA for Hunterase® (CAN101) for Hunter Syndrome in China and Hunterase®. For details, see the sub-section headed “[REDACTED] Investments – 7. Principal Terms of the [REDACTED] Investments” in this section. Upon both rounds of completion, a total number of 7,868,126 Series D-1 Preferred Shares were issued in full on March 10, 2020 and May 21, 2021, respectively, for an aggregate consideration of US\$93,001,246. Pursuant to the same February 15, 2020 agreement mentioned above, Yuanming Healthcare agreed to convert its convertible loan into an aggregate of 481,232 Series C-4 Preferred Shares at a conversion price of approximately US\$10.39 per Series C-4 Preferred Share based on the conversion price of the Series C-3 Preferred Shares. The details are set out below:

Name of Shareholder	Number of Series D Preferred Shares Subscribed	Consideration (US\$)
General Atlantic Singapore CP Pte. Ltd. (“General Atlantic”)	1,015,242 Series D-1 Preferred Shares (first completion)	12,000,160
	676,828 Series D-1 Preferred Shares (second completion)	8,000,107
WuXi PharmaTech Healthcare Fund I L.P.	1,015,242 Series D-1 Preferred Shares (first completion)	12,000,160
	676,828 Series D-1 Preferred Shares (second completion)	8,000,107

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Name of Shareholder	Number of Series D Preferred Shares Subscribed	Consideration (US\$)
RA Capital Healthcare Fund, L.P.	1,298,999 Series D-1 Preferred Shares (first completion)	15,354,168
	865,999 Series D-1 Preferred Shares (second completion)	10,236,108
RA Capital Nexus Fund, L.P.	507,621 Series D-1 Preferred Shares (first completion)	6,000,080
	338,414 Series D-1 Preferred Shares (second completion)	4,000,053
Blackwell Partners LLC – Series A	223,864 Series D-1 Preferred Shares (first completion)	2,646,072
	149,243 Series D-1 Preferred Shares (second completion)	1,764,052
HBC Asia Healthcare Opportunities I LLC	507,621 Series D-1 Preferred Shares (first completion)	6,000,080
	338,414 Series D-1 Preferred Shares (second completion)	4,000,053
Yuanming Healthcare	481,232 Series C-4 Preferred Shares	5,000,000
Hongkong Tigermed Co., Limited	101,524 Series D-1 Preferred Shares (first completion)	1,200,014
	67,683 Series D-1 Preferred Shares (second completion)	800,013
Mark R. Bamforth Irrevocable Trust	84,604 Series D-1 Preferred Shares (first completion)	1,000,019
Total	7,868,126	98,001,246

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Pursuant to the same series D-1 preferred share subscription agreement, the Company agreed to issue to each of General Atlantic and WuXi PharmaTech Healthcare Fund I L.P. (each a “**Series D Leading Investor**”), without any additional consideration, certain warrants pursuant to which each Series D Leading Investor shall be entitled to subscribe for Series D-2 Preferred Shares at the exercise price of US\$13.00 per share. As of May 21, 2021, no Series D-2 Preferred Shares have been issued by our Company pursuant to the abovementioned warrants and General Atlantic and WuXi PharmaTech Healthcare Fund I L.P. have agreed to terminate their rights to exercise such warrants in writing.

Pursuant to agreements dated September 30, 2019 entered into between our Company and China Equities HK Limited (“**CEHK**”), an affiliate of SPD Silicon Valley Bank (“**SSVB**”) in relation to, *inter alia*, a banking facility granted by SSVB and the issuance of warrants by our Company to CEHK (the “**CEHK Warrant**”), pursuant to which CEHK shall be entitled to exercise the CEHK Warrant for cash or, if the fair market value of the warrant shares exceeds the exercise price under the CEHK Warrant, effect a cashless exchange of the CEHK Warrant for a certain number of warrant shares to be issued according to the formula stipulated in the CEHK Warrant (the “**Cashless Exchange**”). As of May 17, 2021, CEHK exercised its right to convert the CEHK Warrant by Cashless Exchange for 21,824 fully paid and validly issued warrant shares that are the Company’s Series D-3 Preferred Shares, in accordance with the terms of the CEHK Warrant. On May 21, 2021, our Company issued a total number of 21,824 Series D-3 Preferred Shares in full to CEHK as set out in the table below:

Name of Shareholder	Number of Series D Preferred Shares Subscribed	Consideration (US\$)
China Equities HK Limited	21,824 Series D-3 Preferred Shares	N.A.
Total	21,824	N.A.

5. Series E Financing

On October 26, 2020, our Company entered into the series E preferred share subscription agreement with, among others, those Series E Preferred Shareholders as set out in the table below, pursuant to which the following Series E Preferred Shareholders agreed to subscribe for an aggregate of 2,914,015 Series E Preferred Shares at a subscription price of US\$14.77, for an aggregate consideration of US\$43,039,999.63, which was fully settled on November 25, 2020. The amounts of consideration were determined based on arm’s length negotiations taking into account prospects in the research and development of drug candidates, including having received IND approval for CAN106 from the Health Sciences Authority of Singapore, and approval in the PRC for Hunterase® (CAN101) as the first mucopolysaccharidosis type II (MPS II) ERT in the PRC and our entry into strategic collaboration with the Horae Gene Therapy

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Center at the UMass Medical School and initiated gene therapy research programs for rare genetic diseases. For details, see the sub-section headed “– [REDACTED] Investments – 7. Principal Terms of the [REDACTED] Investments” in this section. The Series E Preferred Shares (Tranche 1) described above were issued in full by November 11, 2020 as set forth in the table below:

Name of Shareholder	Number of Series E Preferred Shares (Tranche 1) Subscribed	Consideration (US\$)
3W Global Fund	677,048 Series E Preferred Shares	9,999,999
Casdin Partners Master Fund, L.P.	338,524 Series E Preferred Shares	4,999,999
Summer Bridge Holdings Limited	338,524 Series E Preferred Shares	4,999,999
SPDBI Eagle L.P.	338,524 Series E Preferred Shares	4,999,999
Yaly Capital Healthcare Investment 1 Limited (“Yaly Capital”) ⁽¹⁾	338,524 Series E Preferred Shares	4,999,999
Blue Ridge	135,410 Series E Preferred Shares	2,000,006
HBC Asia Healthcare Opportunities I LLC	338,524 Series E Preferred Shares	4,999,999
Hongkong Tigermed Co., Limited	135,410 Series E Preferred Shares	2,000,006
RA Capital Healthcare Fund, L.P.	184,916 Series E Preferred Shares	2,731,209.32
RA Capital Nexus Fund, L.P.	67,705 Series E Preferred Shares	1,000,002.85
Blackwell Partners LLC – Series A	18,198 Series E Preferred Shares	268,784.46
Michael Joseph Glynn	2,708 Series E Preferred Shares	39,997
Total	2,914,015	43,039,999.63

Note:

- Following the allotment of 338,524 Series E Preferred Shares to Yaly Capital on November 11, 2020, Yaly Capital transferred the 203,114 Series E Preferred Shares to I-China Holdings Limited on November 24, 2020.

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On April 26, 2021, our Company entered into the series E preferred share subscription agreement (second tranche) with, among others, those Series E Preferred Shareholders as set out in the table below, pursuant to which the following Series E Preferred Shareholders agreed to subscribe for an aggregate of 1,028,436 Series E Preferred Shares at a subscription price of US\$14.77, for an aggregate consideration of US\$15,190,000.74, which was fully settled on May 7, 2021. The amounts of consideration were determined based on arm’s length negotiations taking into account prospects in the research and development of drug candidates, including the entry into strategic collaboration and licensing agreement with LogicBio and obtained (i) exclusive license to develop, manufacture and commercialize gene therapy candidates for two targets including for the treatment of Fabry and Pompe diseases, (ii) options for the development of AAV sL65-based treatments for two additional targets; and (iii) an option to obtain an exclusive license for LB-001 an investigational in-vivo gene editing technology based on GeneRide™ platform for the potential treatment of methylmalonic acidemia (MMA) in designated areas pursuant to the license agreement. For details, see the sub-section headed “– [REDACTED] Investments – 7. Principal Terms of the [REDACTED] Investments” in this section. The Series E Preferred Shares (Tranche 2) described above were issued in full by May 7, 2021 as set forth in the table below:

Name of Shareholder	Number of Series E Preferred Shares (Tranche 2) Subscribed	Consideration (US\$)
Janus Henderson Biotech Innovation Master Fund Limited	204,501 Series E Preferred Shares	3,020,479.77
Janus Henderson Capital Funds PLC on behalf of its series Janus Henderson Global Life Sciences Fund	253,130 Series E Preferred Shares	3,738,730.10
Janus Henderson Global Life Sciences Fund	296,003 Series E Preferred Shares	4,371,964.31
Janus Henderson Emerging Markets Fund	40,125 Series E Preferred Shares	592,646.25
Janus Henderson Investment Fund Series I – Janus Henderson Emerging Markets Opportunities Fund	65,866 Series E Preferred Shares	972,840.82
Janus Henderson Fund – Janus Henderson Emerging Markets Fund	20,537 Series E Preferred Shares	303,331.49
Yingke Innovation Fund LP	135,410 Series E Preferred Shares	2,000,006
Casdin Partners Master Fund, L.P.	8,802 Series E Preferred Shares	130,006
Michael Joseph Glynn	4,062 Series E Preferred Shares	59,996
Total	1,028,436	15,190,000.74

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6. Capitalization of our Company

The below table summarizes the capitalization of our Company as at the Latest Practicable Date.

Shareholders	As at the Latest Practicable Date ⁽¹⁾										Immediately upon (REDACTED) ⁽¹⁾					
	Ordinary Shares	Series A-1 Preferred Shares	Series A-2 Preferred Shares	Series B-1 Preferred Shares	Series B-2 Preferred Shares	Series C-1 Preferred Shares	Series C-2 Preferred Shares	Series C-3 Preferred Shares	Series C-4 Preferred Shares	Series D-1 Preferred Shares		Series D-3 Preferred Shares	Series E Preferred Shares (Tranche 1)	Series E Preferred Shares (Tranche 2)	Aggregate number of Shares	Aggregate ownership percentage (%)
CTX Pharma ⁽²⁾	2,604,238	-	-	-	-	-	-	-	-	-	-	-	-	2,604,238	7.08	(REDACTED)
Family Trust ⁽³⁾	1,500,000	-	-	-	-	-	-	-	-	-	-	-	-	1,500,000	4.08	(REDACTED)
Wuxi AppTec	-	-	-	180,150	2,055,486	-	106,990	-	1,692,070	-	-	-	-	4,034,696	10.97	(REDACTED)
RA Capital	-	-	-	-	-	-	-	-	3,384,140	-	270,819	-	-	3,654,959	9.93	(REDACTED)
Qiming Venture Entrusters ⁽²⁾	-	978,492	1,134,960	540,449	120,830	240,727	267,475	-	-	-	-	-	-	3,282,933	8.92	(REDACTED)
- Xiangyun Holdings Limited	592,000	-	68,064	-	-	-	-	-	-	-	-	-	-	660,064	1.79	(REDACTED)
- Apollo China Holdings Limited	296,000	-	-	-	-	-	-	-	-	-	-	-	-	296,000	0.80	(REDACTED)
- Sea&Sky Holdings Limited	214,500	-	-	-	-	-	-	-	-	-	-	-	-	214,500	0.66	(REDACTED)
- Clear Stone Holdings Limited	260,000	-	-	-	-	-	-	-	-	-	-	-	-	260,000	0.71	(REDACTED)
- Hongweixx Holdings Limited	592,000	-	-	-	-	-	-	-	-	-	-	-	-	592,000	1.61	(REDACTED)
- Medkevin Holdings Limited	-	-	306,286	-	-	-	-	-	-	-	-	-	-	306,286	0.83	(REDACTED)
- Chengzhang Holdings Limited	-	-	-	180,150	-	-	-	-	-	-	-	-	-	180,150	0.49	(REDACTED)
- Dingkai Holdings Limited	-	-	-	180,150	-	-	-	-	-	-	-	-	-	180,150	0.49	(REDACTED)
- Merrifield Holdings Limited	81,013	-	-	-	-	-	-	-	-	-	-	-	-	81,013	0.22	(REDACTED)
- Flemingtdf Holdings Limited	20,253	-	-	-	-	-	-	-	-	-	-	-	-	20,253	0.06	(REDACTED)
Blue Ridge Mountains Limited	-	-	-	-	-	1,636,945	-	-	-	-	135,410	-	-	1,772,355	4.82	(REDACTED)
General Atlantic Singapore CP Pte. Ltd.	-	-	-	-	-	-	-	-	1,692,070	-	-	-	-	1,692,070	4.60	(REDACTED)
TF Capital	-	587,166	469,639	-	362,493	-	-	-	-	-	-	-	-	1,419,298	3.86	(REDACTED)
Lapam Capital	-	-	-	1,441,197	-	-	-	-	-	-	-	-	-	1,441,197	3.92	(REDACTED)
Yuanming Capital	-	-	-	522,703	120,831	-	267,475	-	481,232	-	-	-	-	1,392,241	3.78	(REDACTED)
HBC Asia Healthcare Opportunities I LLC	-	-	-	-	-	-	-	-	846,035	-	338,524	-	-	1,184,559	3.22	(REDACTED)
Wuxi Biologics Healthcare Venture Janus	-	-	-	-	-	481,454	-	-	-	481,454	-	-	-	962,908	2.62	(REDACTED)
Yuhao	-	-	-	-	-	460,045	-	-	-	-	-	880,162	-	880,162	2.39	(REDACTED)
Beijing Chongde Yingsheng Startup Investment Co., Limited	-	-	-	720,599	-	-	-	-	-	-	-	-	-	720,599	1.96	(REDACTED)
3W Global Fund	-	-	-	-	-	-	-	-	-	-	677,048	-	-	677,048	1.84	(REDACTED)
TigerMed	-	-	-	-	-	-	-	-	169,207	-	135,410	-	-	610,903	1.66	(REDACTED)
Yike Holdings Limited	592,000	-	-	-	-	-	-	-	-	-	-	-	-	592,000	1.61	(REDACTED)

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Shareholders	As at the Latest Practicable Date ⁽¹⁾										Immediately upon [REDACTED] ⁽¹⁾				
	Ordinary Shares	Series A-1 Preferred Shares	Series A-2 Preferred Shares	Series B-1 Preferred Shares	Series B-2 Preferred Shares	Series C-1 Preferred Shares	Series C-2 Preferred Shares	Series C-3 Preferred Shares	Series C-4 Preferred Shares	Series D-1 Preferred Shares	Series D-3 Preferred Shares	Series E Preferred Shares (Tranche 1)	Series E Preferred Shares (Tranche 2)	Aggregate ownership percentage (%)	Aggregate ownership percentage (%)
Beijing Zhongling Yanyuan Startup Investment Centre L.P.	-	-	-	540,449	-	-	-	-	-	-	-	-	540,449	[REDACTED]	[REDACTED]
BioTrack BH Limited	-	-	481,454	-	-	-	-	-	-	-	-	-	481,454	[REDACTED]	[REDACTED]
BGI Co-win	-	-	394,890	-	394,890	-	-	-	-	-	-	-	394,890	[REDACTED]	[REDACTED]
DNV Capital	-	-	288,873	-	-	96,291	-	-	-	-	-	-	385,164	[REDACTED]	[REDACTED]
Casim Partners Master Fund, L.P.	-	-	-	-	-	-	-	-	-	-	338,524	8,802	347,326	[REDACTED]	[REDACTED]
SPDBI Eagle L.P.	-	-	-	-	-	-	-	-	-	-	338,524	-	338,524	[REDACTED]	[REDACTED]
Summer Bridge Holdings Limited	-	-	-	-	-	-	-	-	-	-	338,524	-	338,524	[REDACTED]	[REDACTED]
Spring Wind Holdings Limited	-	97,743	156,546	-	-	-	-	-	-	-	-	-	254,289	[REDACTED]	[REDACTED]
i-China Holdings Limited	-	-	-	-	-	-	-	-	-	-	203,114	-	203,114	[REDACTED]	[REDACTED]
Yaly Capital Healthcare Investment 1 Limited	-	-	-	-	-	-	-	-	-	-	135,410	-	135,410	[REDACTED]	[REDACTED]
Yingke Innovation Fund LP	-	-	-	-	-	-	-	-	-	-	-	135,410	135,410	[REDACTED]	[REDACTED]
Win Yin (HK) Investment Company Limited	135,409	-	-	-	-	-	-	-	-	-	-	-	135,409	[REDACTED]	[REDACTED]
Huangpu River Capital SPC	-	-	110,351	-	110,351	-	-	-	-	-	-	-	110,351	[REDACTED]	[REDACTED]
Grand Path Holdings Limited	-	97,744	-	-	-	-	-	-	-	-	-	-	97,744	[REDACTED]	[REDACTED]
Fortune Creation Ventures Limited	-	-	-	-	-	96,291	-	-	-	-	-	-	96,291	[REDACTED]	[REDACTED]
THE MARK R. BAMFORTH IRREVOCABLE TRUST, U/I/T APRIL 2, 2015	23,938	-	-	-	-	-	-	-	84,604	-	-	-	108,562	[REDACTED]	[REDACTED]
Dr. Xue ⁽⁵⁾	73,305	-	-	-	-	-	-	-	-	-	-	-	73,305	[REDACTED]	[REDACTED]
James Arthur Geraghty	65,000	-	-	-	-	-	-	-	-	-	-	-	65,000	[REDACTED]	[REDACTED]
Leerink Partners	-	-	57,774	-	-	-	-	-	-	-	-	-	57,774	[REDACTED]	[REDACTED]
Fusion Capital Management Limited	33,853	-	-	-	-	-	-	-	-	-	-	-	33,853	[REDACTED]	[REDACTED]
SSVB Group	-	-	-	-	-	-	-	-	-	21,824	-	-	21,824	[REDACTED]	[REDACTED]
Michael Joseph Glynn ⁽⁶⁾	10,000	-	-	-	-	-	-	-	-	-	2,708	-	16,770	[REDACTED]	[REDACTED]
Other optionees:															
- Belinda Termeer	161,667	-	-	-	-	-	-	-	-	-	-	-	161,667	[REDACTED]	[REDACTED]
- Goldberg & Kaiser Family Foundation ⁽⁴⁾	170,000	-	-	-	-	-	-	-	-	-	-	-	170,000	[REDACTED]	[REDACTED]
- Paul Wagner	25,000	-	-	-	-	-	-	-	-	-	-	-	25,000	[REDACTED]	[REDACTED]
- Glenn Hassan	3,846	-	-	-	-	-	-	-	-	-	-	-	3,846	[REDACTED]	[REDACTED]
- Dr. Gerald Cox	30,000	-	-	-	-	-	-	-	-	-	-	-	30,000	[REDACTED]	[REDACTED]
- Nam Kit Lau	41,250	-	-	-	-	-	-	-	-	-	-	-	41,250	[REDACTED]	[REDACTED]
- Gao Guangming	11,979	-	-	-	-	-	-	-	-	-	-	-	11,979	[REDACTED]	[REDACTED]
Total	7,537,271	1,761,145	2,748,067	4,305,847	3,624,926	3,283,518	641,940	481,232	7,868,126	21,824	2,914,015	1,028,436	36,794,092	100.00	100.00

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Notes:

1. Assuming the conversion of the Preferred Shares into Shares on a one-to-one basis has been completed prior to the [REDACTED] and without taking into account the Share Options outstanding as at the Latest Practicable Date.
2. CTX Pharma is an exempted company with limited liability incorporated in the British Virgin Islands and holds 2,604,238 Shares in our Company. CTX Pharma is wholly-owned by Dr. Xue. Pursuant to a voting rights proxy agreement dated February 9, 2020 (the “**Voting Rights Proxy Agreement**”), each of Xiangyun Holdings Limited, Apollo China Holdings Limited, Sea&Sky Holdings Limited, Clear Stone Holdings Limited, Hongweix Holdings Limited, Medkelvin Holdings Limited, Chengzhang Holdings Limited, Dingkai Holdings Limited, Merrifield Holdings Limited and Flemingddf Holdings Limited (the “**Entrusters**”), who in aggregate hold 2,790,416 Shares in our Company, voluntarily entrusted all of the voting rights of their Shares directly held in our Company to CTX Pharma. Accordingly, each of CTX Pharma and Dr. Xue is deemed interested in the Shares held by the Entrusters. Such Voting Rights Proxy Agreement will terminate upon [REDACTED].
3. On July 10, 2021, 1,500,000 Shares of our Company were transferred from CTX Pharma to Dr. Xue and subsequently to the Family Trust. Under the terms of the Family Trust, Dr. Xue has the power to exercise all the voting rights attached to the Shares of our Company. Accordingly, Dr. Xue is deemed interested in the Shares held by the Family Trust.
4. The shares allotted to Mr. Mark Goldberg were subsequently transferred to his family trust.
5. Dr. Xue beneficially holds 73,305 Shares of our Company under his own name.
6. Mr. Michael Joseph Glynn beneficially holds 16,770 Shares of our Company under his own name.

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7. Principal Terms of the [REDACTED] Investments

The below table summarizes the principal terms of the [REDACTED] Investments:

	Series A-1	Series A-2	Series B-1	Series B-2	Series C-1	Series C-2	Series C-3	Series C-4	Series D-1 (First Completion)	Series D-1 (Second Completion)	Series D-3 ⁽¹⁾	Series E (Tranche 1)	Series E (Tranche 2)
Cost per Preferred Share paid or converted (US\$)	2.84	3.26	5.55	8.28	10.39	9.35	10.39	10.39	11.82	11.82	11.82	14.77	14.77
Corresponding valuation of the Company (approximation) (US\$ million)	25.9	38.7	89.8	163.8	239.7	221.7	252.4	257.4	349.1	385.9	386.2	525.6	540.8
Date of the agreements	September 30, 2014	October 8, 2015	February 4, 2017	February 21, 2018	August 10, 2018 and September 30, 2018	August 10, 2018	January 1, 2019 and April 4, 2019	February 15, 2020	February 15, 2020	February 15, 2020	September 30, 2019	October 26, 2020 and April 26, 2021	October 26, 2020 and April 26, 2021
Funds raised by our Group (approximation) (US\$)	5 million	8 million	24 million	30 million	34 million	6 million	6 million	5 million	56 million	37 million	Nil ⁽¹⁾	43 million	15 million
Date on which the investment was fully settled	December 16, 2014	December 29, 2015	June 6, 2017	February 27, 2018	October 25, 2018	February 27, 2018 ⁽¹⁰⁾	February 1, 2019 and April 19, 2019	March 10, 2020	March 10, 2020	May 24, 2021	May 21, 2021	November 11, 2020	May 7, 2021

Basis of determination of the consideration
 The consideration for each round of [REDACTED] Investments were determined based on arm's length negotiation between the respective [REDACTED] Investors and our Group after taking into consideration the timing of the [REDACTED] Investments and the status of our business operations and clinical trials.

Lock-up
 Whilst the [REDACTED] Investors are not subject to any lock-up arrangement at the time of [REDACTED] pursuant to the relevant agreements in relation to the [REDACTED] Investments, each [REDACTED] Investor will give undertakings for lock-up for a period of six (6) months after the [REDACTED] in favour of the [REDACTED] and will not dispose of any of the Shares held by them during the [REDACTED] period except with the prior written consent of the Company and the [REDACTED]. For further information about [REDACTED] arrangements by the [REDACTED] Investors to the [REDACTED], please refer to the section headed “[REDACTED] – [REDACTED] Arrangements and Expenses – [REDACTED] – Undertakings by Our Company” in this document.

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	Series A-1	Series A-2	Series B-1	Series B-2	Series C-1	Series C-2	Series C-3	Series C-4	Series D-1 (First Completion)	Series D-1 (Second Completion)	Series D-3 ⁽¹⁾	Series E (Tranche 1)	Series E (Tranche 2)
Discount to the [REDACTED] (approximation) ⁽²⁾	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Use of [REDACTED] the [REDACTED] Investments and general working capital purposes in accordance with the budget approved by the Board. As of the Latest Practicable Date, approximately [REDACTED]% of the net [REDACTED] from the [REDACTED] Investments has been utilized

We utilized the [REDACTED] for the principal business of our Group as approved by the Board, including, but not limited to, research and development activities, the growth and expansion of our Company's business and general working capital purposes in accordance with the budget approved by the Board. As of the Latest Practicable Date, approximately [REDACTED]% of the net [REDACTED] from the [REDACTED] Investments has been utilized

Strategic benefit from the [REDACTED] Investments

[REDACTED] Investments to our Group

At the time of the [REDACTED] Investments, our Directors were of the view that our Group could benefit from the additional capital that would be provided by the [REDACTED] Investors' investments in our Group and the [REDACTED] Investors' knowledge, experience and business network in the pharmaceutical industry. Despite no specific business opportunities were brought about by the [REDACTED] Investments, our relationship with WuXi Biologics, with which we entered into strategic partnership in 2018 for rare disease therapeutics to develop a range of products including CAN103, and through which we were granted license for additional products including CAN106 in 2019, is inherently reinforced with the respective [REDACTED] Investments they made in our Company.

Conversion rights

Each Preferred Share shall be automatically converted into Shares at the then effective applicable conversion price immediately before completion of the [REDACTED].

Notes:

- The Series D-3 Shares were issued in May 2021 pursuant to the CEHK Warrant issued by our Company to CEHK an affiliate of SSVB, pursuant to certain agreements in relation to, inter alia, a banking facility granted by SSVB to the Company in September 2019. A cashless exchange was effected pursuant to the formula stipulated in the CEHK Warrant, such that there was no consideration for the conversion of the CEHK Warrant. For details, please see “[REDACTED] Investments – 4. Series D Financing” under this section. Our Directors were of the view that our Group could benefit from the issuance of the CEHK Warrant as the issuance of the CEHK Warrant allowed the Company to obtain favourable terms for the banking facility granted by SSVB in September 2019 and allowed the Company to obtain the necessary financing at the time to support its business operations and general working capital needs.
- The discount to the [REDACTED] is calculated based on the assumption that the [REDACTED] is HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED], assuming the conversion of the Preferred Shares into Shares on a one-to-one basis has been completed prior to the [REDACTED] and without taking into account the Share Options outstanding as at the Latest Practicable Date.
- The valuation of the Company increases from Series B-1 financing in early 2017 to Series B-2 financing in early 2018, as we made significant progress in our research and development of drug candidates, having, among other things, submitted the IND application for CAN008 Phase II/III trial in GBM in China and completed patient enrollment for Phase I clinical trial of CAN008 in GBM in Taiwan.
- The valuation of the Company increases from Series B-2 financing in early 2018 to Series C-3 financing in the third quarter in 2019, as we made significant progress in our research and development of drug candidates with, among other things, IND approval received from the NMPA to commence second-line phase II/III trials for CAN008 in China on patients with GBM, and having entered into strategic partnership with WuXi Biologics for rare disease therapeutics to develop a range of products including CAN103.

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5. The valuation of the Company dropped for Series C-2 financing as such round of financing was provided in the form of a bridge loan, for which the parties had agreed to a discount over the valuation of the Company for other rounds of the Series C financing.
6. The cost per Preferred Share paid for Series C-4 financing is lower than that of Series D-1 financing despite the relevant agreements were signed on the same day, as the Series C-4 Preferred Shares were converted from the convertible loan of Yuanming Healthcare at the same time when we completed the Series D financing, when such convertible loan was part of the Series C-3 financing.
7. The valuation of the Company increases from Series D-1 financing in early 2019 to Series E financing in the third quarter of 2020, as we made significant business progress, having, among other things, obtained exclusive license rights for CAN101 to develop and commercialize CAN101 in Greater China and having entered into strategic collaboration with the Horae Gene Therapy Center at the UMass Medical School and initiated gene therapy research programs for rare genetic diseases.
8. The current valuation of the Company increases from Series E financing in the third quarter of 2020. For details, please refer to the sub-section headed “[REDACTED] Investment – 10. Public Float and Market Capitalisation upon [REDACTED]” in this section.
9. The corresponding valuation is calculated based on the proposed post-money capitalization of the Company at the time of investment, which excludes shares then expected to be issued pursuant to any Share Option then outstanding.
10. The investment in Series C-2 financing were paid into the Company in the form of bridge loans pursuant to the Bridge Loan Agreements that were entered into in February 2018, prior to the respective agreements relating to the conversion of the outstanding amount of such loans into Series C Preferred Shares were being entered into in August 2018.
11. CANbridge Life Sciences was in compliance with all PRC applicable laws and regulations in all of the [REDACTED] Investments prior to the Reorganization.

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8. Special Rights of the [REDACTED] Investors

Our Company and, among others, the [REDACTED] Investors entered into the Shareholders Agreement, pursuant to which certain shareholder rights were agreed among the parties. Pursuant to the Shareholders Agreement and the then memorandum and articles of association of our Company, certain [REDACTED] Investors have, among other rights, (i) information rights; (ii) pre-emptive rights; (iii) right of first refusal and right of co-sale; (iv) the right to nominate Directors; (v) drag-along and redemption rights that are exercisable if the [REDACTED] does not take place; and (vi) conversion rights and anti-dilution rights.

All special rights of the [REDACTED] Investors granted under the foregoing documents will be automatically terminated upon, among other things, the consummation of the Company’s first firm [REDACTED] sale of the Shares (or American Depository Shares, where applicable) to the public in an [REDACTED] pursuant to which such securities will be [REDACTED] on the Stock Exchange or other recognized exchanges as approved by the Board in accordance with the Shareholders Agreement and the Articles of Association then in effect.

9. Information about the [REDACTED] Investors

Our [REDACTED] Investors includes certain Sophisticated Investors, such as WuXi PharmaTech Healthcare Fund I L.P., WuXi AppTec (HongKong) Limited, Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P., RA Capital Healthcare Fund, L.P., RA Capital Nexus Fund, L.P. and Blackwell Partners LLC – Series A. Set out below is a description of our [REDACTED] Investors.

WuXi PharmaTech Healthcare Fund I L.P. and WuXi AppTec (HongKong) Limited

WuXi PharmaTech Healthcare Fund I L.P. and WuXi AppTec (HongKong) Limited are Sophisticated Investors. WuXi PharmaTech Healthcare Fund I L.P. is an exempted limited partnership established in the Cayman Islands in 2011 and specializes in the investment of pharmaceutical, biotech and healthcare companies. The general partner of WuXi PharmaTech Healthcare Fund I L.P. is a wholly owned subsidiary of WuXi AppTec Co., Ltd. (“**WuXi AppTec**”) and all the limited partnership interests of WuXi PharmaTech Healthcare Fund I L.P. are also wholly owned by WuXi AppTec. WuXi AppTec (HongKong) Limited is a company incorporated in Hong Kong on March 26, 2012 and specializes in business development and trade services. WuXi AppTec (HongKong) Limited is a wholly owned subsidiary of WuXi AppTec. WuXi AppTec is a leading global pharmaceutical R&D services platform listed on the Stock Exchange (stock code: 2359.HKSE) and the Shanghai Stock Exchange (stock code: 603259.SSE).

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RA Capital Healthcare Fund, L.P., RA Capital Nexus Fund, L.P. and Blackwell Partners LLC – Series A

RA Capital Healthcare Fund, L.P., RA Capital Nexus Fund, L.P. and Blackwell Partners LLC – Series A are Sophisticated Investors. Each of RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund, L.P. is an affiliate of RA Capital Management, L.P.. Blackwell Partners LLC – Series A is a separately managed account. The general partner of RA Capital Healthcare Fund, LP is RA Capital Healthcare Fund GP, LLC and the general partner of RA Capital Nexus Fund, LP is RA Capital Nexus Fund GP, LLC. RA Capital Management, L.P. serves as investment manager of RA Capital Healthcare Fund, L.P., RA Capital Nexus Fund, L.P. and Blackwell Partners LLC – Series A. RA Capital Management L.P., a Delaware limited partnership and investment adviser registered with the United States Securities and Exchange Commission, is a multi-stage investment manager with approximately US\$11.5 billion of assets under management as of the year end of 2020. It is dedicated to evidence-based investing in public and private healthcare and life science companies developing drugs, medical devices, and diagnostics.

Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P.

Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P. (collectively, “**Qiming Venture**”) are Sophisticated Investors. They are venture capital funds operated under Qiming Venture Partners and registered as exempted limited partnerships in the Cayman Islands, with their focus on investments in companies in the telecommunication, media and technology (“**TMT**”) and healthcare sectors across China. Qiming GP IV, L.P. is the general partner of Qiming Venture Partners IV, L.P, whereas Qiming Corporate GP IV, Ltd. is the general partner of both Qiming GP IV, L.P. and Qiming Managing Directors Fund IV, L.P..

Qiming Venture Partners is a leading China venture capital firm with over US\$5.9 billion of assets under management, and its portfolio companies include some of today’s most influential brands in their respective sectors, such as Xiaomi Corporation (stock code: 1810 (HKSE)), Meituan (stock code: 3690 (HKSE)), Beijing Roborock Technology Co., Ltd. (stock code: 688169 (SHSE)), Bilibili Inc. (stock ticker/code: BILI (NASDAQ), 9626 (HKSE)), Venus Medtech (Hangzhou) Inc. (stock code: 2500 (HKSE)), Hangzhou Tigermed Consulting Co., Ltd. (stock code: 300347 (SZSE), 3347 (HKSE)), Zai Lab Limited (stock ticker/code: ZLAB (NASDAQ), 9688 (HKSE)), Shanghai Sanyou Medical Co., Ltd. (stock code: 688085 (SHSE)) and Amoy Diagnostics Co., Ltd. (stock code: 300685 (SZSE)).

Chongde Yingsheng

Chongde Yingsheng is a government-invested fund incorporated in the PRC with a scale of RMB204.2 million. It is owned by Beijing Shuanglu Pharmaceutical Co., Limited (北京雙鷺藥業股份有限公司), a company listed on the the Shenzhen Stock Exchange (stock code: 002038.SZ) as to 37.96% and ultimately controlled by Xu Mingbo (徐明波), an independent third party. Chongde Yingsheng is primarily dedicated to strategic emerging industries such as medicine and health industry. Chongde Yingsheng has invested in more than ten innovative

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drugs, innovative medical devices and precision medicine projects. Its business scope includes: venture capital business, venture capital consultation business, and provision of venture capital management service to venture enterprises. Owing to government resources and policy support, the pharmaceutical industry resources of its substantial shareholders, and the professional background and management experience of its management team, Chongde Yingsheng is able to provide strong value-added services to accelerate the business development of investment subjects.

Zhongling Yanyuan

Zhongling Yanyuan is a limited partnership established in the PRC on April 14, 2015 and is principally engaged in venture investment and investment related consultation business. The general partner of Zhongling Yanyuan is Yanyuantongde (Beijing) Investment Fund Management Co., LTD, which in turn is ultimately controlled by Mr. Sun Fei (孫飛), an independent third party. All of its limited partners are independent third parties.

Lapam Fund II and Lapam Fund III

Lapam Fund II is a limited partnership established and validly existing in accordance with the laws of China, registered in Beijing, China. Lapam Fund II is the second fund established and managed by Lapam Capital, focusing on equity investment in innovative drugs and medical devices. Shiji Yangguang Holding Group Co., Ltd., the limited partner of Lapam Fund II, is the entity with the largest interest in the fund, with a shareholding ratio of 29.54%. Beijing Longpan Investment Management Consultant Centre (G.P.) (北京龍磐投資管理諮詢中心(普通合夥)) is the general partner and manager of the fund and is ultimately controlled by Yu Zhihua (余治華), an independent third party. Lapam Fund II's Investments in biomedicine and medical devices sector include, Eyebright Medical (stock code: 688050.SSE), Kawin Technology (stock code: 688687.SSE), Kangdini Pharmaceutical, etc.

Lapam Fund III is a limited partnership established and validly existing in accordance with the laws of China and is registered in Beijing, China (together with Lapam Fund II, “**Lapam Capital**”). Lapam Fund III is the third fund established and managed by Lapam Capital, and focusing on equity investment in innovative drugs and medical devices. SDIC Chuanghe National Emerging Industry Venture Capital Guiding Fund (L.P.), the limited partner of Lapam Fund III, is the entity with the largest interest in the fund, with a shareholding ratio of 21.16%. Tibet Longpan Yijing Venture Capital Centre L.P. (西藏龍磐怡景創業投資中心(有限合夥)) is the general partner, and Beijing Longpan Investment Management Consultant Centre (G.P.) (北京龍磐投資管理諮詢中心(普通合夥)), who is ultimately controlled by Yu Zhihua (余治華), an independent third party, is the manager of Lapam Fund III. Lapam Fund III's investments in biomedicine sector include RemeGen Co., Ltd. (stock code: 09995.HKSE), Kawin Technology (stock code: 688687.SSE), Clover Biopharmaceuticals, Siwei Biotechnology, etc..

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Blue Ridge

Blue Ridge is a limited liability company incorporated in Hong Kong and is owned by LYFE Capital Fund, L.P., LYFE Capital Fund-A, L.P., LYFE Capital Fund II, L.P., and Smart Healthcare Limited. LYFE Capital GP, L.P. is the general partner of LYFE Capital Fund, L.P. and LYFE Capital Fund-A, L.P.. LYFE Capital GP II, L.P. is the general partner of LYFE Capital Fund II, L.P. and is ultimately controlled by Zhao Jin, an independent third party.

Maxtec Group Limited and Mayfair Holdings Limited

Maxtec Group Limited is a limited company incorporated in the British Virgin Islands with limited liabilities and is wholly owned by Taitong Fund L.P., an exempted limited partnerships in the Cayman Islands. The general partner of Taitong Fund L.P. is Taitong Management Co., Ltd. Taitong Management Co., Ltd. is a limited company incorporated in the Cayman Islands and controlled by Ms. Chiang Chen Hsiu- Lien, an independent third party.

Mayfair Holdings Limited is a limited company incorporated in the British Virgin Islands with limited liabilities, which is owned by Taitong Late Stage Fund L.P. and Taitong Fund L.P. The general partner of Taitong Late Stage Fund L.P. is TF Venture Capital Management Co., Ltd. The limited partners of Taitong Fund L.P. and Taitong Late Stage Fund L.P. are professional investment companies and high net worth individuals.

General Atlantic

General Atlantic is a private company limited by shares, incorporated under laws of Singapore. It is wholly-owned by General Atlantic Singapore Fund Pte. Ltd. (“GASF”). GASF, which is incorporated in Singapore, is a private equity fund based in Singapore that makes and holds investments in growth companies in Asia, including the PRC, Hong Kong, India, Singapore, Indonesia and other regions of Asia. It is part of the General Atlantic private equity group, a leading global growth equity firm providing capital and strategic support for growth companies. The manager of GASF is General Atlantic Singapore Fund Management Pte. Ltd. (“GASFM”). GASFM is wholly-owned by General Atlantic Service Company, L.P., an investment advisor registered with the United States Securities and Exchange Commission with approximately US\$65 million of assets under management.

Shenzhen Yuanming and Yuanming Healthcare

Shenzhen Yuanming is a limited liability partnership established in the PRC, and whose general partner is Shenzhen Qianhai Yuanming Asset Management Co., Ltd. (深圳前海元明資產管理有限公司), who is ultimately controlled by Tian Yuan (田源), an independent third party. This cross-border investment company seeks to invest in pharmaceutical research, creative medical instruments development and advanced medical service companies in China and America.

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Yuanming Healthcare is a limited company incorporated in the British Virgin Islands with over US\$38.4 million of unaudited assets under management as of June 2021. Yuanming Prudence SPC is the sole shareholder of Yuanming Healthcare Holdings Limited. Yuanming Prudence SPC pursues its objective by investing primarily in a managed portfolio of private equity investments to achieve long term capital appreciation.

HBC Asia Healthcare Opportunities I LLC

HBC Asia Healthcare Opportunities I LLC (“**HBC Asia I**”) is a Delaware Limited Liability Company founded in 2020 and is a wholly owned subsidiary of Hudson Bay Master Fund Ltd., which is in turn owned by Hudson Bay Fund LP, Hudson Bay International Levered Fund Ltd. and Hudson Bay International Fund Ltd. HBC Asia I is managed by Hudson Bay Capital Management LP (“**HBC**”). HBC has been managing assets on behalf of outside investors since 2006 and now has approximately US\$11 billion of assets under management. The firm promotes an integrated team culture emphasizing collaboration and cross-pollination of ideas and employs a diverse group of investment strategies aiming to achieve consistent returns on an absolute basis with low correlations to the major equity and debt markets. Investments include Asia healthcare companies.

WuXi Biologics HealthCare Venture

WuXi Biologics HealthCare Venture (藥明生物產業基金) (“**WuXi Biologics**”) is a limited partnership enterprise incorporated in Hong Kong. WuXi Biologics is specialized in investing in Biopharmaceutical, Biotechnological, Medical and Healthcare companies. WuXi Biologics is an indirect-wholly owned entity of WuXi Biologics (Cayman) Inc. (藥明生物技術有限公司) (“**WuXi Cayman**”), a leading global pharmaceutical R&D services platform listed on the Stock Exchange (stock code: 2269.HKSE). All the limited partnership interests of WuXi Biologics are wholly owned by WuXi Cayman.

Janus Henderson Biotech Innovation Master Fund Limited, Janus Henderson Global Life Sciences Fund, Janus Henderson Emerging Markets Fund, Janus Henderson Capital Funds PLC, Janus Henderson Investment Fund Series I and Janus Henderson Fund

Janus Henderson Biotech Innovation Master Fund Limited is a company limited by shares organized pursuant to the laws of the Cayman Islands. It is a private fund (a pooled investment vehicle). Each of Janus Henderson Global Life Sciences Fund and Janus Henderson Emerging Markets Fund is a series of a business trust, Janus Investment Fund, organized pursuant to the laws of Massachusetts. They are investment companies registered pursuant to the Investment Company Act of 1940 of the United States as pooled investment vehicles. Janus Henderson Capital Funds PLC is a public limited company organized pursuant to the laws of the Republic of Ireland, and with respect to the investment in our Company, has acted on behalf of its sub-fund Janus Henderson Global Life Sciences Fund. Janus Henderson Investment Fund Series I is a series of Janus Henderson Emerging Markets Opportunities Fund, an open-end investment company (OEIC) (a pooled investment vehicle) organized pursuant to the laws of the United Kingdom. Janus Henderson Fund is a UCITS fund organized pursuant to the laws

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of Luxembourg, and with respect to the investment in our Company, has acted on behalf of its sub-fund Janus Henderson Emerging Markets Fund (a pooled investment vehicle). The investment manager of Janus Henderson Biotech Innovation Master Fund Limited, Janus Henderson Global Life Sciences Fund, Janus Henderson Emerging Markets Fund, Janus Henderson Capital Funds PLC, Janus Henderson Investment Fund Series I and Janus Henderson Fund (collectively, “**Janus Henderson**”) is Janus Capital Management LLC. Janus Henderson Group PLC reported US\$427.6 billion of assets under management as of the second quarter of 2021.

3W Global Fund

3W Global Fund is a company limited by shares incorporated under the laws of the Cayman Islands, managed by 3W Fund Management Limited (“**3W Fund Management**”) as its investment manager. 3W Fund Management is an investment management firm with expertise in equity investments. 3W Fund Management is licensed by the SFC to carry out type 9 (asset management) regulated activity and mainly manages assets for institutional investors.

Hangzhou Tigermed and Hongkong Tigermed Co., Limited

Hangzhou Tigermed is a company established in the PRC listed on the Stock Exchange (stock code: 3347.HKSE) and on the ChiNext market of the Shenzhen Stock Exchange (stock code: 300347.SSE). Hangzhou Tigermed, and its subsidiaries, is a leading China-based provider of comprehensive biopharmaceutical R&D services, and principally engaged in the provision of clinical trial services to meet the needs of pharmaceutical companies. Hongkong Tigermed Co., Limited is a limited liability company incorporated under the laws of Hong Kong, and a wholly-owned subsidiary of Hangzhou Tigermed.

BioTrack BH Limited

BioTrack BH Limited is a limited company incorporated in the British Virgin Islands with limited liabilities and is wholly owned by BioTrack Capital Fund I, LP (“**BioTrack Capital**”). BioTrack Capital is a Cayman Islands exempted limited partnership and is targeting to achieve long-term capital appreciation through equity and equity-related investments primarily in healthcare and healthcare related opportunities. BioTrack Fund I, GP, LP acts as the sole general partner of BioTrack Capital and the limited partners of BioTrack Capital include family offices, foundations, fund of funds, endowments and other qualified investors. The sole general partner of BioTrack Fund I GP, LP, is BioTrack Fund I GP Limited, a Cayman Islands exempted company, which is ultimately controlled by Zhi Zhongji, an independent third party.

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Nanjing BGI-Cowin No.1 Venture Investment Partnership and Shenzhen BGI-Usum Venture Investment Centre

Nanjing BGI-Cowin No.1 Venture Investment Partnership L.P. (南京華大共贏一號創業投資企業(有限合夥)) and Shenzhen BGI-Usum Venture Investment Centre L.P. (深圳華大渝商創業投資中心(有限合夥)) are limited liability partnerships incorporated in the PRC, which are both controlled by Liu Yu. BGI CoWin (Shenzhen) Private Equity Co., Ltd is the managing partner of both Nanjing BGI-Cowin No. 1 Venture Investment Partnership L.P. and Shenzhen BGI-Usum Venture Investment Centre L.P. (collectively, “**BGI Co-win**”). BGI CoWin (Shenzhen) Private Equity Co., Ltd was founded by a team of investment professionals in collaboration with BGI Genomics (“**BGI**”, stock code: 300676.SZSE), one of the world’s leading life science and genomics companies. In the field of life science, BGI Co-win works together to create a market-oriented investment platform for the life and health industry and to promote resource sharing and win-win cooperation of industrial resources, fund investors, and investment projects. Under the guidance of the idea of “R&D driven investment”, BGI Co-win adheres to focusing on the core technology or platform projects of gene technology, digital medicine, biomedicine, etc. As of February 2021, BGI Co-win has been in operation for over three years and has invested in more than 20 life science projects, and managed an asset of more than RMB1 billion. The BGI Co-win team has managed a cumulative asset of RMB3 billion, and a total of more than 80 investment projects.

SACF GP I, L.P. and Jumbo Hero Limited

SACF GP I, L.P. is a venture capital fund registered as exempted limited partnerships in the Cayman Islands with US\$3.3 million of assets under management. It focuses on investment in company in healthcare industry. DNV Capital Limited is the general partner of SACF GP I, L.P. and Yunfeng Lin (林雲峰) serves as the director of SACF GP I, L.P. Jumbo Hero Limited is an exempted company with limited liability incorporated under the laws of the British Virgin Islands with US\$1 million of assets under management. It focuses on investment in company in healthcare industry. Xiangwei Zhai is the director of Jumbo Hero Limited. Jumbo Hero Limited concentrates on venture capital investment in start-up period and growth period. Xiangwei Zhai is also the partner of DNV Capital Limited and has 20 years of rich experience in financial and strategic investment areas. DNV Capital Limited is an international venture capital firm focuses on investment in healthcare and innovative technology industry.

Yuhao HK Limited and Yuhao Holdings Limited

Yuhao HK Limited is a private company limited by shares incorporated in Hong Kong on February 4, 2019. Yuhao Holdings Limited is a BVI business company incorporated in the British Virgin Islands on April 11, 2018. Yuhao HK Limited and Yuhao Holdings Limited are both ultimately controlled by Qian Hui (錢輝).

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Casdin Partners Master Fund, L.P.

Casdin Partners Master Fund, L.P. is a Cayman Islands exempted limited partnership and a private pooled investment master fund. Casdin Partners GP, LLC, a Delaware limited liability company, is the general partner of the Fund and has approximately US\$ 3.8 billion of assets under management.

SPDBI Eagle L.P.

SPDBI Eagle L.P. is an investment holding vehicle managed by SPDB International which is a wholly owned subsidiary of Shanghai Pudong Development Bank. Shanghai Pudong Development Bank is a leading PRC bank incorporated on October 19, 1992 with the approval of the People’s Bank of China. Shanghai Pudong Development Bank was listed on the Shanghai Stock Exchange (stock code: 600000) on November 10, 1999.

Summer Bridge Holdings Limited

Summer Bridge Holdings Limited is a limited liability company established under the laws of BVI and is owned by Summer Master Fund Limited, a Cayman Islands incorporated mutual fund (“**Summer Master**”) and Summer Healthcare Fund, L.P., a limited partnership established under the laws of Cayman Islands (“**Summer Healthcare**”). Summer Master and Summer Healthcare are both controlled by Summer Capital Limited (“**Summer Capital**”). Summer Capital is a multi-strategy investment advisory company, focusing on advising investments in the healthcare, fintech and technology-driven consumption sectors.

I-China Holdings Limited

I-China Holdings Limited is a limited company with US\$3 million of assets under management. and is ultimately controlled by Ng Hoi Ting Vincent, an independent third party.

Yaly Capital Healthcare Investment 1 Limited

Yaly Capital Healthcare Investment 1 Limited is a special purpose vehicle incorporated in British Virgin Islands in 2018 ultimately controlled by WONG YEE MAN, an independent third party, and an affiliate of Yaly Capital. Yaly Capital is a Cayman Islands-registered private equity fund managed by Yaly Capital General Partners Limited.

Yingke Innovation Fund LP

Yingke Innovation Fund LP is a Cayman Islands exempted limited partnership, acting as a private fund registered in Cayman Islands Monetary Authority dedicated to investment in the healthcare, TMT, advanced manufacturing, new energy and clean technologies, consumer, financial and business services sectors in companies across all equity stages. The general partner of Yingke Innovation Fund LP is Yingke PE Co., Ltd. which has approximately US\$50 million of assets under management.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Win Yin (HK) Investment Company Limited

Win Yin (HK) Investment Company Limited is a limited company incorporated under the laws of Hong Kong and is ultimately controlled by Chen Wenbin, a private investor and an independent third party.

Huangpu River Capital SPC

Huangpu River Capital SPC is incorporated under the laws of the Cayman Islands focusing on investing in integrated circuit, biomedicine and artificial intelligence technology industries and is ultimately controlled by Zhao Bowen (趙博文) and others, each a private investor and an independent third party.

Fortune Creation Ventures Limited

Fortune Creation Ventures Limited is a private company with limited liability incorporated under the laws of the British Virgin Islands and is ultimately controlled by Ivan Xu, a private investor and an independent third party.

The Mark R. Bamforth Irrevocable Trust

The Mark R. Bamforth Irrevocable Trust is a family trust ultimately controlled by Mark Bamforth, a private investor and an independent third party.

SVB Leerink Holdings LLC and Healthcare Innovation Investment Fund LLC

SVB Leerink Holdings LLC is a limited liability company organized in Delaware, United States and is owned by SVB Financial Group, a publicly traded financial holding company (NASDAQ: SIVB). Healthcare Innovation Investment Fund LLC is a limited liability company organized in Massachusetts, United States. The managers of Healthcare Innovation Investment Fund LLC are Jeff Leerink, Joe Gentile, Barry Blake and Dan Dubin, each of whom is an independent third party.

Fusion Capital Management Limited

Fusion Capital Management Limited is a limited liability company established under the laws of BVI and is ultimately controlled by Wong Yan Ki Angel (黃欣琪), an independent third party.

China Equities HK Limited

China Equities HK Limited is a private company limited by shares incorporated in Hong Kong on March 1, 2013. China Equities HK Limited is owned by Benjamin Greenspan and China Equity Investors, LLC, a limited liability company incorporated in Delaware. China

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Equity Investors, LLC is owned by Andrew Kahn and DCI Consultants, LLC, an investment vehicle wholly owned by Donald Campbell. Each of Benjamin Greenspan, Andrew Kahn and Donald Campbell is an independent third party.

10. Public Float and Market Capitalisation upon [REDACTED]

Pursuant to a voting rights proxy agreement dated February 9, 2020, each of Xiangyun Holdings Limited, Apollo China Holdings Limited, Sea&Sky Holdings Limited, Clear Stone Holdings Limited, Hongweix Holdings Limited, Medkelvin Holdings Limited, Chengzhang Holdings Limited, Dingkai Holdings Limited, Merrifield Holdings Limited and Flemingddf Holdings Limited voluntarily entrusted all of the voting rights of their Shares directly held in our Company to CTX Pharma. Such voting rights proxy agreement will terminate upon [REDACTED]. Therefore, upon completion of the [REDACTED] (assuming the Share Options outstanding as at the Latest Practicable Date and the [REDACTED] are not exercised), Dr. Xue will be entitled to control and/or exercise approximately [REDACTED]% of voting rights in the Company’s issued share capital through CTX Pharma, and such Shares will not be counted towards the public float.

Save as disclosed above in this section and in the section headed “Substantial Shareholders” in this document, to the best of the Directors’ knowledge, all other [REDACTED] Investors and Shareholders are not connected persons of our Company. As a result, an aggregate of at least [REDACTED]% of the total issued Shares (upon completion of the [REDACTED], assuming the Share Options outstanding as at the Latest Practicable Date and the [REDACTED] are not exercised) with a market capitalization of approximately HK\$[REDACTED] (based on the [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range) will count towards the public float; hence, over 25% of our Company’s total issued Shares with a market capitalization of at least HK\$[REDACTED] will be held by the public upon completion of the [REDACTED] as required under Rule 8.08(1)(a) and Rule 18A.07 of the Listing Rules.

Assuming the [REDACTED] is between HK\$[REDACTED] and HK\$[REDACTED], upon completion of the [REDACTED], we will have a market capitalization in the range of approximately HK\$[REDACTED] to HK\$[REDACTED], representing a significant increase in post money valuation as compared with the Company’s post money valuation immediately after the completion of the Series E financing in May 2021. Such increase reflected the higher liquidity of our Shares upon [REDACTED], as well as the business progress we made during or shortly after the completion of the Series E financing, including but not limited to the entering of the strategic collaboration and licensing agreement with LogicBio and Mirum and having received IND approval for CAN106 from the NMPA and IND approval for CAN103 from the NMPA . For details of these developments, please refer generally to the section headed “Business” in this document.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

11. Compliance with Interim Guidance and Guidance Letters

The Joint Sponsors confirm that the investments by the [REDACTED] Investors are in compliance with the Guidance Letter HKEX-GL29-12 issued in January 2012 and updated in March 2017 by the Stock Exchange, the Guidance Letter HKEX-GL43-12 issued in October 2012 and updated in July 2013 and in March 2017 by the Stock Exchange and the Guidance Letter HKEX-GL44-12 issued in October 2012 and updated in March 2017 by the Stock Exchange.

REASONS FOR THE [REDACTED]

Our Board is of the view that the net [REDACTED] of approximately HK\$[REDACTED] from the [REDACTED], after deducting the [REDACTED] commissions and other estimated [REDACTED] expenses payable by us, and assuming the initial [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range set forth on the cover page of this document, and assuming the [REDACTED] is not exercised, will provide us with further capital to fund ongoing and future R&D, as described in more details in the section headed “Future Plans and Use of [REDACTED]” in this document.

PRC REGULATORY REQUIREMENTS

Our PRC Legal Adviser has confirmed that the PRC subsidiaries in our Group have obtained the requisite government approvals in all material respects in respect of the relevant transfers of equity interests as described in this section. The transfers of equity interests described above have been properly settled and legally completed.

M&A Rules

Pursuant to the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》) (the “M&A Rules”) effective on September 8, 2006 and amended on June 22, 2009, mergers and acquisitions of a domestic enterprise by foreign investors means (i) acquiring the equity of a domestic enterprise so as to convert the domestic enterprise into a foreign-invested enterprise, or subscribing for the increased capital of a domestic enterprise so as to convert the domestic enterprise into a foreign-invested enterprise; (ii) establishing a foreign-invested enterprise that purchases and operates the assets of a domestic enterprise, or purchasing the assets of a domestic enterprise and invest such assets to establish a foreign-invested enterprise. And according to Article 11 of the M&A Rules, where a domestic company, enterprise or natural person intends to acquire its or his/her related domestic company through an overseas company established or controlled by it or him/her, the acquisition shall be subject to the approval of the MOFCOM.

CANbridge Life Sciences, CANbridge (Suzhou) Bio-pharma Co., Ltd. and Care Pharma Shanghai are already foreign-invested enterprises since their establishment. In addition, Dr. Xue is an US citizen not a PRC citizen. Therefore, the M&A Rules shall not apply under such circumstances.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

SAFE Circular 37

Pursuant to the Circular of the SAFE on Foreign Exchange Administration of Overseas Investment, Financing and Round-trip Investments Conducted by Domestic Residents through Special Purpose Vehicles (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the “SAFE Circular 37”) effective on July 4, 2014, a PRC resident must register with the local SAFE branch before he or she contributes assets or equity interests to an overseas special purpose vehicle that is directly established or indirectly controlled by the PRC resident for the purpose of conducting investment or financing. Pursuant to the Notice on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》), the power to accept SAFE registration was delegated from local SAFE branch to local banks where the assets or interests in the domestic entity are located.

Dr. Xue is an US citizen not a PRC citizen. Mr. Liu Bing (劉兵) and other ten individuals who are PRC citizens and indirectly hold shares in the Company have completed their registration under the SAFE Circular 37 in relation to their interests in the Company.

[REDACTED] EQUITY INCENTIVE PLAN

Our Company adopted the 2019 Equity Incentive Plan on July 25, 2019 which replaced the CANbridge Beijing Equity Incentive Plan adopted by our Company in April 2016. The purpose of the [REDACTED] Equity Incentive Plan is to provide incentives to Directors and employees of the Company or any other third party that the Board considers as contributed or will contribute to the Company. The principal terms of the 2019 Equity Incentive Plan are set out in the section headed “[Appendix IV – Statutory and General Information – D. [REDACTED] Equity Incentive Plan]” in this document.

[REDACTED] RSU SCHEME

Our Company [has] conditionally adopted a [REDACTED] RSU Scheme by Shareholders’ resolutions dated [●], 2021. The purpose of the [REDACTED] RSU Scheme is to align the interests of the eligible persons’ with those of our Group through ownership of Shares, dividends and other distributions paid on Shares and/or the increase in value of the Shares, and to encourage and retain such eligible persons to make contributions to the long-term growth and profits of our Group. The principal terms of the [REDACTED] RSU Scheme are set out in the sub-section headed “[Statutory and General Information – E. [REDACTED] RSU Scheme]” in this document. The aggregate number of Shares underlying all grants made pursuant to the [REDACTED] RSU Scheme (excluding awards which have been forfeited in accordance with the [REDACTED] RSU Scheme) will not exceed 5% of the issued share capital of the Company as of the date of approval of the [REDACTED] RSU Scheme without Shareholders’ approval.

As of the Latest Practicable Date, no RSU had been granted or agreed to be granted under the [REDACTED] RSU Scheme.

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

[REDACTED] SHARE OPTION SCHEME

Our Company [has] conditionally adopted a [REDACTED] Share Option Scheme by Shareholders’ resolutions dated [●], 2021. The [REDACTED] Share Option Scheme is established to reward employees for their past contribution to the success of the Company, and to provide incentives to them to further contribute to the Company. The principal terms of the [REDACTED] Share Option Scheme are set out in the sub-section headed “[Statutory and General Information – F. [REDACTED] Share Option Scheme]” in this document. The maximum number of Shares in respect of which Options may be granted under the [REDACTED] Share Option Scheme when aggregated with the maximum number of Shares in respect of which Options may be granted under any other option scheme over Shares shall not exceed 10% of the issued share capital of the Company as of the date of approval of the [REDACTED] Share Option Scheme (or of the refreshing of the 10% limit) by the shareholders of the Company.

As of the Latest Practicable Date, no option had been granted or agreed to be granted under the [REDACTED] Share Option Scheme.

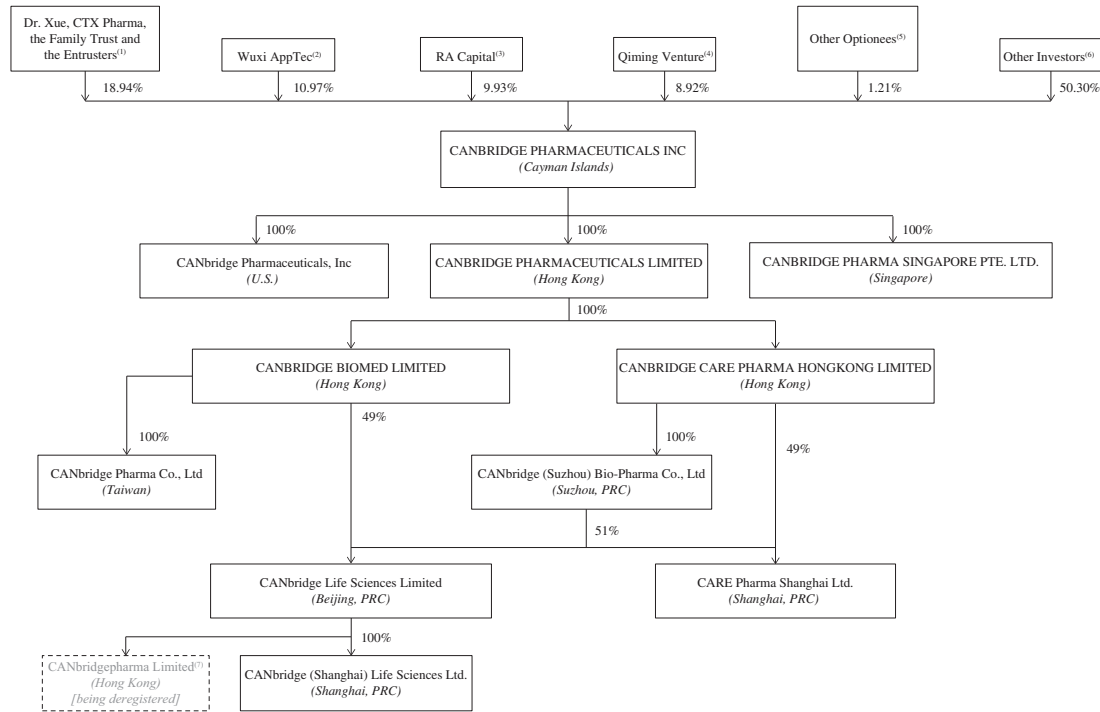
SHARE SUBDIVISION AND CONVERSION

On [●], our Shareholders resolved to, among other things, conduct the Share Subdivision pursuant to which each share in our then issued and unissued share capital was split into 10 shares of the corresponding class with par value of US\$0.00001 each effective upon the conditions of the [REDACTED] being fulfilled, following which our share capital will be divided into (i) 4,691,110,250 are designated as Ordinary Shares; (ii) 17,611,450 are designated as Series A-1 Preferred Shares; (iii) 27,480,670 are designated as Series A-2 Preferred Shares; (iv) 43,058,470 are designated as Series B-1 Preferred Shares; (v) 36,249,260 are designated as Series B-2 Preferred Shares; (vi) 32,835,180 are designated as Series C-1 Preferred Shares; (vii) 6,419,400 are designated as Series C-2 Preferred Shares; (viii) 5,777,450 are designated as Series C-3 Preferred Share; (ix) 4,812,320 are designated as Series C-4 Preferred Shares; (x) 78,681,260 are designated as Series D-1 Preferred Shares; (xi) 15,384,820 are designated as Series D-2 Preferred Shares; (xii) 1,154,960 are designated as Series D-3 Preferred Shares; and (xiii) 39,424,510 are designated as Series E Preferred Shares. Our Shareholders also resolved to, immediately upon completion of the Share Subdivision, conduct the Conversion, pursuant to which each Preferred Share shall be converted into Ordinary Share on a one-to-one basis.

OUR STRUCTURE IMMEDIATELY PRIOR TO THE SHARE SUBDIVISION, CONVERSION AND [REDACTED]

The following chart sets forth our corporate and shareholding structure after the Share Subdivision and Conversion immediately prior to completion of the [REDACTED].

HISTORY, REORGANIZATION AND CORPORATE STRUCTURE



Notes:

1. CTX Pharma directly held 2,604,238 Shares of our Company and is wholly-owned by Dr. Xue, our founder, executive Director and Chief Executive Officer. Dr. Xue directly holds 73,305 shares in our Company. Pursuant to a voting rights proxy agreement [dated February 9, 2020, each of Xiangyun Holdings Limited, Apollo China Holdings Limited, Sea&Sky Holdings Limited, Clear Stone Holdings Limited, Hongweix Holdings Limited, Medkelvin Holdings Limited, Chengzhang Holdings Limited, Dingkai Holdings Limited, Merrifield Holdings Limited and Flemingddf Holdings Limited (the “Entrusters”), which held an aggregate of 2,790,416 Shares, voluntarily entrusted all of the voting rights of the Shares directly held by them to CTX Pharma. The Family Trust held 1,500,000 shares of our Company and under the terms of the Family Trust, Dr. Xue has the power to exercise all the voting rights attached to the Shares of our Company. As such, Dr. Xue is deemed to be interested in an aggregate of 6,967,959 Shares. Such voting rights proxy agreement will terminate upon [REDACTED].
2. Wuxi Entities include WuXi AppTec (HongKong) Limited and WuXi PharmaTech Healthcare Fund I L.P. For details of the relationships between these entities, see the section headed “Substantial Shareholders”.
3. RA Entities include RA Capital Healthcare Fund, L.P., RA Capital Nexus Fund, L.P. and Blackwell Partners LLC. For details of the relationships between these entities, see the section headed “Substantial Shareholders”.
4. Qiming Entities include Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P.. For details of the relationships between these entities, see the section headed “Substantial Shareholders”.
5. The other optionees are grantees under the [REDACTED] Equity Incentive Plan who had, as at the Latest Practicable Date, exercised Share Options. The other optionees include Ms. Belinda Termeer, Mr. Mark Goldberg, Mr. Paul Wagner, Mr. Glenn Hassan, Dr. Gerald Cox, Mr. Nam Kit Lau and Dr. Guangping Gao. These Optionees held an aggregate of 443,742 Shares. For their respective number of Shares held and shareholding percentage and additional information, please refer to the sub-sections headed “Issue of Shares to [REDACTED] Equity Incentive Plan Optionees” and “[REDACTED] Investments – 6. Capitalization of our Company” in this section.
6. This includes all our other [REDACTED] Investors and other early investors, who are Independent Third Parties. These investors consist of Blue Ridge Mountains Limited, General Atlantic Singapore CP Pte. Ltd., TF Capital, Lapam Capital, Yuanming Capital, HBC Asia Healthcare Opportunities I LLC, Wuxi Biologics Healthcare Venture, Janus, Yuhao, Beijing Chongde Yingsheng Startup Investment Co., Limited, 3W Global Fund, TigerMed, Yike Holdings Limited, Beijing Zhongling Yanyuan Startup Investment Centre L.P., Biotrack

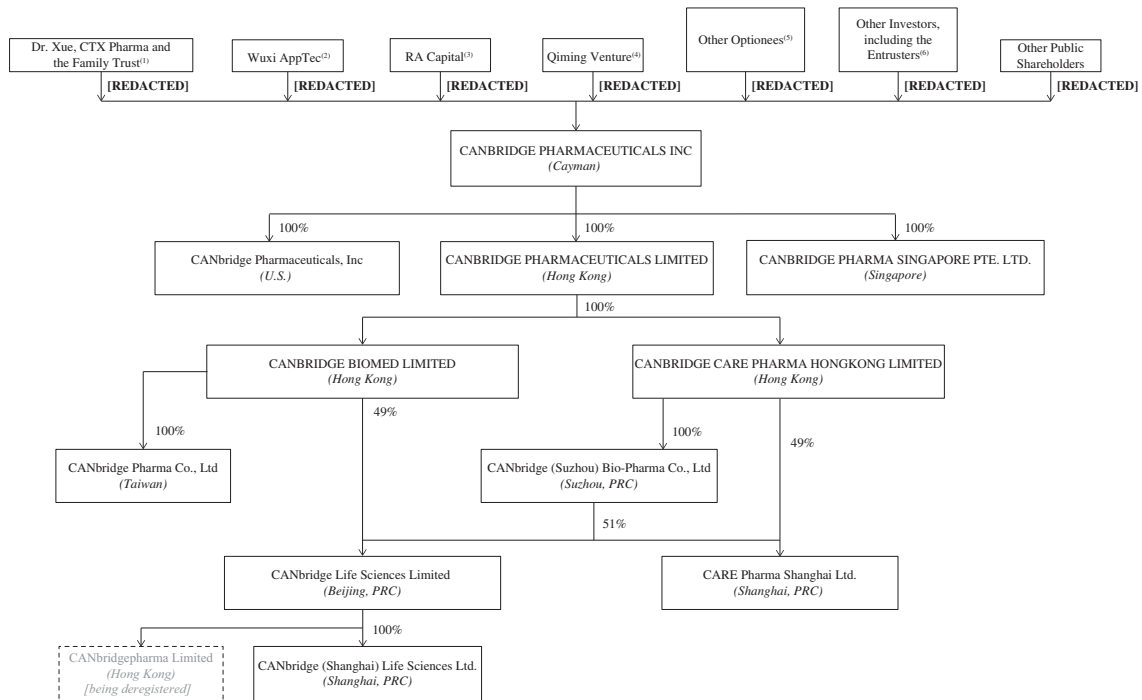
HISTORY, REORGANIZATION AND CORPORATE STRUCTURE

Capital, BGI Co-win, DNV Capital, Casdin Partners Master Fund, L.P., SPDBI Eagle L.P., Summer Bridge Holdings Limited, Spring Wind Holdings Limited, I-China Holdings Limited, Yaly Capital Healthcare Investment 1 Limited, Yingke Innovation Fund LP, Win Yin (HK) Investment Company Limited, Huangpu River Capital SPC, Grand Path Holdings Limited, Fortune Creation Ventures Limited, The Mark R. Bamforth Irrevocable Trust, U/I/T April 2, 2015, Leerink Partners, Fusion Capital Management Limited, SSVB Group, and Michael Joseph Glynn. These investors held an aggregate of 183,108,450 Shares. For their respective number of shares held and shareholding percentage and additional information, please refer to the sub-sections headed “[REDACTED] Investments – 6. Capitalization of our Company” and “[REDACTED] Investments – 9. Information about the [REDACTED] Investors” in this section.

7. The application of deregistration of CANbridgepharma Limited was submitted on March 5, 2021.

OUR STRUCTURE IMMEDIATELY FOLLOWING THE [REDACTED]

The following chart sets forth our corporate and shareholding structure immediately following completion of the Share Subdivision, Conversion and [REDACTED], assuming the Share Options outstanding as at the Latest Practicable Date and the [REDACTED] are not exercised.



Notes (1) to (4): Please refer to the notes contained under the sub-section headed “Our Structure Immediately Prior to the Share Subdivision, Conversion and [REDACTED]” in this section.

(5): The above chart does not take into account of subscription of Shares by our existing Shareholders or their close associates as [REDACTED] investors under the [REDACTED].

BUSINESS

OVERVIEW

We are a China-based, rare disease-focused biopharmaceutical company founded in 2012 that is committed to the research, development and commercialization of biotech therapies. As of the Latest Practicable Date, we had developed a comprehensive pipeline of 13 drug assets with significant market potential targeting some of the most prevalent rare diseases as well as rare oncology indications, including three marketed products, four drug candidates at clinical stage, one at IND-enabling stage, two at preclinical stage, and three gene therapy programs at lead identification stage. CAN008, our Core Product, is a glycosylated CD95-Fc fusion protein being developed for the treatment of GBM. We are developing the other 12 of drug candidates in our pipeline as of the Latest Practicable Date.

We are led by a management team with significant industry experience in rare diseases, spanning R&D, clinical development, regulatory affairs, business development and commercialization, supported by a pool of talent of 173 employees where 22 had a Ph.D. and/or M.D. degree, more than 80% of our employees had experience working at multinational biopharmaceutical companies as of the Latest Practicable Date. Our management team collectively has a track record of successfully commercializing rare disease therapies across the key markets including China, the United States, Europe, Latin America, and Southeast Asia. Leveraging our management’s expertise, we play an active role in advancing the rare disease industry and shaping the rare disease ecosystem in China. For example, our founder Dr. Xue is currently serving as the Deputy Director General of China’s Alliance for Rare Disease (CHARD).

Since our inception in 2012, we have built a comprehensive portfolio targeting diseases with validated mechanisms of action with significant market potential, consisting of biologics, small molecules, and gene therapy solutions. We adopted an in-licensing business model and apart from our internal efforts in developing gene therapy solutions for neuromuscular disorders, all of our product pipeline as of the Latest Practical Date have been in-licensed from our business partners. We will continue to enrich it via business partnerships and collaborations with academic institutions, together with in-house research and development.

- In the rare disease area, we have seven biologics and small molecules products and product candidates for the treatment of Hunter Syndrome (MPS II) and other lysosomal storage disorders (LSDs), complement mediated disorders, hemophilia A, metabolic disorders, and rare cholestatic liver diseases including Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA). Among these, we obtained the marketing approval for Hunterase[®] (CAN101) for MPS II in mainland China in September 2020. We initiated a Phase 1 clinical trial in healthy volunteers for CAN106 in Singapore in February 2021, and obtained the IND approval from the NMPA for PNH in July 2021 for a Phase 1 study in China.

BUSINESS

- In the rare oncology area, we are developing CAN008 for the treatment of glioblastoma multiforme (GBM). In 2018, we completed a Phase 1 clinical trial for CAN008 in Taiwan, which has successfully bridged CAN008 to Asian patients with newly diagnosed GBM on the back of clinical data previously obtained in overseas trials. We have obtained IND approval from the NMPA to commence first-line Phase 2 clinical trial of CAN008 and dosed the first patient in a Phase 2 clinical trial of CAN008 for the first-line treatment of GBM patients in mainland China in October 2021. We also obtained marketing approval for two other oncology products, Caphosol™ (CAN002) in mainland China and Nerlynx® (CAN030) in Greater China.

In addition to biologics and small molecules, we are investing in next-generation technology for gene therapies. Gene therapies provide a potentially one-time, durable treatment for various rare genetic diseases with limited treatment options. As of the Latest Practicable Date, we are using AAV sL65 capsid vector for the treatment of Fabry disease and Pompe disease licensed in from LogicBio Therapeutics to develop two gene therapy products, with options to develop two additional indications using the same vector, and a clinical-stage gene editing program for the treatment of methylmalonic acidemia (MMA) pursuant to our collaboration agreements with LogicBio Therapeutics. We are also working with our research partner UMass on sponsored research programs to develop gene therapy solutions for neuromuscular disorders, with the exclusive option to license-in the assets for development. In addition, we are internally developing an adeno-associated virus (AAV) delivery platform targeting different tissues such as the central nervous system (CNS) and muscle.

BUSINESS

The following chart summarizes our portfolio and the development status of each product or product candidate as of the Latest Practicable Date:

Product	Modality (Drug Category, Drug Class, Therapeutic Indication, and Administration) (Law) ⁽²⁾	Mechanism	Indication	Discovery/Pre-clinical	IND-enabling	Ph I	Ph II/III	NDA	Marketed	Partner	Commercial Rights ⁽³⁾	In-licensing Date	Granted Patents FN ⁽¹⁰⁾	Patent Applications FN ⁽¹⁰⁾
★ CAN008 (Aumerept)	Biologic (Cat.1 of Biological Drugs)	CD95-Fc fusion protein	Glioblastoma Multiforme ⁽²⁾	Taiwan Phase I trial completed China Phase 2 trial initiated						apogenix	Greater China	June 26, 2015 (with exclusive rights to develop, manufacture and commercialize)	3	2
Humirax® (CAN100) (infliximab beta)	Biologic (Cat.3 of Biological Drugs)	ERT dimeric-2-sulfanase (IDS) protein	Hunter syndrome (Mucopolysaccharidosis type II) ⁽⁴⁾	China Phase 1 trial initiated						GCC Pharma	Greater China	January 3, 2019 (with exclusive rights to develop and commercialize; commercialization commenced in May 2020)	1	2
CAN 108 (maralixibat)	Small molecule (ALGS, Cat.5 of Chemical Drugs, PFC; Cat.2,4 of Chemical Drugs)	ASBT-inhibitor	Alagille Syndrome ⁽⁴⁾ Progressive Familial Intrahepatic Cholestasis ⁽⁴⁾	China Pre-IND ⁽⁵⁾ China Phase 1 trial initiated China Phase 2 trial initiated						Amgen	Greater China	April 28, 2021 (with exclusive rights to develop, manufacture and commercialize)	2	5
CAN 106	Biologic (Cat.1 of Biological Drugs)	Anti-C5 mAb	Biliary Atresia ⁽⁴⁾	Global (U.S., Europe and China) Phase 2 initiated						WuXi Biologics / Privus	Greater China	January 7, 2019 (with exclusive rights to develop and commercialize)	0	23
CAN 103	Biologic (Cat.1 of Biological Drugs)	ERT GBA	Paroxysmal nocturnal hemoglobinuria (PNH) and other Complement Disorders ⁽⁴⁾	Singapore Phase 1 trial initiated China Phase 1 trial IND approved by NMPA						WuXi Biologics	Global / Greater China	October 25, 2018 (with exclusive rights to develop and commercialize)	0	2
CAN 107	Biologic (Cat.1 of Biological Drugs)	Anti-FGF23 mAb	X-linked hypophosphatemia	China Phase 1 trial IND approved by NMPA						WuXi Biologics / Privus	Greater China / Global (*)	January 7, 2019/March 25, 2021 (with exclusive rights to develop and commercialize)	0	2
CAN 104	Biologic	ERT GLA	Fabry Disease							WuXi Biologics	Global	January 7, 2019 (with exclusive rights to develop and commercialize)	0	0
CAN 105	Biologic	Anti-Factor DabX hexab	Fabry Disease							WuXi Biologics	Greater China	January 7, 2019 (with exclusive rights to develop and commercialize)	0	0
Undiscovered⁽⁶⁾	Gene Therapy	AAV	Neuromuscular Disorders ⁽⁶⁾							University of Maryland System	Global	September 1, 2021 (sponsored rights to develop and commercialize)	0	0
CAN 201	Gene Therapy	AAV ΔL65 GLA	Fabry Disease ⁽⁶⁾							University of Maryland System	Global	April 26, 2021 (with exclusive rights to develop, manufacture and commercialize)	0	3
CAN 202	Gene Therapy	AAV ΔL65 GNA	Pompe Disease ⁽⁶⁾							LogicBio	Global	April 26, 2021 (with exclusive rights to develop, manufacture and commercialize)	0	3
Capbio⁽⁷⁾	Medical Device ⁽⁸⁾ (Class III Medical Device)	Calcium phosphate rinse	Oral Mucositis							TESA/Pharma	China	July 20, 2018 (commercialization commenced in October 2018)	0	0
Nerlynx® (Neratinib)	Small molecule (Cat.2,1 of Chemical Drugs)	Tyrosine kinase inhibitor	HER2+ Breast Cancer HER2+ Metastatic Breast Cancer							Pierre Fabre	Hong Kong, Taiwan, Mexico ⁽¹¹⁾	February 24, 2021 (commercialization commenced in December 2019)	12	7

★ Core Product █ Clinical trials performed by license partner ▨ Next Milestone

BUSINESS

Notes:

1. Greater China includes mainland China, Hong Kong, Taiwan and Macau.
2. After in-licensing, we have completed Phase 1 trial in Taiwan and obtained IND approval for the first line GBM Phase 2 clinical trial in China, for which we dosed the first patient in October 2021.
3. After in-licensing, we obtained a clinical trial waiver on the pivotal trial and the NDA approval for Hunterase® (CAN101) for MPS II from the NMPA in September 2020.
4. Mirum received the FDA approval for CAN108 for the treatment of cholestatic pruritus in patients with ALGS in September 2021. Mirum has also filed an MAA for ALGS for CAN108 with the EMA in September 2021. After in-licensing, we have started preparation of NDA for ALGS for CAN108 and expect to file NDA in Greater China in December 2021 based on data obtained by our license partner in global studies.
5. For BA, we are supporting the patient recruitment and clinical site management in China for a global Phase 2 clinical trial initiated by our license partner in the U.S. and Europe. IND approval was obtained from the NMPA in May 2021 and we plan to begin patient enrollment in China as part of the global Phase 2 trial in the first half of 2022.
6. After in-licensing, initiated a Phase 1 clinical trial for CAN106 in Singapore in February 2021 and obtained the IND approval from the NMPA for PNH for a Phase 1 study in China in July 2021.
7. Greater China rights granted from Wuxi Biologics. Worldwide excluding Greater China rights granted from Privus.
8. The Company obtained IND approval from NMPA in October 2021 for Gaucher Disease for a Phase 1 study in China. We plan to initiate patient enrollment in the first half of 2022.
9. Gene therapy programs at lead identification stage, including two programs (CAN201 and CAN202) licensed from LogicBio and one undisclosed program with exclusive option to enter into a licensing agreement with UMass (the program name is not available yet).
10. Caphosol™ is an oral electrolyte solution and designated as a prescription medical device.
11. We have entered into a distribution agreement with Pierre Fabre pursuant to which Pierre Fabre appointed us as its distributor with exclusive rights to sell Nerlynx® (CAN030) for Pierre Fabre in Hong Kong, Macau, and Taiwan. Pierre Fabre has the exclusive rights to develop and commercialize Nerlynx® (CAN030) in Greater China.
12. Patents were granted on each drug and patent applications were filed on each drug by the collaboration partners.
13. Each category refers to different registration pathway of a drug's approval process. For the drug assets not assigned a category, they are still at early stage and the Company has not yet decided the registration process in applying for the NDA. Each assigned category is referring to the following:
 - Cat.1 of Biological Drugs: Innovative therapeutic biologics not commercialized in China or overseas;
 - Cat.3 of Biological Drugs: Domestically or overseas marketed biological products;
 - Cat.2.4 of Chemical Drugs: Drugs with new indications containing known active ingredients that are not commercialized in China or overseas;
 - Cat.3 of Chemical Drugs: Generic drugs applied by domestic applicant, with an innovative drug that has been marketed overseas but not marketed domestically. Such drugs should be consistent with the quality and efficacy of the reference listed drug;
 - Cat.5.1 of Chemical Drugs: Domestic application for an innovative drug or a modified drug that has been marketed overseas. The modified drug should have obvious clinical advantages.

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We strategically combine global collaborations and internal research to build and diversify our drug portfolio. As the Chinese rare disease market rapidly expands, many international biopharmaceutical companies are interested in accessing this growing and untapped market but lacks the local expertise. Leveraging our global collaborations and R&D capabilities, we believe we can serve as a gateway to China and a preferred partner for international biopharmaceutical companies. As of the Latest Practicable Date, our global partners include Apogenix, GC Pharma, Mirum, Wuxi Biologics, Privus, UMass and LogicBio. In 2019, we in-licensed Hunterase[®] (CAN101) from an international biopharmaceutical company, GC Pharma, which is our first commercialized rare disease product to address unmet needs in China, supported by clinical validation and marketing authorization in over 10 countries worldwide by GC Pharma. We are working with our research partner UMass on sponsored research programs to develop gene therapy solutions for neuromuscular disorders, with the exclusive option to license-in the assets for development. We also seek to replicate the model by working with China-based academic institutions. In addition, our experienced research team continues our efforts in identifying and developing drug candidates to further expand our portfolio. For example, our internal research team is developing gene therapy solutions for neuromuscular disorders.

We leverage our commercialization capabilities to maximize the market potential of our drug candidates. We established key operation hubs in Beijing and Shanghai and offices in other locations in Greater China, and plan to expand to each of the key target provinces with local offices in mainland China. We are currently expanding our targeted, in-house commercialization team, which is expected to expand into over 300 members in the next five years.

Leveraging our experienced management team, a comprehensive product portfolio and an integrated platform with access to industry leading rare disease technologies, we believe we are well positioned to capture the vast rare disease market in China and globally.

Market opportunities in the rare disease industry

The global rare disease industry is a sector of biopharmaceutical market focusing on the discovery and commercialization of medicines for the treatment of diseases which affect a small number of people, as compared with other more prevalent diseases in the general population. Driven by its unique features, the rare disease industry is considered to be a highly efficient business model. According to Frost & Sullivan, most rare diseases are caused by genetic mutations with well-defined pathology, which leads to higher probability of technical and regulatory success (“PTRS”) in the research & development (“R&D”) of rare disease drugs. Certain rare disease patients are treated at a limited number of specialized hospitals and therefore sales efforts for rare disease drugs can be much more targeted. The unique nature of rare diseases has also led to a favorable regulatory environment in various countries, such as the Orphan Drug Act in the United States, which helps accelerate the development and commercialization process of rare disease drugs.

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The global rare disease drug market has grown rapidly since 1983, when the Orphan Drug Act was first promulgated by the US FDA, which set standards for regulatory pathways that have been followed by other jurisdictions. The size of global rare disease drug market grew from US\$109.0 billion in 2016 to US\$135.1 billion in 2020, representing a CAGR of 5.5%. It is estimated to further grow to US\$383.3 billion in 2030 at a CAGR of 11.0% from 2020 to 2030. Growing awareness of rare disease has augmented the demand for special treatments, together with rising healthcare expenditure, positively impacting the rare disease treatment market growth. The U.S. and Europe remain the largest rare diseases markets globally.

The rare disease markets in developing countries are relatively underpenetrated due to limited access to diagnosis and treatments of rare diseases. The market size of rare disease drugs in China was only approximately US\$1.3 billion in 2020, far below that in the U.S or Europe. Applying the definition of rare disease used by the FDA in the U.S., the prevalence of rare diseases in China in 2019 indicates a patient pool potentially over four times larger than the U.S. according to Frost & Sullivan. The discrepancy between patient population and market size suggests significant room for rare disease drug growth in China. According to Frost & Sullivan, the rare disease drug market in China is expected to grow dramatically from US\$1.3 billion in 2020 to US\$25.9 billion in 2030 at a CAGR of 34.5%, as compared to the market growth in the U.S. and the rest of the world in the same period at a CAGR of 10.5% and 10.0%, respectively. The China rare disease drug market accounted for 0.4% and 1.0% of the global rare disease market in 2016 and 2020, respectively, and is expected to account for 6.8% in 2030, indicating favorable rare disease market outlook. With a concentrated population of untreated patients larger than that of the U.S. and Europe, China offers great opportunities for rare disease pharmaceutical companies to capture a massive market at potentially lower costs than other disease areas. In response to such significant market opportunity, many leading pharmaceutical companies such as Sanofi have launched products in China and other developing countries. We believe that companies like CANbridge is uniquely positioned to bridge the gap and provide sustainable solutions to the medical needs of global patients in an efficient manner.

In addition, the rare disease industry in China is expected to benefit from various regulatory initiatives. In recognition of the urgency for the development of effective rare disease treatment and the unique clinical challenges associated with such development, authorities in the U.S. and Europe have provided regulatory incentives and adopted special regulatory frameworks to encourage development and commercialization of drugs to treat rare diseases and to support companies with a focus on rare disease treatment. In 2018, China published the first edition of the Rare Disease List that includes 121 rare diseases, hallmarking the transformational debut of the Chinese rare disease market. Similar to the U.S. and Europe, a high degree of regulatory flexibility has been introduced to rare disease drug approval process in China, including simplified application process, flexibility in clinical trial design, higher likelihood of clinical trial waiver on the basis of overseas clinical data and post-approval clinical trials. China has also moved towards a more favorable reimbursement environment for rare diseases. After years of efforts in providing insurance mechanism of rare diseases at local level, an aggregate of 29 provinces have implemented insurance policies for rare disease with various reimbursement models. For more details, see “Industry Overview –

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Unmet Medical Needs and Market Opportunities”. In 2021, the initiation of formulation of the second edition of the Rare Disease List was announced by the National Health Commission of the PRC and more rare disease drugs are expected to be included, according to Frost & Sullivan.

Enabled by new technologies, gene therapies have become an emerging solution for rare diseases. Approximate 80% of rare diseases result from genetic disorders, according to Frost & Sullivan. Gene therapies serve as a promising solution for a broad spectrum of rare diseases by fundamentally addressing the underlying cause of the diseases. Recent advances in genetic engineering and recombinant viral vector development have ignited interest in the field, with several gene therapy products gaining approvals. The success of several pioneering clinical trials in gene therapy validated its efficacy and safety, such as SPINRAZA developed by Biogen, and Zolgensma developed by Novartis and AveXis, making targeted treatments available for spinal muscular atrophy (SMA), and thus marking the potential of gene therapies to provide solutions to rare diseases that currently have no specific therapeutic options.

OUR STRENGTHS

A rare disease focused biopharmaceutical company dedicated to addressing unmet medical needs

Our Company is a China-based, rare disease-focused biopharmaceutical company devoted to providing targeted therapies for rare disease patients in China and worldwide. As a pioneer in developing rare disease therapies in China, we contributed to developing the rare disease ecosystem in China by working closely with key stakeholders including regulatory authorities, key opinion leaders (KOLs), doctors, patients through patient registry and advocacy groups, center of excellence, as well as reimbursement and insurance institutions. At the same time, we have built a comprehensive product portfolio, an integrated platform and access to global rare disease markets, which we believe will position us to capture the vast and untapped rare disease market in China and globally.

Our Portfolio. We have built a comprehensive portfolio targeting diseases with validated mechanisms of action, consisting of biologics and small molecules solutions, addressing unmet medical needs in rare diseases and rare oncology indications. As of the Latest Practicable Date, our portfolio is comprised of three marketed products, four product candidates at the clinical stage, one at IND-enabling stage, two at preclinical stage and another three gene therapy programs at lead identification stage, featuring both innovative and validated targets with improved characteristics to maximize PTRS and commercialization opportunities. We are also one of the few R&D-driven Chinese pharmaceutical companies investing in innovative and early-stage candidates. We are actively exploring next-generation technology in gene therapy through a combination of external collaborations and in-house research. As of the Latest Practicable Date, we are using adeno-associated virus (AAV) sL65 capsid vector licensed in from LogicBio Therapeutics to develop two gene therapy products for the treatment of Fabry disease and Pompe disease, with options to develop two additional indications using the same vector and a clinical-stage gene editing program for the treatment of methylmalonic

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acidemia (MMA) pursuant to our collaboration agreements with LogicBio Therapeutics. We are also working with our research partner UMass on sponsored research programs to develop gene therapy solutions for neuromuscular disorders, with the exclusive option to license-in the assets for development.

Our Platform. We have built an in-house biopharmaceutical platform, spanning preclinical research, clinical development and commercialization. We are also developing proprietary technologies through global collaborations with leading biopharmaceutical companies such as GC Pharma and Apogenix, whose previous overseas clinical data helped us obtain a clinical trial waiver for Hunterase[®] (CAN101) and a clinical trial approval for CAN008 in China, respectively. We established a strategic partnership with WuXi Biologics to develop biologics for treating LSDs, other genetic metabolic diseases, and complement mediated diseases. We are also committed to bringing some of the most innovative therapies, such as gene therapies, to China, through collaborations with top medical companies and institutions including LogicBio Therapeutics and UMass. We are building gene therapy CMC operations with AAV research process development laboratory and pilot plants enabling translational studies in the Greater Boston area. We are also internally establishing an AAV delivery platform targeting different tissues such as central nervous system (CNS) and muscles. We believe our full-fledged platform and collaboration partnerships also afford us with opportunities to pursue drug development in rare diseases and quickly generate clinical proof-of-concept and data for global development. As we grow and scale up our infrastructure, we expect to enjoy a cost advantage which will enable us to optimize our pricing and bring our rare disease therapies to as many overseas markets as possible.

A comprehensive portfolio of rare disease focused therapies with significant revenue potential

Our Company was founded on the commitment in developing innovative therapies that address unmet medical needs in rare diseases. To that end, we strategically combine global collaborations and internal research and have built a portfolio of therapies targeting some of the most prevalent rare diseases in China with limited treatment options available, including, among others, GBM and mucopolysaccharidosis type II (MPS II or Hunter Syndrome). We acquired our first rare disease asset CAN103 for LSD, in 2018, and in-licensed Hunterase[®] (CAN101) for Hunter syndrome in 2019 as our first commercialized rare disease product to address unmet needs in China. We are further expanding our partnership in developing multiple additional product candidates and potential novel programs both in China and globally, such as the collaborative program with UMass on gene therapies.

As of the Latest Practicable Date, we had a comprehensive and differentiated portfolio of 13 drug assets with both late-stage and early-stage drug candidates, among which three are at commercial stage, four are at clinical stage, one is at IND-enabling stage, two are at preclinical stage and another three gene therapy programs are at lead identification stage.

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Selected late-stage assets

CAN008 is an artificially engineered antibody-like fully human fusion protein for the treatment of GBM. It binds to CD95L and blocks its interaction with the CD95 receptor. As our Core Product, CAN008 has demonstrated robust efficacy and favorable safety profiles in both the completed and ongoing clinical trials, presenting a potentially effective option in the treatment of GBM. A Phase 2 pivotal trial conducted by Apogenix has shown statistically significant improvements by over 50% in 4-month to 6-month progression-free survival and quality of life as well as a positive trend in overall survival in patients with relapsed GBM. We completed the Phase 1 trial in Taiwan and results show CAN008 was generally well tolerated in patients with GBM. No dose-limiting toxicity was observed and no treatment-related serious adverse events were reported. We have also obtained the IND approval for a Phase 2 clinical trial for the first-line treatment of GBM patients in mainland China and dosed in the first patient in October 2021.

Hunterase[®] (CAN101) is the first ERT approved for the treatment of Hunter Syndrome (MPS II) in China. Given that ERT is the standard of care for Hunter Syndrome and there is currently no other drug treatment available in China, we believe there is a significant market opportunity for Hunterase[®] (CAN101). We successfully received the marketing approval from China’s NMPA for Hunterase[®] (CAN101) in September 2020. Hunterase[®] (CAN101) is currently marketed in over 10 countries worldwide by GC Pharma. In a head-to-head Phase 1 study, Hunterase[®] (CAN101) demonstrated favorable efficacy as compared to Elaprase[®], a drug commonly used to treat Hunter Syndrome globally. We commercially launched Hunterase[®] (CAN101) in China in May 2021. We are currently expanding a dedicated, in-house commercialization team and expect to assemble a full-fledged commercialization team following the launch of Hunterase[®] (CAN101) in China with over 300 members in the next five years.

CAN108 (maralixibat) is an oral, minimally-absorbed agent designed to selectively inhibit apical sodium-dependent bile acid transporter (ASBT) and treat rare cholestatic liver diseases, including Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA). Maralixibat possesses an extensive safety dataset, having been evaluated in more than 1,600 human subjects. Maralixibat has been studied in a number of completed and ongoing clinical trials in ALGS and PFIC with over 120 children treated and some on study for over seven years. In ICONIC, a Phase 2b placebo-controlled randomized clinical trial conducted for ALGS by Mirum, our collaboration partner in the U.S., patients receiving maralixibat experienced significant reductions in bile acids and pruritus compared to placebo, improvements in quality of life and xanthomas and accelerated long-term growth. In INDIGO, a Phase 2 study conducted for PFIC by Mirum, our collaboration partner in the U.S., patients who responded to maralixibat were shown to have significant improvement in transplant-free survival and experienced improvements across multiple parameters including normalization of liver enzyme and bilirubin levels, decreased pruritus, and improvements in growth. Mirum obtained FDA approval for maralixibat for ALGS in September 2021.

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We have started preparation of NDA for ALGS for CAN108 and expect to file a NDA in December 2021 in mainland China and Taiwan based on data obtained by Mirum, our collaboration partner in global studies. For BA, we are supporting the patient recruitment and clinical site management in China for a Phase 2 global multi-center clinical trial initiated in May 2021 by Mirum, our collaboration partner.

CAN106 is humanized monoclonal antibody against complement C5 being developed for the treatment of complement-mediated diseases including paroxysmal nocturnal hemoglobinuria (PNH) and various other complement mediated diseases that are targeted by approved anti-C5 antibodies and other new potential indications. We have obtained global rights to develop and commercialize this drug candidate from WuXi Biologics and Privus in 2019 and 2020 respectively. Based on preclinical data, *CAN106* has demonstrated a favorable PK/PD profile and tolerability, indicating that *CAN106* has the potential to effectively inhibit C5 in patients with PNH and potentially with reduced dosing frequency. We initiated a Phase 1 clinical trial in healthy volunteers for *CAN106* in Singapore in February 2021 and obtained the IND approval from the NMPA for PNH in July 2021 for a Phase 1 study in China.

Selected preclinical stage assets

CAN105 is a treatment being developed for the treatment of Hemophilia A with significant market potential. It is a recombinant, humanized, bispecific monoclonal antibody that bridges activated factor IX and factor X to restore the function of the missing activated factor VIII, which is not expected to be affected by existing factor VIII inhibitors or induce new development of such inhibitors. *CAN105* is expected to enter preclinical research phase in the first half of 2022.

AAV Delivery Platform

In addition to our biologics and small molecules portfolio, we are also building a gene therapy platform focusing on adeno-associated virus (AAV) as our next research engine. AAV is widely recognized as a safe gene delivery vehicle with the potential as one-time durable therapy for many genetic diseases. Our first gene therapy candidate will focus on a neuromuscular disorder, with high unmet medical need and significant commercial potential. All genetic muscular dystrophies, currently have no curative treatment options, according to Frost & Sullivan. We are internally developing an AAV delivery platform targeting different tissues such as the central nervous system (CNS) and muscle, and also exploring a next generation AAV gene therapy for neuromuscular disorders through collaboration with UMass. In addition, we are also collaborating with LogicBio, a U.S. based biopharmaceutical company to develop AAV gene therapies for LSDs, including Fabry disease (CAN201) and Pompe disease (CAN202), and have obtained an option for two additional indications. We also have an option to acquire a clinical-stage gene editing program for the treatment of MMA pursuant to our collaboration agreements with LogicBio.

For more details and our other assets, please see “– Our Portfolio.”

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Extensive strategic partnerships to source innovative therapies globally

We believe we are an ideal gateway partner for global rare disease biopharmaceutical companies trying to access the Chinese market. As the growth of the Chinese rare disease market accelerates, many global biopharmaceutical companies are interested in accessing this large market but lack local expertise and resources. We offer unique “best of both worlds” value propositions with our management’s global and domestic drug development know-how, our deep expertise in rare disease drug development, comprehensive drug portfolio, and the manufacturing and commercial capabilities we are developing.

Our management and clinical development teams have vast experience working at leading multinational and domestic biopharmaceutical companies. They possess extensive experience in the Chinese and international regulatory frameworks and unique insights to the rare disease industry in China to help accelerate clinical trials, drug registration and commercialization. Furthermore, given the large pool of treatment-naive rare disease patients in China, we are well positioned to generate high quality clinical data from local trials as a valuable addition to facilitate global registration, and maintain operational efficiency given the relatively low cost of clinical trials in China. We believe our experience in sales and marketing and the reimbursement pathway will also contribute to the successful commercialization of our future drug candidates.

We have a proven track record of in-licensing innovative and validated therapies from global innovators and quickly progress through clinical development to commercialization, including but not limited to Apogenix, GC Pharma, Mirum, Wuxi Biologics, Privus, UMass and LogicBio. Since we obtained exclusive license rights in Hunterase[®] (CAN101) from GC Pharama in January 2019, our own R&D efforts led to a clinical trial waiver and NDA submission to the NMPA in July 2019. In addition, we have conducted a Phase 1 clinical trial for our late-stage drug candidate CAN008 in Taiwan, which has successfully bridged the drug candidate to Asian patients with newly diagnosed GBM on the back of the clinical data previously obtained in European trials by our partner, Apogenix. We dosed the first patient in a first line Phase 2 clinical trial for CAN008 on GBM patients in mainland China in October 2021. Given the deep patient pool in China, we contributed to generating high quality clinical data from local trials as a valuable addition to facilitate potential global registration.

Our collaborations with top international partners have also enabled us to draw on the strengths from the global science frontier. For example, we initiated two research programs in 2020 with the Horae Gene Therapy Center at the UMass for gene therapy research for rare genetic diseases, with a focus on neuromuscular conditions. We are potentially among the first China based companies to commence global-level collaboration in AAV gene therapy. In 2021, we obtained an exclusive worldwide license from LogicBio Therapeutics for a next generation capsid platform for use in gene editing and gene therapy, which further fueled our potential to extend our rare disease portfolio by integrating next-generation technology as we advance as a global leader in the treatment of rare diseases in the future.

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A rare disease platform positioned to drive rapid and comprehensive product development and market access in China and globally

We have built a platform that covers the entire spectrum of drug development functionalities, including preclinical research, clinical development, manufacturing and commercialization. Through our integration, we are able to be responsible for every stage of the drug development process, bringing our products from preclinical research through to commercialization.

Preclinical Research. Leveraging our integrated platform and industry leading CRO/CMO partners, our teams of rare disease experts and our U.S. based research team strive to bring promising therapies to China and worldwide and accelerate the drug development. Our insights on the drug ability, clinical trials and commercialization also feed into early research to cultivate promising targets with clinical and commercial potential. We plan to conduct early R&D on gene therapy in the U.S. and have opened our R&D center in Greater Boston opened in March 2021 for our in-house development of AAV platform. We are also in the process of building our AAV research and process development lab in Greater Boston area, which is expected to be opened in 2022. In addition, we plan to set up China research site in Suzhou for preclinical research, CMC, and early research, and expand further as programs enter late-stage development. The Suzhou site is expected to be opened in 2023.

Clinical Development. Apart from our preclinical research capabilities, we have also streamlined our clinical development process to accelerate registration. We have completed the Phase 1 trial on CAN008 in Taiwan in September 2018 and dosed the first patient in a Phase 2 clinical trial for the first-line treatment of GBM patients in China in October 2021. We initiated a Phase 1 clinical trial in healthy volunteers for CAN106 in Singapore in February 2021, and obtained the IND approval from the NMPA for PNH in July 2021 for a Phase 1 study. Apart from our in-house R&D capabilities, we also leverage strong relationships with governmental authorities and KOLs to enhance the efficiency and effectiveness of our drug development process. For example, opinions delivered by KOLs during the advisory board meetings we organized formed a key part of our trial waiver application for Hunterase[®] (CAN101). Similarly, we worked closely with the Center for Drug Evaluation (CDE) and secured regulatory approval for Nerlynx[®] (CAN030) (neratinib) in China in 2020. In addition, we also benefit from collaborations with global rare diseases players with a track record of drug development and regulatory success. For example, we leveraged data of pivotal trials of Hunterase[®] (CAN101) from GC Pharma and successfully obtained approval from the NMPA to directly submit NDA and have obtained waiver for clinical trials. We also leveraged overseas data from Phase 2 studies completed by Apogenix for CAN008 to obtain NMPA approval in a Phase 2 clinical trial in China and dosed the first patient in October 2021.

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Manufacturing. We have secured manufacturing capacity for selected in-licensed programs, including from third party collaboration partners such as WuXi Biologics, GC Pharma and LogicBio Therapeutics. We are also entitled to the transfer of all relevant manufacturing technologies with respect to the product for development by our third party partners, including but not limited to an upstream process and a downstream affinity purification process. We aim to balance cost-efficiency and control over quality of our drug products and will establish our in-house process development and manufacturing infrastructures. In an effort to scale up our gene therapy development, we are in the process of building our AAV process development lab in Greater Boston, which is expected to be opened in 2022, primarily for the manufacturing our gene therapy products. In addition, we are also establishing our manufacturing facilities in Suzhou, which is designed to comply with cGMP with several production lines. The Suzhou facilities are expected to be opened in 2023, which are mainly for supporting the production of CAN008 and other pipeline products.

Commercialization. With our late-stage drug candidates entering into the commercialization stage, we have established our key operation hubs in both Beijing and Shanghai with offices in other locations in Greater China, and plan to expand to each of the key target provinces with local offices in mainland China. We have already set up a commercialization team dedicated to our late-stage drug candidates that can be quickly expanded in line with our business growth to over 300 members to cover the China market for rare diseases in the next five years, comprising three major functions including marketing and sales, medical affairs and patient advocacy and assistance, with the mission to execute medical engagement plan for KOL development, promote community awareness and explore industry insights for better drug development and marketing strategy.

Management team with deep industry experience and a track record of commercializing rare disease therapies globally

We are led by a global management team of members with significant industry experience in rare diseases, spanning R&D, clinical development, regulatory, business development and commercialization, together with a track record of successfully commercializing rare disease therapies across various key markets including China, Southeast Asia, the United States, Latin America and Europe.

Our visionary founder, Chairman and CEO, Dr. Xue (Ph.D., M.B.A.), is a veteran entrepreneur over 22 years of experience in medical and pharmaceutical companies. Serving as the founding general manager of Genzyme China, he had successfully managed the launch of several life-saving drugs for the treatment of hematologic cancer and rare metabolic diseases in China, including but not limited to Thymoglobulin and Cerezyme. He is also the Deputy Director General at CHARD, Vice Chair of R&D Committee of China Pharmaceutical Innovation and Research Development Association (PhIRDA) and a member of Leadership Council of Joint Institute of Peking University Health Science Center and University of Michigan Medical School.

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Besides Dr. Xue, other key management members are also leaders in their respective fields globally or in China, heading clinical, medical, business development, commercial or corporate functions in globally renowned biopharmaceutical companies or multi-national corporations before joining us:

Dr. Gerald Cox (M.D., Ph.D), our Chief Development Strategist and interim CMO, has 21 years of biotechnology executive management experience and served as the former CMO at Editas Medicine and VP at Genzyme. He oversaw multiple global rare disease clinical development programs, including Cerdelga, olipudase alfa, Hectorol, Cerezyme, Myozyme, Aldurazyme and Elaprase at Genzyme. Having made major contributions to 4 INDs and 3 orphan drug marketing authorizations for serious and life-threatening diseases that have generated a total of over \$3.0 billion revenue for Genzyme, Dr. Cox is also the author of over 100 publications at local, regional, national and international venues for academic, patient foundation, and industry-sponsored conferences.

Mr. Glenn Hassan, our Chief Financial Officer, has more than 15 years of extensive banking, investment, and strategy consulting experience in the healthcare sector around the globe. Before joining our Company, Mr. Hassan was a director in the healthcare investment banking division at China Renaissance, where he advised prominent life science companies across Greater China and the United States on their cross-border transactions and corporate financing efforts. Mr. Hassan was also a veteran public market healthcare investor with experience at major investments firms, such as Citadel LLC and Fidelity Management & Research Company.

Dr. Yunxiang Zhu (Ph.D), our Vice President and Head of Global Research, has nearly 20 years of R&D leadership experience in the biotechnology industry. Before joining us, Dr. Zhu served as Senior Vice President at Shenogen Pharma Group, where he was responsible for company strategy in drug discovery and development, and designed more than five first-in-class bispecific and trifunctional antibody lead candidates. Before then, Dr. Zhu had over 17 years' extensive experience at Sanofi Genzyme, progressing through various positions such as principal scientist and senior director in charge of muscle disease research, during which period his research led to the invention of the second-generation ERT.

Mr. Yijun Lu, our China General Manager, is a seasoned business executive with extensive experience and outstanding performance in oncology and rare disease areas. He used to serve as oncologist at Shanghai No. 1 People's Hospital and as a senior leader with diverse roles in top pharmaceutical companies. Before joining us, Mr. Lu served as head of hemophilia and rare disease at Takeda China, where he led the launch and development of certain products related to rare diseases, such as Replagal, Vpriv, Takhzyro and Firazyr.

Mr. Marcelo Cheresky, our Chief Business Officer, has nearly 20 years of business leadership experience in the biotechnology industry. Mr. Cheresky has in-depth industry knowledge and extensive execution capabilities through his previous employments at reputable biopharmaceutical companies such as Bioverativ, Ultragenyx, Synageva Biopharma and Genzyme.

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We have a growing pool of talent to support our management team in achieving our mission to treat patients beyond borders with innovative and differentiated therapies. As of the Latest Practicable Date, we had a total of 173 employees, among whom 22 have a Ph.D. and/or M.D. degree, and more than 80% of our employees had experience working at multinational biopharmaceutical companies. Our R&D team members have an average of approximately 10 years of relevant industry experience.

Our R&D efforts are also supported by a scientific advisory board with reputable key opinion leaders in the pharmaceutical industry, covering rare disease and gene therapy, including but not limited to Dr. Mark Goldberg, Mr. Mark Bamforth and Dr. Guangping Gao. Dr. Mark Goldberg has been a member of our advisory board since 2013 and served as our Acting Chief Medical Officer from 2015 to 2018, bringing over 30 years of clinical and industry experience as a seasoned oncologist, hematologist and corporate medical/regulatory strategist. Dr. Goldberg is a medical oncologist and hematologist on the faculty of Brigham & Women’s Hospital and Harvard Medical School, a veteran biotech executive, and long-time American Cancer Society (ACS) and ACS Cancer Action Network (CAN) volunteer. He is the past-chair of the Eastern New England Area Board of the American Cancer Society and currently serves as a member of its national board of directors. Dr. Goldberg previously served on the executive management team of Synageva Biopharma from 2011 to 2014, including as Executive Vice President, Medical and Regulatory Strategy. Prior to joining Synageva, Dr. Goldberg served in various management capacities of increasing responsibility at Genzyme Corporation from 1996 to 2011, most recently as Senior Vice President, Clinical Development and Global Therapeutic Head, Oncology, Genetic Health, and as Chairman of Genzyme’s Early Product Review Board. Mr. Mark Bamforth has been a member of our advisory board since 2019. Mr. Bamforth has an industry experience of over 30 years in manufacturing complex biological products including viral vector manufacturing for gene and cell therapies. Mr. Bamforth founded Arranta Bio to build a microbiome CDMO in 2019. Previously, Mr. Bamforth founded Brammer Bio, a viral vector CDMO for cell and gene therapies. In 2010, Mr. Bamforth founded a biologics CDMO, Gallus BioPharmaceuticals, and acquired a world-class facility and team. Mr. Bamforth previously spent over 20 years in the UK and the U.S. at Genzyme, latterly running the 12-site global manufacturing operation and a pharmaceutical CMO business and serving as a corporate officer for 9 years. Dr. Guangping Gao joined us as the advisory board member for gene therapy initiative collaboration with UMass in June 2020. Dr. Gao is an internationally recognized gene therapy researcher who has played a key role in the discovery and characterization of new AAV serotypes. He currently serves as President of the American Society of Gene and Cell Therapy, Director of Horae Gene Therapy Center and Viral Vector Core, Co-director of Li Weibo Institute for Rare Diseases Research and Penelope Booth Rockwell Professor at UMass. Dr. Gao has authored over 250 research papers, six book chapters, four edited books and holds 131 patents and 221 pending applications. Dr. Gao was ranked 4th of Top 20 Translational Researchers from 2013 to 2017 by Nature Biotechnology. He is also the co-founder of Voyager Therapeutics and Aspa Therapeutics.

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Since our Company’s establishment, we have received investments from industry-leading investors, including strategic investors Wuxi AppTec, Tigermed and WuXi Biologics and financial investors such as Qiming Venture Partners, Hudson Bay, LYFE Capital, Casdin Capital, RA Capital and General Atlantic. This blue-chip investor profile is a testament to our clinical development capability, and provided us with necessary funding and resources to support our growth.

OUR STRATEGIES

Further solidify our position in the China’s rare disease ecosystem and build a global rare diseases franchise

At the forefront of driving research and clinical development of innovative rare diseases drugs and bringing established life-changing therapies from overseas markets to China, we endeavor to continue to shape the practice of diagnosis, orphan drug definition and treatment guidelines of rare diseases in China by leveraging:

Regulatory Initiative and Market Awareness: Our management team consists of industry leaders who play an active role in advancing the rare disease industry and shaping the rare disease ecosystem in China. Our founder, Dr. Xue, is the sole industry representative serving as Deputy Director General of CHARD. Dr. Xue is currently also on the editorial board of the textbook *Textbook on Rare Disease*, which is part of the textbook series for postgraduate medical students in China published under the supervision of the National Health Commission of the People’s Republic of China. Led by Dr. Xue, we have obtained the marketing authorization of our first rare disease drug Hunterase[®] (CAN101) in China and commercially launched it in China in May 2021. In addition, we obtained the IND approval for CAN103 from the NMPA in October 2021. We will also continue to connect the full range of stakeholders in the rare disease value chain to promote social awareness and to improve access to diagnosis and treatments. We support patient advocacy for rare disease funding by helping patient organization build advocacy capabilities. In addition, we have partnered with a commercial insurance service company to alleviate payment burden on eligible patients. We have initiated a Hunterase[®] patient assistance program in collaboration with a medical payment services provider to improve patients’ access to Hunterase[®], resulting in better prognosis and good quality of life. Eligible patients in the program have access to high-quality health consultation and exclusive medication consisting of 26 coupons valid for a 26-week treatment.

Our Platform: We will continue to leverage our strong capabilities across R&D, regulatory, commercial and market access to improve our platform with a specialist focus and national network in China. We will provide high quality clinical data from local trials to facilitate global registration, and maintain operational efficiency by leveraging the abundant clinical trial resources in China. As we own global rights to most of our assets, we plan to realize the value of our therapies beyond China. We will continue to leverage the cost-efficient and rapid clinical development capabilities of our fully integrated platform to produce drug candidates beyond the proof-of-concept stage and bring cost-efficient rare disease therapies to global markets.

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Our Portfolio: Since acquiring our first asset in 2014, we continue to harness strategic partnerships in China, the U.S. and the EU to expand our portfolio. We will continue to adopt a strategic approach combining in-licensing late-stage drugs for China, developing promising drugs and building a next generation global portfolio.

Drive commercialization of our late-stage assets in Greater China

We successfully received the marketing approval from China’s NMPA for Hunterase[®] (CAN101) in September 2020. Hunterase[®] (CAN101) is the first approved treatment in our rare disease portfolio and the first ERT for Hunter Syndrome in China.

As of the Latest Practicable Date, our commercialization team consisted of 81 members, which is expected to be further expanded into a team of over 300 members to cover the China market for rare diseases in the next five years. We’re building value proposition of our assets by enhancing promotion effectiveness, and expect to improve diagnosis, standard of care and patient access in collaboration with healthcare professionals. Our commercialization team comprises three major functions including marketing and sales, medical affairs and patient advocacy and assistance, with the mission to execute medical engagement plan for KOL development, promote entire community awareness and explore industry insights for better drug development strategy. Internally, our marketing team helps align the research and business sides by formulating patient-centric development strategies, and providing compliance guidance. Externally, our marketing team plans to further build up and execute medical engagement plan for KOL development, increasing community awareness and collects industry insights for better drug development strategy.

Our marketing approach is initially focused on providing education and promoting awareness of the entire rare disease community, including physicians, KOLs and patients, as means to increase the rate of diagnosis and treatment, patient advocacy and market access.

Our regional coverage to commercialize Hunterase[®] (CAN101) includes the Greater China. We are establishing the nationwide management system to facilitate the implementation of Hunter Syndrome treatment guidelines, product supply network, and develop market access and reimbursement initiatives.

In mainland China, we plan to adopt a tiered provincial market-entry approach with the goal of achieving nationwide coverage in the medium term. Our priority over the next 12 months is to initially focus on top tier provinces that have favorable reimbursement coverage and high patient volume capture. Our Beijing and Shanghai offices serve as our key operation hubs. We plan to build commercial offices in each of the key target provinces in China in the next five years.

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As we expand into tier 2 and other lower tier provinces, we plan to continue to invest in building our on-the-ground presence and coverage. We seek to strengthen our relationship with key stakeholders in each province to drive diagnosis and treatment, and also to support reimbursement negotiation into provincial formulary. For example, we are working closely with the Children’s Hospital of Zhejiang University and thought KOLs in the pediatric society, to promote, train and standardize the practice for the diagnosis and treatment for Hunter Syndrome and other rare diseases we’re targeting.

Rapidly advance and expand our portfolio

Leveraging our global R&D capabilities, we are developing a comprehensive portfolio of innovative drug candidates for rare diseases and rare oncology indications, with programs spanning preclinical, IND-enabling and clinical stages.

With the addition of Dr. Yunxiang Zhu, our Vice President and Head of Global Research and the former Head of neuromuscular diseases at Genzyme, we are intensifying our R&D efforts to rapidly advance our programs into clinical development and proof-of-concept.

We anticipate that most of our R&D activities for biologics and small molecules pipeline will be carried out in Asia in the near term, leveraging the cost effectiveness and access to a large pool of target patients with unmet needs in China. We plan to set up China research site in Suzhou with a dedicated team for preclinical research, CMC analytical operation, and early research, and expand further as programs enter late-stage development. We are also in the process of building our R&D and manufacturing facilities in Suzhou, which is designed to comply with cGMP with several production lines.

We plan to focus our R&D in gene therapy in the U.S. and have opened our R&D center in Greater Boston area in March 2021 for our in-house development of AAV platform, as well as to engage with external academic and biotech companies for potential collaborations and partnerships. We are also in the process of establishing our dedicated research facilities to host our AAV and other programs, as well as CMC plant in the Greater Boston hub, which is expected to be opened in 2022.

In rare diseases, we expect to file at least two INDs in 2021. For CAN106, an anti-C5 antibody for the treatment of multiple complement-mediated diseases, we initiated a Phase 1 clinical trial in healthy volunteers in Singapore in February 2021 and obtained the IND approval from the NMPA for PNH in July 2021 for a Phase 1 study. For CAN103, an ERT for GD, we obtained the IND approval for CAN103 from the NMPA in October 2021. We are also accelerating the preclinical development of other candidates, for CAN104, an ERT for the treatment of Fabry disease, CAN105, a bispecific antibody for Hemophilia A and CAN107, a monoclonal antibody for the treatment of XLH.

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In rare oncology, we seek to allocate appropriate resources and optimize the value for our retained oncology products including CAN008. CAN008 is currently in umbrella Phase 1/2, a clinical stage of molecularly matched targeted therapies plus radiotherapy in patients with newly diagnosed GBM without MGMT (O6-methylguanine-DNA methyltransferase) promoter methylation in Europe led by our partner Apogenix. The umbrella Phase 1/2 trial is a study to test different treatment options in cohorts using the same inclusion/exclusion criteria and primary/secondary endpoints in newly diagnosed GBM patients. Apogenix joined the umbrella study with other companies to explore the first line potential of CAN008/APG101 in the European Union but this trial has limited relation to our activities in Greater China as the GBM treatment guidelines and clinical practices differ in China and the U.S. versus the European Union. We therefore continue to lead clinical development in the Greater China. We have completed Phase 1 clinical trial in Taiwan and dosed the first patient in a first line Phase 2 clinical trial for CAN008 on GBM patients in China in October 2021. As of the Latest Practicable Date, APG101 was not yet commercialized in Europe.

Maximize value creation through partnership and collaboration

Collaboration is a key part of our growth strategy as we continue to build and diversify our rare disease portfolio. We have established multiple strategic partnerships to date and plan to continue seek complementary assets globally.

Our partnership approaches correlate with our product selection strategy to in-license late-stage drugs to address huge unmet medical needs in China, develop innovative drugs in attractive markets with reasonable cost to patients and develop next generation gene therapies in the longer term. We retain exclusive global rights to seven of our drug assets and may strategically enter into strategic collaborations or other partnerships with leading biopharmaceutical companies to accelerate our development timelines and maximize the commercial value of our product candidates in designated markets.

We continue to invest in our next-generation technology development and expand our in-house R&D activity to generate promising leads for treatment of rare diseases. In particular, we dedicate efforts in developing gene therapies, which we believe are the next innovation for the treatment of multiple rare diseases. We are a pioneer in gene therapy in China and our technology has the potential for global application. In addition to our UMass research collaborations and exclusive license obtained from LogicBio, our immediate goal and initial strategy for gene therapy are to in-license mid- to late-stage assets that can address unmet medical need in China. We aim to leverage the deep patient pool in China and our strength in clinical development to bring these products to market in the near future. In addition to our efforts to secure promising drug candidates with exclusive global rights, we are also diligently establishing our own gene therapy platform. Led by Dr. Yunxiang Zhu, our innovation center/research site in Greater Boston is designed to and has been developing the proprietary AAV engineering strategies that aims to greatly improve muscle and central nervous system (CNS) tropisms of AAV and drug candidates with global rights, with a focus in neuromuscular disease area.

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Enhance capabilities with in-house drug research, development and manufacturing infrastructure in global and Greater China markets

We are progressively building our in-house R&D platform and enhancing our in-house drug research, clinical development, business development, regulatory and marketing capabilities for rare diseases with the goal to become a fully integrated company in the long term, spanning preclinical research, clinical development and manufacturing with global market coverage.

While we continue to collaborate with our partners globally, we anticipate that most of our R&D activities will be carried out in Asia in the near term with the exception of preclinical research and pilot gene therapy CMC programs in the U.S., with the goal to localize manufacturing in China in the mid-term, as supplemented by a reliable supply chain from our manufacturing partner WuXi Biologics, LogicBio Therapeutics and alternative CDMOs. In particular, we plan to invest in our own gene therapy manufacturing and technology capabilities, including building our internal cGMP facilities to ensure quality and retain control over vector production. We are also entitled to the transfer of all relevant manufacturing technologies with respect to the product for development by LogicBio Therapeutics, including but not limited to upstream process and a downstream affinity purification processes, which we will leverage to optimize our own gene therapy manufacturing capabilities.

With established infrastructure in China, we target to expand our footprints globally. We have an experienced global management team and are building a global rare disease specialty coverage as we continue to innovate and enrich portfolio by leveraging our proprietary technologies, including small molecule, enzyme replacement, monoclonal antibody and gene therapy. Leaning towards the focus on proprietary rights in addition to in-licensing, we are actively generating in-house IP and conducting R&D to expand the development and application of our candidates to address unmet medical needs globally.

We are currently building a CMC and process development capabilities centering recombinant enzymes, antibodies and AAV gene therapy. We will seek continuous improvements and more cost-efficient options in manufacturing and quality control process with a combination of internal investment and outsourcing. For products of critical financial impact and with no replacements, we will develop and implement parallel manufacturing sites and inventory management to ensure patient safety and to mitigate any systemic risks. In gene therapy, we plan to build fully integrated gene therapy CMC operations with research laboratories and pilot plants enabling translational studies in Greater Boston area. We will continue to leverage external expertise and capacity such as those from Wuxi Biologics to build over time a robust global manufacturing and supply network to allow access of our products by patients globally.

OUR PORTFOLIO

We have built a broad portfolio of therapies targeting prevalent rare diseases, including rare oncology diseases in China with limited treatment options available. As of the Latest Practicable Date, we had built a comprehensive and differentiated pipeline of 13 products and product candidates with significant market potential, consisting of three marketed products, four drug candidates at clinical stage, one at IND-enabling stage, two at preclinical stage and another three gene therapy programs at lead identification stage.

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The following chart summarizes our portfolio and the development status of each drug asset as of the Latest Practicable Date:

Product	Modality (Drug Category, Drug Class, Drug Subclass, Drug Administration, Law) ⁽¹⁾	Mechanism	Indication	Discovery/Pre-clinical	IND-enabling	Ph I	Ph II/III	NDA	Marketed	Partner	Commercial Rights ⁽²⁾	In-licensing Date	Granted Patents FN ⁽³⁾	Pending Applications FN ⁽³⁾
★ CAN008 (Aumerept)	Biologic (Cat.1 of Biological Drugs)	CD95-Fc fusion protein	Glioblastoma Multiforme ⁽²⁾	Taiwan Phase I trial completed China Phase 2 trial initiated						apogenix	Greater China	June 26, 2015 (with exclusive rights to develop, manufacture and commercialize)	3	2
Herceptin® (CAN100) (trastuzumab beta)	Biologic (Cat.3 of Biological Drugs)	ERT, dromone-2, sulfonamide (IDS)	Hunter syndrome (Mucopolysaccharidosis type II) ⁽¹⁾							GC Pharma	Greater China	January 3, 2019 (with exclusive rights to develop and commercialize; commercialization commenced in May 2020)	1	2
CAN 108 (maralixibat)	Small molecule (ALGS, Cat.5 of Chemical Drugs, PFC; Cat.2,4 of Chemical Drugs)	ASBT-inhibitor	Alagille Syndrome ⁽⁴⁾ Progressive Familial Intrahepatic Cholestasis ⁽⁴⁾	China Pre-IND ⁽⁵⁾ China Phase 1 trial initiated and Phase 2 initiated						Amgen	Greater China	April 28, 2021 (with exclusive rights to develop, manufacture and commercialize)	2	5
CAN 106	Biologic (Cat.1 of Biological Drugs)	Anti-C5 mAb	Biliary Atresia ⁽⁶⁾	Singapore Phase 1 trial initiated China Phase 1 trial IND approved by NMPA						WuXi Biologics / Privus	Greater China / Global ⁽⁷⁾	January 7, 2019 (with exclusive rights to develop and commercialize)	0	23
CAN 103	Biologic (Cat.1 of Biological Drugs)	ERT GBA	Gaucher Disease ⁽⁸⁾							WuXi Biologics	Global	October 25, 2018 (with exclusive rights to develop and commercialize)	0	2
CAN 107	Biologic (Cat.1 of Biological Drugs)	Anti-FGF23 mAb	X-linked hypophosphatemia							WuXi Biologics / Privus	Greater China / Global ⁽⁷⁾	January 7, 2019 (with exclusive rights to develop and commercialize)	0	2
CAN 104	Biologic	ERT GLA	Fabry Disease							WuXi Biologics	Global	January 7, 2019 (with exclusive rights to develop and commercialize)	0	0
CAN 105	Biologic	Anti-Factor DabX	Hemophilia A							WuXi Biologics	Greater China	January 7, 2019 (with exclusive rights to develop and commercialize)	0	0
Undiscovered⁽⁹⁾	Gene Therapy	AAV	Neuromuscular Disorders ⁽⁶⁾							University of Maryland System / Privus	Global	September 1, 2021 (sponsored partner rights)	0	0
CAN 201	Gene Therapy	AAV ΔL65 GLA	Fabry Disease ⁽⁶⁾							University of Maryland System	Global	April 26, 2021 (with exclusive rights to develop, manufacture and commercialize)	0	3
CAN 202	Gene Therapy	AAV ΔL65 GNA	Pompe Disease ⁽⁶⁾							LogicBio	Global	April 26, 2021 (with exclusive rights to develop, manufacture and commercialize)	0	3
Capbio⁽¹⁰⁾	Medical Device ⁽¹⁰⁾ (Class III Medical Device)	Calcium phosphate rinse	Oral Mucositis							TESA/Pharma	China	July 20, 2018 (commercialization commenced in October 2018)	0	0
Nerlynx® (Neratinib)	Small molecule (Cat.3.1 of Chemical Drugs)	Tyrosine kinase inhibitor	HER2+ Breast Cancer HER2+ Metastatic Breast Cancer							Pierre Fabre	Hong Kong, Taiwan, Mexico ⁽¹¹⁾	February 24, 2021 (commercialization commenced in December 2019)	12	7

★ Core Product █ Clinical trials performed by license partner ▬ Next Milestone

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Notes:

1. Greater China includes mainland China, Hong Kong, Taiwan and Macau.
2. After in-licensing, we have completed Phase 1 trial in Taiwan and obtained IND approval for the first line GBM Phase 2 clinical trial in China, for which we dosed the first patient in October 2021.
3. After in-licensing, we obtained a clinical trial waiver on the pivotal trial and the NDA approval for Hunterase® (CAN101) for MPS II from the NMPA in September 2020.
4. Mirum received the FDA approval for CAN108 for the treatment of cholestatic pruritus in patients with ALGS in September 2021. Mirum has also filed an MAA for ALGS for CAN108 with the EMA in September 2021. After in-licensing, we have started preparation of NDA for ALGS for CAN108 and expect to file NDA in Greater China in December 2021 based on data obtained by our license partner in global studies.
5. For BA, we are supporting the patient recruitment and clinical site management in China for a global Phase 2 clinical trial initiated by our license partner in the U.S. and Europe. IND approval was obtained from the NMPA in May 2021 and we plan to begin patient enrollment in China as part of the global Phase 2 trial in the first half of 2022.
6. After in-licensing, initiated a Phase 1 clinical trial for CAN106 in Singapore in February 2021 and obtained the IND approval from the NMPA for PNH for a Phase 1 study in China in July 2021.
7. Greater China rights granted from Wuxi Biologics. Worldwide excluding Greater China rights granted from Privus.
8. The Company obtained IND approval from NMPA in October 2021 for Gaucher Disease for a Phase 1 study in China. We plan to initiate patient enrollment in the first half of 2022.
9. Gene therapy programs at lead identification stage, including two programs (CAN201 and CAN202) licensed from LogicBio and one undisclosed program with exclusive option to enter into a licensing agreement with UMass (the program name is not available yet).
10. Caphosol™ is an oral electrolyte solution and designated as a prescription medical device.
11. We have entered into a distribution agreement with Pierre Fabre pursuant to which Pierre Fabre appointed us as its distributor with exclusive rights to sell Nerlynx® (CAN030) for Pierre Fabre in Hong Kong, Macau, and Taiwan. Pierre Fabre has the exclusive rights to develop and commercialize Nerlynx® (CAN030) in Greater China.
12. Patents were granted on each drug and patent applications were filed on each drug by the collaboration partners.
13. Each category refers to different registration pathway of a drug's approval process. For the drug assets not assigned a category, they are still at early stage and the Company has not yet decided the registration process in applying for the NDA. Each assigned category is referring to the following:
 - Cat.1 of Biological Drugs: Innovative therapeutic biologics not commercialized in China or overseas;
 - Cat.3 of Biological Drugs: Domestically or overseas marketed biological products;
 - Cat.2.4 of Chemical Drugs: Drugs with new indications containing known active ingredients that are not commercialized in China or overseas;
 - Cat.3 of Chemical Drugs: Generic drugs applied by domestic applicant, with an innovative drug that has been marketed overseas but not marketed domestically. Such drugs should be consistent with the quality and efficacy of the reference listed drug;
 - Cat.5.1 of Chemical Drugs: Domestic application for an innovative drug or a modified drug that has been marketed overseas. The modified drug should have obvious clinical advantages.

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Our drug candidates are subject to NDA approval by the relevant authorities, such as the NMPA, before commercialization in the relevant jurisdictions. As of the Latest Practicable Date, we had not received any material concerns, objections or negative statements raised by the NMPA or other relevant authorities that we are not able to address in a timely manner. We believe we are on track to advance the development of our clinical-stage drug candidates as described in “– Our Portfolio.”

Late Stage Drug Products and Candidates

CAN008 CD95-Fc fusion protein for GBM

Overview

CAN008, our Core Product, is a glycosylated CD95-Fc fusion protein being developed for the treatment of GBM. We commenced a Phase 1 trial of CAN008 in combination with radiation therapy (RT) and temozolomide (TMZ) in patients with newly diagnosed GBM since September 2016 in Taiwan under the authorization of the Taiwan Food and Drug Administration (“TFDA”). A Phase 2 trial of CAN008 was completed by Apogenix AG (Apogenix) in recurrent GBM in Europe in September 2014. We completed the Phase 1 trial in Taiwan in September 2018 after 24 months of clinical research and development and results show CAN008 was generally well tolerated in patients with GBM. No dose-limiting toxicity was observed and no treatment-related serious adverse events were reported. We, on the back of the data obtained from the Phase 1 trial in Taiwan and results from the Phase 2 trials completed overseas by Apogenix, received the IND approval for CAN008 from the NMPA in March 2018 for a second-line Phase 2 trial and subsequently amended our IND application to a first-line Phase 2 trial based on the positive preliminary efficacy results obtained in the Phase 1 trial in Taiwan, which suggested the potential of CAN008 to become a standard-of-care treatment. We received the approval for a first-line Phase 2 trial in China on patients with GBM in April 2021 and dosed the first patient in a first line Phase 2 clinical trial for CAN008 on GBM patients in China in October 2021.

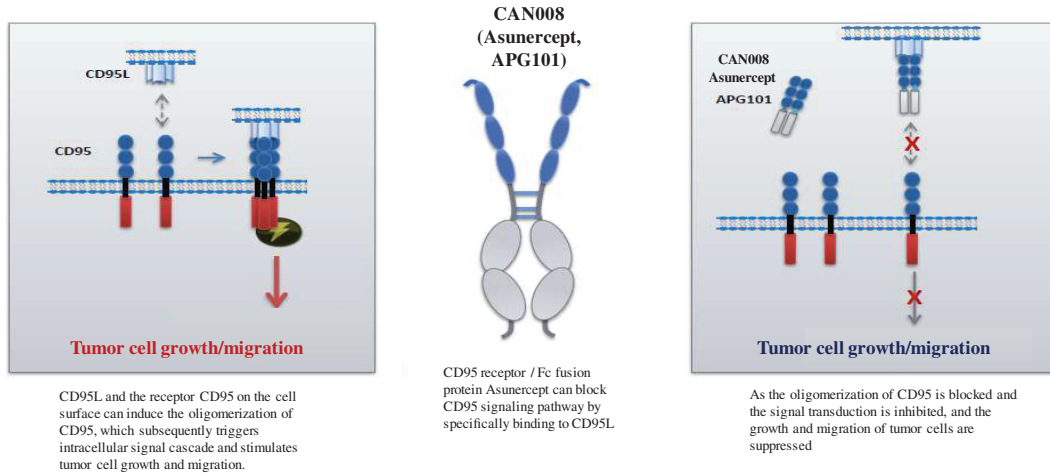
Mechanism of Action

CD95 (Fas/APO-1), a death receptor family member, has been linked to tumorigenicity in multiple cancers, including GBM. Binding of CD95 ligand (CD95L) to the CD95 receptor on the cell surface induces multimerization of CD95, which triggers an intracellular signaling cascade, resulting in stimulation of tumor cell growth and migration.

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CAN008 is an engineered fully human CD95-Fc fusion protein that binds to CD95L, thus blocks its interaction with the cognate CD95 receptor. As such, signal transduction triggered by CD95- multimerization is inhibited, thereby reducing the invasive growth and migration of tumor cells. In addition, CAN008 also blocks the apoptosis of T cells by inhibiting CD95/CD95L engagement on T cells to restore immune function.

The diagram below illustrates the mechanism of action of CAN008:



Source: Company data

Market Opportunity and Competition

GBM is a fast-growing glioma that develops from glial cells (astrocytes and oligodendrocytes) or their precursors that support the health of the nerve cells within the brain. It is the most common and malignant type of glioma in adults. About 45% of gliomas are glioblastoma multiforme, which is classified as Grade IV (most serious) astrocytoma, is the most common and aggressive brain cancer where a large portion of tumor cells are reproducing and dividing at any given time, with an estimated 5-year survival of 5.5% globally and below 5% in China. The tumor is predominantly made up of abnormal astrocytic cells, but also contain a mix of different cell types (including blood vessels) and areas of dead cells (necrosis). GBM is infiltrative and is the most invasive type of glial tumors, rapidly growing and commonly spreading into nearby brain tissue. It can also sometimes spread to the opposite side of the brain through connection fibers (corpus callosum). GBM is characterized as a disease with one of the highest unmet needs in oncology, with patients having a median overall survival between one and two years.

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Although GBM is a rare oncology with lower incidence as compared to the other cancer types, the high level of unmet need in this market creates ample opportunities for players with effective therapies. GBM is the most common malignant tumor of the central nervous system and is the most common and aggressive brain cancer. The incidence of GBM represents 46.6% of the total brain cancer incidence in China and has reached 54.7 thousand in 2020 with a CAGR of 2.0% from 2016 to 2020. With factors including increasing aging population, ionizing radiation and air pollution, the incidence of GBM in China is expected to grow to 59.8 thousand in 2025 and 64.4 thousand in 2030.

The standard of care for GBM consists of surgical resection, adjuvant chemotherapy with temozolomide (TMZ). However, radiation and chemotherapy always come with adverse events that greatly undermine the life quality of patients. In addition, tumor cells may develop some resistance to TMZ. Current GBM therapies have limited improvement in progression-free survival (PFS) with an estimated 5-year survival of 5.5% globally and below 5% in China. The current therapy treatment options for GBM in China include surgery and radiotherapy combined with TMZ concurrent chemotherapy.

The fusion protein developed in CAN008 has competitive advantages in the treatment of GBM over other treatment options, including a validated novel mechanism of action, improved efficacy and potential for combination therapy. We are developing CAN008 as a first-line therapy for GBM, which is the most common and invasive primary brain tumor. GBM has a high unmet medical need with a long-term survival rate around only 5% at the current standard of care. Other approved therapies for GBM have shown only marginal improvements in outcomes or face a restricted label. Our Phase 1 study of CAN008 in addition to the standard of care in newly diagnosed GBM patients showed a remarkable PFS at 12 months of 57% at the 400 mg dose. This outcome is approximately twice as high as those reported in the literature for the standard of care (25%) and tumor-treating fields (30%). As a targeted biological therapy that avoids many of the adverse events associated with non-specific chemotherapies, we believe that CAN008 has the potential to be a transformational therapy for newly diagnosed GBM. CAN008 has been well tolerated with a favorable safety profile and promising efficacy in multiple clinical trials, highlighting its potential to play a significant role in GBM treatment. For details on the competitive landscape of targeted therapies for GBM, see “Industry Overview – Glioblastoma Multiforme (GBM)”.

Summary of Clinical Trial Data

Phase 1 Clinical Trial in Taiwan Conducted by CANbridge

Overview: The Phase 1 trial was an open-label, single-arm, dose escalation study that enrolled 10 patients with newly diagnosed and surgically accessible GBM with the goal to investigate the safety, pharmacokinetics, tolerability, preliminary efficacy and seek recommended dosage for the Phase 2 trial of CAN008 in combination with RT and TMZ. Study results demonstrated that CAN008 was generally well tolerated in patients with GBM. No dose-limiting toxicity was observed and no treatment-related serious adverse events were reported. The results of this study provide supportive information and implications for the future approach to study the add-on treatment of CAN008 for newly diagnosed GBM in the Asian populations.

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Trial Design: All 10 patients were Asian, 8 were male and 2 were female, age ranged from 34 to 73 years. The primary objective of the Phase 1 trial is to evaluate the safety and tolerability of CAN008 when administered in combination with RT and TMZ. The secondary objectives of the Phase 1 trial include to evaluate the pharmacokinetics and preliminary efficacy of CAN008 when administered in combination with RT and TMZ and to evaluate the recommended dosage for the Phase 2 trial. As a part of standard care for GBM treatment, patients received 60 Gy radiation therapy, with 2 Gy/day from Monday to Friday, 10 Gy/week, for a total of 30 radiation treatments (about 6 weeks). The study consisted of three phases: a screening phase of approximately 4 weeks, the first treatment phase of CAN008 in combination with RT and TMZ for 7 weeks with weekly visits, followed by the second treatment phase of CAN008 with concomitant TMZ every four weeks until disease progression. Patients were assigned to two treatment cohorts: 200mg weekly for the first cohort and 400mg weekly for the second cohort. The study included a dose escalation scheme to identify dose limiting toxicity and adverse events.

Trial Status: The study was initiated in September 2016 and completed in September 2018.

Safety Data: No specific safety issue was observed by CAN008 treatment in combination with RT and TMZ and no anti-drug antibodies were detected. There were two patients in Cohort 2 who reported serious adverse events (SAEs) – one with hemorrhoids and the other with seizure, which were considered not related to any study treatment and both patients recovered. There was no case of discontinuation due to treatment-emergent adverse events and no patients in the Phase 1 trial experienced dose-limiting toxicity. No patients in the study experienced DLT. Taken together with the efficacy results, the maximum administered dose of CAN008 at 400 mg weekly was recommended as the RP2D by the safety monitoring committee (SMC).

Efficacy Data: The efficacy of CAN008 concurrent treatment with chemo-radio therapy for newly diagnosed GBM was evaluated by progression-free survival (“PFS”). In Cohort 1, the PFS rates were both 33.33% at 3 and 6 months after the dose, and all patients in Cohort 1 experienced disease progression within 9 months. In Cohort 2, the PFS rate at 3 months was 71.42%, whereas PFS rates at 6, 9, and 12 months were all at 57.14%. The median PFS was 2.37 months for Cohort 1 patients. Median PFS was not evaluable for Cohort 2 since 4 patients had ongoing treatment without disease progression at the time of data cutoff on September 28, 2018. Whereas methylation of the O6-methylguanine-DNA methyltransferase (MGMT) gene did not correlate with the efficacy of CAN008, low methylation of CpG2 in the CD95L gene promoter and higher CD95L protein expression correlated with the efficacy of CAN008, suggesting that they could be used as predictive biomarkers to screen patients who will benefit more from CAN008 treatment.

We strategically chose to complete Phase I clinical trial of CAN008 in Taiwan because (i) while the technical requirements, R&D preparation and standards and effort of conducting and completing its trial in Taiwan and Mainland China would be substantially the same, getting the requisite approval to carry out the trial in Taiwan was faster; (ii) The Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs (海峽兩岸醫藥衛生合作協議) (“Cross-Strait

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Agreement”) formalized the interchangeable use of certain data from clinical trials across Mainland China and Taiwan, which covered data such as data obtained during the Phase I clinical trial of CAN008 in Taiwan. As a result, the clinical data generated by a Phase I trial of CAN008 in Taiwan could be submitted to the NMPA to support an IND application for commencement of Phase II clinical trials in Mainland China.

We believe the Phase I clinical trial of CAN008 in Taiwan is equivalent to the Phase I clinical trial conducted in Mainland China in all material aspects under the regulation of NMPA based on communications with NMPA. The Phase I clinical trial of CAN008 contained all principal criteria of a typical Phase I trial conducted under the NMPA, including pharmacokinetics and pharmacodynamics and safety.

As advised by our PRC counsel, prior consultation with the NMPA for the plan to use the clinical trial data from Taiwan and overseas is not mandatorily required in China by any laws and regulations. However, we orally communicated the plan to conduct a Phase I trial in Taiwan and use such data to support the IND approval in Taiwan with the NMPA and received positive feedbacks in July 2016. We also voluntarily included such information when we submitted the application materials for a meeting with the NMPA in September 2016. Such application materials had set out, amongst others, the design of the Phase I trial in Taiwan, that the Phase I trial would be carried out and that the trial data from Taiwan would be used to support clinical trials in Mainland China. The NMPA accepted the Company’s data from the Phase I trial of CAN008 in Taiwan to support the Company’s IND application for commencement of Phase II clinical trials in Mainland China. The Cross-Strait Agreement provides that data from clinical trials conducted at certain Taiwanese hospitals can be directly admitted for NDA filings in Mainland China which would reduce repetitive clinical trials. The NMPA has acknowledged that the Phase I trial of CAN008 by the Company had been conducted in drug clinical trial organizations identified under the Cross-Strait Agreement. In addition, NMPA and TFDA are both members of the ICH. The Phase I clinical trial of CAN008 was conducted in accordance with GCP and ICH guidelines mutually recognized in Mainland China and Taiwan. As a result, the NMPA has noted in its communication with the company that clinical trial design in Mainland China and Taiwan is highly consistent and bore scientific continuity, and results from the Phase I trial in Taiwan could be accepted for the IND application, which demonstrates that the Phase I clinical trial of CAN008 in Taiwan is equivalent to the Phase I clinical trial conducted in Mainland China in all material aspects under the regulation of the NMPA.

In addition, in conducting the Phase 1 trial in Taiwan, we referred to the safety data collected by Apogenix in its Phase 2 trial in Europe. Study results in the Phase 1 trial conducted by us in Taiwan demonstrated that CAN008 was generally well tolerated in Asian patients with GBM, indicating no material ethnicity difference between European and Asian patients in terms of safety data. We determined to administer 400 mg weekly in the Phase 1 trial conducted by us in Taiwan and confirmed it to be the RP2D. As we target to first commercialize CAN008 in China as a first-line treatment, the data collected in Taiwan on Asian patients is critical. Based on the data above, the NMPA granted the IND approval in April 2021.

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International Phase 2 Randomized Clinical Trial Conducted by Apogenix

Overview: The Phase 2 trial (NCT01071837) was a multicenter, randomized, open-label controlled study in recurrent glioblastoma (GBM) patients at first or second progression of the disease, to investigate efficacy and safety of APG101/asunercept (name of CAN008 outside Greater China). The trial compared the efficacy and safety of a combination therapy of CAN008 (asunercept) and radiotherapy versus radiotherapy (rRT) alone in recurrent GBM patients experience first or second progression of the disease and were candidates for a reirradiation. Study results show improvements in progression-free survival at 6 months (PFS6): 12 patients (20.7%, 95% confidence interval (CI), 11.2 – 33.4) for rRT + CAN008 (asunercept) and 1 patient (3.8%, 95% CI, 0.1 – 19.6) treated with rRT (P=0.048). Recently published longitudinal analysis of quality of life (QoL) demonstrated that treatment with CAN008 (asunercept) + rRT significantly prolongs time to deterioration and maintains QoL versus rRT alone in recurrent glioblastoma patients. Study results support demonstrating the potential efficacy of CAN008 (asunercept) in the treatment of recurrent GBM patients. An update on overall survival of patients has revealed that 7% of asunercept/radiotherapy-treated recurrent glioblastoma patients were alive after 5 years compared to 0% of the patients treated with radiotherapy alone. Patients displaying a low level of methylation responded best to asunercept therapy (hazard ratio 0.19, 95% CI 0.06 – 0.58). There was a significant survival benefit for patients with low methylation when treated with a combination of asunercept and radiotherapy vs radiotherapy alone (HR 0.34, p=0.024), suggesting differential CD95L promoter methylation may represent a potential biomarker to predict response to asunercept treatment. During treatment with CAN008 (asunercept), no product-related serious adverse events were observed, indicating acceptable safety profile and good tolerability of CAN008 (asunercept).

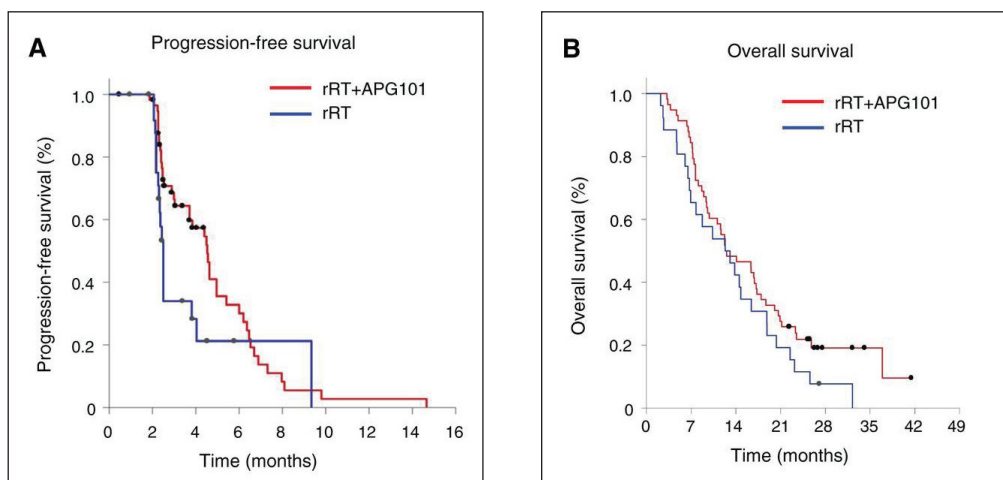
Trial Design: The study (NCT01071837) followed a Simon two-stage design. The study was approved by the ethics committees (EC) of all 25 participating sites. Patients were centrally randomised 1:2 to receive rRT (36 Gy) along or rRT (36 Gy) in combination with CAN008 (asunercept) 400 mg weekly until progression. Treatment following disease progression was recorded. In this open-label, multinational trial, the first 9 patients constituted a predefined run-in phase to evaluate the safety of rRT + CAN008 (asunercept). An independent Data and Safety Monitoring Board (DSMB) reviewed all relevant patient data after completion of the rRT and endorsed further accrual to the trial. CAN008 (asunercept) was given at 400 mg weekly as a 30-minute i.v. infusion.

Trial Status: The study was commenced in December 2009 and completed in October 2014.

Safety Data: Most patients tolerated both treatments well. 84.6% of patients in the rRT armed received the planned treatment while 98.3% in the rRT + CAN008 (asunercept) arm received the planned treatment.

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Efficacy Data: The primary endpoint was the proportion of patients free of progression and alive at 6 months (PFS-6), calculated in days from randomization. In the control arm, rRT resulted in a PFS-6 rate of 3.8% (95% – CI: 0.1 – 19.6), i.e. one patient was free of progression, whereas PFS-6 in the rRT + CAN008 (asunercept) arm was 20.7% (95% – CI: 11.2 – 33.4), i.e. 12 patients, one less than prespecified, were free of progression. The difference in PFS-6 rates was 16.9% (95% – CI: 4.1 – 29.6, $p=0.0485$, Chi-Square test). The median PFS was 2.5 months in the rRT arm, as compared to 4.5 months in the rRT + CAN008 (asunercept) arm (Fig A). As demonstrated by the charts below, CAN008 (asunercept) achieved improvements of over 50% in 6-month progression-free survival, as well as a positive trend in overall survival in biomarker positive patients with relapsed GBM.



Source: Wick et al. *Clin Cancer Res* 2014; 20:6304-6313

Licensing

We entered into a license agreement with Apogenix on June 26, 2015 as amended by the First Addendum Agreement in December 2015, under which Apogenix granted us the exclusive rights to develop, manufacture and commercialize CAN008 (APG101) in Greater China. For details, please refer to “– Collaboration and Licensing Arrangements.”

Our R&D Efforts since In-Licensing

Since in-licensing CAN008 from Apogenix in June 2015, we have led all R&D strategy and been primarily responsible for all clinical development activities related to CAN008 in Greater China, which includes the biomarker study, the Phase 1 study, and the first line Phase 2 study. We have engaged in substantial R&D work for more than 12 months on CAN008, primarily including:

- (a) From July 2015 to January 2016, we completed a biomarker study for expression of CD95L, the first of its kind in China, in over 60 Chinese patients with GBM. We led the strategy and study design, prepared the protocol, closely monitored the

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execution and finalized the study reports. The biomarker study confirmed the existence of CD95L in Chinese GBM patients and demonstrated a high degree of consistency of CD95L expression between geographically diverse Chinese and Western GBM patients;

- (b) From April 2016 to July 2016, we consulted a CRO on managing clinical trials in Taiwan and their experience with going through TFDA consultation, researched and compared contract research organizations and engaged another CRO to support the project management of the Phase 1 trial of CAN008 in Taiwan. We were fully responsible for the trial design, trial operation and data analysis of this Phase I trial. We also prepared pre-IND materials for communications with the TFDA. We submitted the Taiwan IND application in March 2016 and received approval from the TFDA in July 2016.
- (c) From September 2016 to September 2018, we completed a Phase 1 trial of CAN008 in combination with RT and TMZ in 10 patients with newly diagnosed GBM in three hospitals in Taiwan under the authorization of the TFDA: Chang Gung Memorial Hospital, Linkou, National Taiwan University Hospital and Tri-Service General Hospital. We sponsored the Phase 1 study and our company's medical monitor was responsible for writing the study protocol, providing medical input during the study, and assuring that the clinical report accurately results of the study carried out at three sites in Taiwan. Several CROs supported us in conducting the study with responsibility over clinical operational tasks such as study management, pharmacovigilance, pharmacokinetics, and anti-drug antibody analyses. On the back of the Phase 1 trial, we filed an IND application with the NMPA in June 2017, which was accepted in July 2017. In applying for IND, we were responsible for all regulatory interactions with the NMPA's CDE and led pre-IND consultation, protocol design, medical advisory board and IND dossier preparation.
- (d) Since April 2016, in parallel with the Phase 1 trial of CAN008 in Taiwan, we have invested significant development efforts into the chemistry and manufacturing and control (CMC) tech transfer of CAN008 to manufacture it in China. For example, it underwent antibody effector function testing. A 30-month stability test was also included to extend batch stability monitoring of CAN008.
- (e) Since we received IND approval from the NMPA for CAN008's Phase 2 trial in March 2018, we have continued to dedicate extensive R&D efforts into the preparation of the trial, including:
 - (i) engaging experts from over 15 hospitals in China and Europe, to evaluate and refine the clinical trial protocol design;
 - (ii) assessing 9 clinical trial sites for potential participation in the trial based on their patient flow, medical capabilities and doctors' experience; and

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- (iii) holding site-initiation visits at Beijing Tiantan Hospital, Tianjin Medical University General Hospital, Huashan Hospital Fudan University, Peking Union Medical College Hospital, Tongji Medical College of Huazhong University of Science & Technology and Harbin Medical University Cancer Hospital, and discussed with principal investigators on study design, safety monitoring and mitigation plan, efficacy endpoints, as well as patient screening and enrollment.
- (iv) engaging a reputable Chinese CRO in December 2020 in preparation of our multi-center, randomized, double-blind, and placebo-controlled Phase 2 clinical trial, for which we design the trials, oversee clinical processes, monitor CRO’s performance, and jointly share responsibility with the CRO for protocol development and investigational product management while the CRO will be responsible for clinical monitoring, pharmacovigilance, medical monitoring and data management.
- (f) We had a team of 9 members, 11 members and 17 members for the research and development of CAN008 for the year ended 2019, 2020 and the six months ended June 30, 2021, respectively, covering the full life cycle of drug development including pre-clinical research, clinical operation, regulatory affair, CMC development, quality assurance, medical assistance and project management. For the Phase 2 trial of CAN008 planned in China, we currently have a dedicated clinical team of four members led by a clinical operation leader with over 10 years industry experience responsible for developing operational plans based on corporate milestones and overseeing clinical operational quality. One of these four members joined us in 2015 and the other three joined in the past two years after the completion of Phase I trial in Taiwan. These four members have been involved in the research and development since they joined us, whose responsibilities include but not limited to study design, clinical operation, data and IP management, and project management.

Clinical Development Plan

While the Phase 2 trial previously approved by the NMPA was for a second-line trial, we submitted updated Phase 2 first-line clinical trial application for CAN008 in December 2020 and have received CDE clearance in April 2021. The Phase 2 trial is a mandatory trial required by the NMPA. We will independently develop CAN008 in China, and Apogenix will only play a passive role in the development process of CAN008 in China. We have engaged an industry leading CRO for the Phase 2 clinical trial, for which we will design the trials, provide guidance to the CRO’s activities, oversee clinical processes, monitor CRO’s performance, while the CRO will be responsible for clinical monitoring, pharmacovigilance, medical monitoring and data management. We have also engaged a CMO to produce raw materials for the trial. We dosed the first patient in a first-line Phase 2 clinical trial for CAN008 on GBM patients in China in October 2021. It is designed to be multi-center, randomized, double-blind and placebo-controlled to investigate the efficacy and explore the correlation of different

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biomarkers with treatment outcome. The trial will compare standard-of-care (tumor removal, followed by RT plus TMZ) with placebo, to standard-of-care with CAN008. At this stage, we primarily target to commercialize CAN008 in mainland China first.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN008 SUCCESSFULLY.

Hunterase[®] (CAN101) targeting MPS II/Hunter syndrome

Overview

Hunterase[®] (CAN101) is an ERT for the treatment of mucopolysaccharidosis type II (“MPS II” or “Hunter syndrome”). We in-licensed Hunterase[®] (CAN101) from GC Pharma (or “GC”) in January 2019. Multiple clinical trials have been conducted to date by GC to evaluate the safety and efficacy of Hunterase[®] (CAN101), including the pivotal Phase 1/2 trial for the approval from MFDS and certain post-approval studies. The pivotal study indicated significant subject benefit, a significant decrease in uGAG level from baseline, and an improvement in the primary endpoints. Hunterase[®] (CAN101) is currently marketed in over 10 countries worldwide by GC Pharma. It received marketing authorization as an orphan drug from the MFDS in January 2012. As of the Latest Practicable Date, Hunterase[®] (CAN101) has received marketing authorization from authorities in Algeria, Belarus, Kazakhstan and Russia and has been available for prescription in Brazil, Egypt, India, Malaysia, Oman, Turkey and Venezuela, for treatment of Hunter syndrome. We obtained a clinical trial waiver and the NDA approval for Hunterase[®] (CAN101) for MPS II from the NMPA in September 2020.

Mechanism of Action

MPS II, also known as Hunter syndrome, is an X-linked lysosomal storage disorder caused by deficient or defective activity of iduronate-2-sulfatase (IDS), which cleaves O-linked sulfate moieties from two human glycosaminoglycans (GAG), dermatan sulfate and heparan sulfate. In the absence of or with deficient activity of IDS, these GAGs accumulate in almost all body organs and tissues including the brain, heart, lung, bone, muscle, gut, and skin. Accumulation of GAG leads to cellular engorgement, organomegaly, tissue destruction, and organ system dysfunction.

Currently, there is no cure for Hunter syndrome. ERT is recommended as the standard of care by worldwide treatment guidelines and expert consensus. ERT provides exogenous IDS enzyme for uptake into cellular lysosomes through the binding of M6P residues on its oligosaccharide chains to M6P receptors on the cell surface, leading to cellular internalization of the enzyme, targeting to intracellular lysosomes, and subsequent catabolism of accumulated GAG. ERT is effective in delaying disease progression, clearing accumulated GAG, controlling symptoms and disease manifestations, such as organ enlargement, decreased cardiac, respiratory system and bone functions, and has been proven to improve health outcomes of patients with Hunter syndrome.

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Hunterase[®] (CAN101) is a purified form of recombinant human iduronate-2-sulfatase (rhIDS) produced in CHO DG44 cells using a serum-free process. It is an ERT that acts via specific uptake into lysosomes and subsequent degradation of GAGs that accumulate in the cells of patients with a deficiency in IDS enzyme.

Market Opportunity and Competition

Hunter syndrome or MPS II is a lysosomal storage disorder caused by the deficiency of iduronate-2-sulfatase (IDS), which leads to a massive accumulation of GAG and a wide variety of symptoms. MPS II is a rare, disabling and life-threatening genetic disease. Patients appear healthy at birth, with initial symptoms appearing between 18 months and 4 years of age. Life expectancy of patients with severe MPS II (60%-80% of cases) is significantly reduced, with death occurring generally before the age of 15 as a result of cardio-respiratory complications. In East Asian countries, MPS II is the most prevalent MPS disorder, occurring in an estimated 1.57/100,000 in newborn. According to Frost & Sullivan, the MPS II market in China remains stable as it is a genetically-related rare disease but with limited treatment options. The prevalence of MPS II in Greater China reached 8,005 in 2020 and is estimated to reach 8,175 in 2030.

The treatment of MPS II was palliative prior to the introduction of ERT. The first ERT for MPS II is Elaprase approved by the FDA in 2006. While ERT is the standard of care, there is currently no treatment available in China, with Elaprase being added to the “Second list of drugs urgently needed in China” in March 2019. Compared to Elaprase, Hunterase[®] (CAN101) has shown higher specific enzyme activity with significant reduction in the urinary GAG (uGAG) level and increase in the 6-MWT in clinical settings. We also believe that the serum-free production process of Hunterase[®] (CAN101) is more efficient than Elaprase, which eliminates the infectious agents transmitted in blood.

With Hunterase as the only approved treatment in China and an estimated number of over 8,000 patients countrywide in 2020, there is a high level of unmet need and the Chinese government has included MPS II on the “National Rare Disease List” as a disease group to target. We are planning to enroll Hunterase[®] in national and provincial reimbursement drug lists in China over the next few years. We have submitted the application to the national reimbursement drug list (NRDL) this year and are targeting 13 provinces for provincial reimbursement drug lists (PRDL). Hunterase is the only approved drug for MPSII treatment in China so it does not face competitors on the NRDL yet. For details on the competitive landscape of targeted therapies for MPS II, see “Industry Overview – Mucopolysaccharidosis Type II (MPS II or Hunter syndrome)”.

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Summary of Clinical Trial Data

Multiple clinical trials have been conducted to date by GC to evaluate the safety and efficacy of Hunterase[®] (CAN101), including the pivotal Phase 1/2 trial for the approval from MFDS and certain post-approval studies. The pivotal study indicated significant subject benefit, a significant decrease in uGAG level from baseline, and improvement in the primary endpoints. The ongoing trials continue to investigate the long-term safety and efficacy, and have obtained positive interim results.

Selected Completed trials: Phase 1/2 trial

Overview: The Phase 1/2 trial indicated favorable efficacy of Hunterase[®] (CAN101) through a significant decrease in Urine GAG (uGAG) level from baseline, and improvements in the primary endpoints including the 6-MWT. It has also validated the safety profile of Hunterase[®] (CAN101) by the well tolerance in patients.

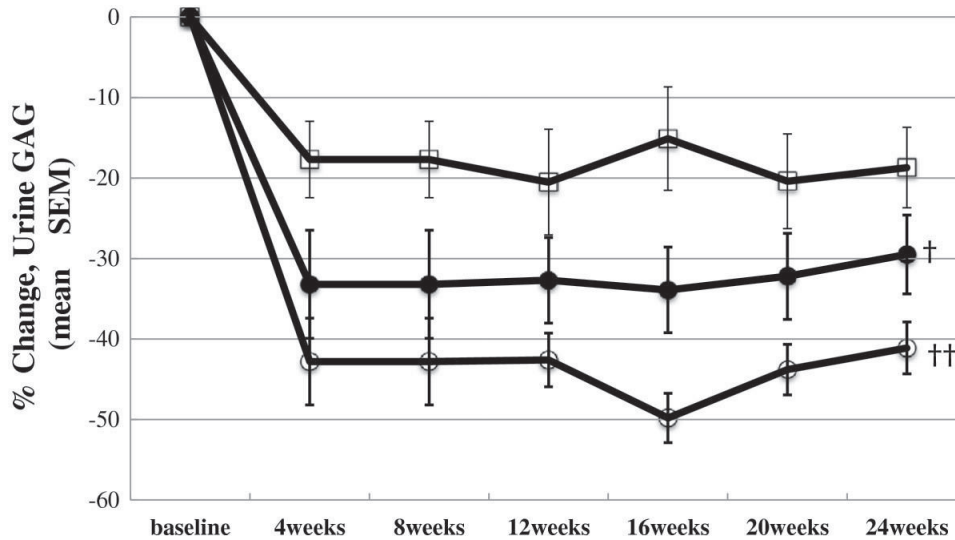
Trial Design: The Phase 1/2 trial was a randomized, single-blind, active-controlled study with the primary objective to evaluate the efficacy of Hunterase[®] (CAN101) based on the percentage change in uGAG from baseline to week 24, and the secondary objectives to evaluate the efficacy of Hunterase[®] (CAN101) based on the change and percentage change in the 6-minute walk test (6-MWT), liver volume, heart size, joint mobility, cardiac function and lung function, from baseline to week 24. 31 patients were randomized into one of three treatment arms: a comparator group, 0.5 mg/kg/week; a Hunterase[®] (CAN101) group, 0.5 mg/kg/week; and a Hunterase[®] (CAN101) group, 1.0 mg/kg/week. All the enrolled patients were previously treated with Elaprase, which also served as the active control in this trial.

Trial Status: The Phase 1/2 study was commenced in May 2010 and completed in March 2011.

Safety Data: In the Phase 1/2 trial, Hunterase[®] (CAN101) was shown to be well-tolerated and elicited no serious adverse drug reactions in all three groups. The most frequent adverse events were urticaria and skin rash, which were easily controlled with administration of antihistamines.

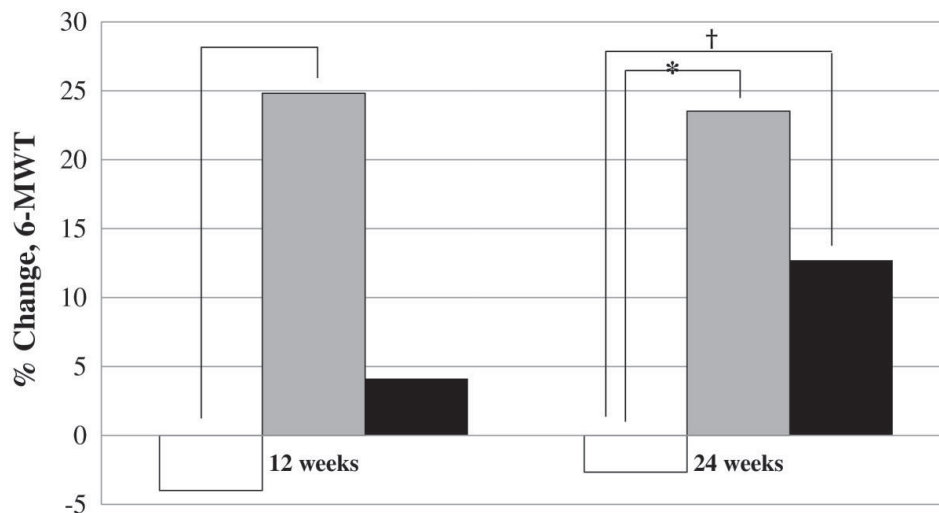
Efficacy Data: Urinary GAG reduction has been used as the main efficacy measurement. The uGAG level is considered a reliable indicator of biologic activity *in vivo*, and in some cases is predictive of clinical efficacy. As shown in the table below, the Phase 1/2 trial has demonstrated statistically significant decrease in uGAG from baseline to 24 weeks. After 24 weeks of treatment, the percent changes in uGAG levels were significantly greater in Hunterase[®] (CAN101) groups treated at dosages of 0.5 mg/kg/week and 1.0 mg/kg/week, compared to the comparator group ($\dagger P = 0.043$ and $\dagger\dagger P = 0.002$, respectively). Squares represent the comparator group (N = 11), closed circles represent the Hunterase[®] (CAN101) 0.5 mg/kg/week group (N = 10), and open circles represent the Hunterase[®] (CAN101) 1.0 mg/kg/week group (N = 10).

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Source: Orphanet Journal of Rare Diseases (March 2013)

The Six Minute Walk Test (6-MWT) is a functional endpoint that reflects the ability to walk a moderate distance that is important for normal community ambulation. This was the main secondary endpoint in the Phase 1/2 study. Patients with MPS II showed statistically significant and clinically meaningful improvements in the 6-MWT distance. At 24 weeks, the percent changes in 6MWT distance were significantly higher in Hunterase[®] (CAN101) groups treated at dosages of 0.5 mg/kg/week (*P = 0.003) and 1.0 mg/kg/week (†P = 0.015), compared to comparator group. White bars represent the comparator group (N= 8), grey bars represent the Hunterase[®] (CAN101) 0.5mg/kg/week group (N= 6), and black bars represent the Hunterase[®] (CAN101) 1.0mg/kg/week group (N= 7) in the chart below. The magnitudes of change are comparable to or exceed those seen in the pivotal clinical trials of ERTs for other MPS disorders.



Source: Orphanet Journal of Rare Diseases (March 2013)

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Licensing

We obtained exclusive license rights in Hunterase[®] (CAN101) from South Korea-based Green Cross Corporation (“GC”) through a license agreement dated January 3, 2019 to develop and commercialize Hunterase[®] (CAN101) in Greater China, and elected under the license agreement not to commercialize in Shanxi, Guizhou, Gansu, Qinghai, Xizang, Jilin and Yunnan. For details, please refer to “– Collaboration and Licensing Arrangements.”

Clinical Development Plan

We plan to initiate a post-approval study in China as required by the NMPA in the first half of 2023.

CAN108 (maralixibat)

Overview

CAN108 (maralixibat) is an oral, minimally-absorbed agent designed to selectively inhibit apical sodium-dependent bile acid transporter (ASBT) and treat rare cholestatic liver diseases, including Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA). In April 2021, we obtained an exclusive license from Mirum to develop, manufacture and commercialize CAN108 (maralixibat) in Greater China for ALGS, PFIC and BA.

Mechanism of Action

CAN108 is an inhibitor of the apical sodium-dependent bile acid transporter (ASBT). ASBT is primarily responsible for recycling bile acids from the intestine back to the liver. ASBT inhibition results in more bile acids being excreted in the feces, leading to lower levels of bile acids systemically, thereby reducing bile acid mediated effects and liver damage. CAN108 is a potent, highly selective ASBT inhibitor as demonstrated in cell-based assays. It is minimally absorbed due to its large molecular weight (710 Da) and the presence of a positively charged quaternary nitrogen atom, therefore maximizing the local exposure of the molecule to its target and minimizing unnecessary systemic exposure. CAN108-mediated blockade of intestinal reabsorption of bile acids by ASBT interrupts the enterohepatic circulation, thereby increasing fBA excretion and lowering sBA levels. By targeting bile acids in these settings, maralixibat has the potential to improve long-term outcomes and symptoms in our targeted settings and provide an alternative treatment to liver transplant.

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Market Opportunity and Competition

Pharmacological therapies that ameliorate the complications of the disease and improve patients’ quality of life without need for invasive surgical treatment are highly desirable. Pharmacologic interruption of the enterohepatic circulation through inhibition of the apical sodium dependent bile acid transporter (ASBT) with a minimally absorbed compound such as maralixibat is an attractive alternative to surgical interventions such as liver transplant.

Maralixibat is the first agent to demonstrate significant treatment benefit across a range of clinically relevant parameters in patients with ALGS. Maralixibat also possesses competitive advantages of a well-demonstrated safety profile, having been evaluated in more than 1,600 human subjects. Mirum obtained FDA approval for maralixibat for ALGS in September 2021, being the first and only targeted drug for ALGS worldwide. Maralixibat will also potentially be the first ASBT inhibitor and the first specific treatment of cholestatic pruritus in patients with ALGS in China. Furthermore, CAN108 is indicated for ALGS, PFIC and BA, and currently has no commercialized comparable products. For details on the competitive landscape of therapies for ALGS, PFIC and BA, see “Industry overview – Rare Cholestatic Liver Diseases.”

Clinical Development Plan

Maralixibat has been studied in a number of completed and ongoing clinical trials in ALGS and PFIC with over 120 children treated and some on study for over seven years. CAN108’s clinical development program in children with cholestatic liver diseases in ALGS and PFIC includes five completed studies in participants with ALGS, three completed or ongoing studies in participants with PFIC, and one ongoing long-term study that includes participants with ALGS or PFIC who have completed previous CAN108 studies.

Maralixibat has a well-demonstrated safety profile, having been evaluated in more than 1,600 human subjects, including over 120 pediatric participants with ALGS and PFIC and over 60 adult participants with cholestatic liver disease in the indications of PBC and PSC. A completed pivotal clinical study of maralixibat for ALGS demonstrated that maralixibat at a single daily dosage of 380 g/kg safely improved the key burdens of ALGS liver disease, including cholestasis (sBA), pruritus, xanthomas, growth, and patients’ quality of life. A completed open-label, long-term study for PFIC showed that patients with serum bile acid control can experience native liver survival with long-term maralixibat treatment for over five years, along with normalization of ALT, AST and bilirubin, as well as improved growth and controlled pruritus.

Mirum, our collaboration partner in the U.S., obtained FDA approval for maralixibat for ALGS in September 2021. We have started preparation of NDA for ALGS for CAN108 and expect to file a NDA in December of 2021 in mainland China and Taiwan based on data obtained by Mirum, our collaboration partner in global studies. For BA, we are supporting the patient recruitment and clinical site management in China for a Phase 2 global multi-center clinical trial initiated in May 2021 by Mirum, our collaboration partner. We target to initiate patient enrollment in China for such Phase 2 trial in the first half of 2022.

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WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN108 SUCCESSFULLY.

CAN106 long-acting anti-C5 antibody for complement disorders

Overview

CAN106 is a humanized long-acting monoclonal antibody against complement C5 being developed for the treatment of complement-mediated diseases including paroxysmal nocturnal hemoglobinuria (PNH), and various other complement mediated diseases that are targeted by approved anti-C5 antibodies and other new potential indications. We have obtained global rights to develop and commercialize this drug candidate. Based on preclinical data, CAN106 has demonstrated a favorable PK/PD profile and tolerability, indicating that CAN106 has the potential to effectively inhibit C5 in patients with PNH and potentially with reduced dosing frequency. We submitted an IND application for a Phase 1 clinical trial of CAN106 in Singapore in October 2020 and received IND approval from Health Sciences Authority (HSA) in December 2020. We initiated a Phase 1 clinical trial in healthy volunteers in Singapore in February 2021 and obtained the IND approval from the NMPA for PNH in July 2021 for a Phase 1 study. The IND approval from NMPA is not based on the Phase I clinical data from Singapore, however, findings from clinical trial in Singapore may be helpful for our communication with the NMPA in the future.

Mechanism of Action

C3 and C5 are protease complexes in the complement system that protect against invading organisms. During their hydrolysis, C3 releases the anaphylatoxin C3a and the fragment C3b. C3b can form C3bBb and C3b2Bb, which catalyze the hydrolysis of C3 and C5, respectively. C5 releases the anaphylatoxin C5a and C5b that initiates assembly of membrane attack complex (MAC), a pore-like structure that inserts into the cell membranes, causing cell lysis.

C5 complement inhibitors block the complement cascade at the level of C5, so it can stop the immune responses that cause disease. C5 complement inhibitors preserve the generation of C3b, which is essential for the clearance of circulating immune complexes and the normal phagocytosis of bacterial and fungal pathogens. CAN106 is a humanized anti-C5 monoclonal antibody that binds to the α chain of C5, which prevents C5 from being cleaved into C5a and C5b by C5 convertase.

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Market Opportunity and Competition

The unmet medical need and the treatments available vary depending on the continent. In Western countries, treatment with recombinant humanized anti-C5 monoclonal antibodies is the standard of care and there is limited unmet medical need. The prevalence of PNH has experienced steady growth both globally and in China. From 2016 to 2020, the prevalence of PNH have increased from 23.3 thousand to 23.8 thousand, and is predicted to reach 24.3 thousand in 2025 and 24.5 thousand in 2030. The recent acquisition and collaboration by other leading pharmaceutical companies regarding complement-mediated diseases also reflected the current market-heat in complement inhibitors. Alexion acquired Achillion Pharmaceuticals, Inc. in January 2020, adding two clinical-stage oral small molecule Factor D inhibitors to Alexion’s pipeline and provides the foundation and expertise for a broader oral Factor D inhibition development platform with the potential to treat numerous additional complement-mediated diseases. In the same month, Argenx and Zai Lab Announce Strategic Collaboration for Efgartigimod, a treatment to generalized myasthenia gravis (gMG) in Greater China.

In Asian countries, and in China in particular, the unmet medical need remains high due to the inability to pay for high-priced Western treatments and lack of local drugs. We are developing CAN106 to be a less expensive treatment option in China, with a view to gaining approval in Western countries later in the clinical development program. In addition, complement C5 plays an important role in various rare diseases due to its function in inflammatory and cell killing processes, and China remains to be the largest untapped market.

For details on the competitive landscape of anti-C5 antibodies, see “Industry Overview – Complement Mediated Diseases”.

Summary of Preclinical Data

We have completed the non-clinical studies to support our IND submission for CAN106 in China in March 2021.

Overview: The non-GLP nonclinical pharmacology and PK studies conducted with CAN106 demonstrated favorable properties of CAN106 and corresponding improved duration of PD effect on inhibiting hemolysis out to 35 days post administration of a single intravenous dose in mice supplemented with human C5 and the specific binding of CAN106 to human C5 is demonstrated.

In a study conducted on *in vitro* human wildtype C5 using surface plasmon resonance SPR, the results showed differential association and dissociation kinetics at pH 7.4 and pH 6.0, which can potentially improve the PK of CAN106 by addressing target-mediated drug disposition (TMDD).

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The design of the structure of CAN106 enables differential association and dissociation kinetics of binding to FcRn at pH 7.4 and pH 6.0, and showed improved binding to human FcRn protein and permitted more efficient recycling of CAN106.

In a study conducted on chicken red blood cells (RBCs) *ex vivo* with CAN106, the dose-dependent inhibition of hemolysis of chicken RBCs in the presence of human serum C5 was observed (Figure 1).

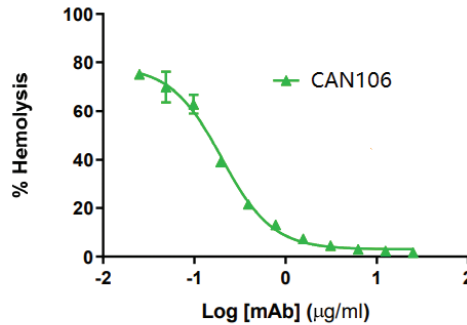


Figure 1. Hemolysis inhibition assay with CAN106 and wild-type human C5 protein

Source: Company data

Another study was conducted on nonobese diabetic (NOD)/severe combined immunodeficiency (SCID) mice with vehicle or CAN106 (5 or 15 mg/kg once IV by tail vein injection) with and without human C5 (250mcg loading dose on Day -1 with subsequent doses of 50mcg administered twice daily for 5 weeks). Results revealed that in the presence of human C5, CAN106 persisted for an extended period of 35 days with little to no TMDD. Mouse serum containing CAN106 inhibited hemolysis of chicken RBCs *ex vivo* over the course of the study (for up to 35 days) even in the presence of human C5 (Figure 2).

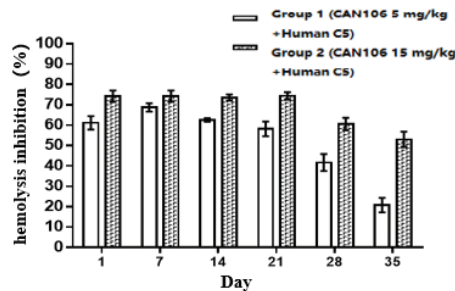


Figure 2: Pharmacodynamic effects (hemolysis inhibition percentage at different post-dosing days) of CAN106 in serum from NOD/SCID mice supplemented with human C5

Source: Company data

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Other studies were conducted on Cynomolgus monkey to investigate the toxicology and safety pharmacology. The no-observed-adverse-effect level (NOAEL) in the 4-week repeated dose in Cynomolgus monkey for the off-target toxicity investigation was 150 mg/kg/week. The *in vitro* hemolysis, tissue cross reactivity and local tolerance test did not show any obvious abnormality or toxicity.

Conclusion: CAN106 exhibits pH-dependent binding to human C5 and FcRn that can result in improved CAN106 recycling and reduced TMDD, leading to improved PK and PD properties *in vivo*. Reduced TMDD was demonstrated in the NOD/SCID mouse model supplemented with human C5. Enhanced duration of PD effect (inhibition of C5-mediated hemolysis of chicken RBCs *ex vivo*) was demonstrated in the same model and correlated with the reduction in TMDD. CAN106 was well tolerated in the completed preclinical toxicity studies in Cynomolgus monkeys. These data indicate that CAN106 may have the potential to effectively inhibit C5 in patients with PNH with reduced dosing frequency.

Licensing

We entered into a licensing agreement with WuXi Biologics Ireland Limited (WuXi Biologics) on January 7, 2019, which granted us an exclusive, transferable and royalty-bearing right to the anti-C5 antibody owned by WuXi Biologics in Greater China. On May 9, 2020, we entered into another license agreement with Privus Biologics, LLC (“Privus”), wherein Privus granted to us an exclusive, transferable and royalty-bearing right to the anti-C5 antibody owned by Privus in worldwide except for Greater China. We have global rights to develop and commercialize the CAN106 with the strategic collaboration with WuXi Biologics and Privus to manufacture the drug products. For details, please refer to “– Collaboration and Licensing Arrangements.”

Clinical Development Plan

This first-in-human study being conducted in Singapore in 2021 is designed to be a randomized, double-blind, placebo-controlled and single ascending dose study in 31 healthy volunteers to evaluate the safety, pharmacokinetics, pharmacodynamics and development of anti-drug antibodies of CAN106. Subjects will initially be enrolled at the lowest dose level (0.25 mg/kg) and dose escalations will proceed after reviewing of the safety data by the Scientific Review Committee (SRC). A sentinel dosing strategy will be employed in cohort 3-6. The first 2 subjects in a cohort will be randomized to receive CAN106 or placebo at a 1:1 ratio, and the remaining subjects will be enrolled in the same cohort if tolerated. The remaining subjects will receive CAN106 or placebo at least 24 hours after the second sentinel subject has been dosed. A Phase 1 study is planned in China and the data readout expected to be obtained in the first quarter of 2023.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN106 SUCCESSFULLY.

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CAN103

CAN103 is an ERT for Gaucher Disease (GD) being locally developed in China and the first rare disease asset we acquired in 2018 from WuXi Biologics, which we have global proprietary rights to develop and commercialize. It is produced in an engineered cell line that produces recombinant beta-glucocerebrosidase (GCase) with highly exposed mannose for efficient uptake by macrophage and Kupfer cells in Gaucher patients to break down glucocerebrosides (GL1), the fatty chemicals that accumulates in the body of patients with GD. GD is a lysosomal storage disorder due to mutations in the GBA gene. It is one of the best known and prototypical rare diseases in China with approximately 3,000 patients in 2020. There are limited effective treatments for GD as only one ERT drug has been approved in China. CAN103 faces a market of unmet needs as GD is one of the largest treatment-naive patient pools globally. For more information on the competitive landscape of treatments for GD, see “Industry – Other Lysosomal Storage Diseases (LSDs) – Gaucher Disease (GD)”.

CAN103’s preclinical data profile demonstrates promising efficacy and safety results in animal studies. Completed in vitro and in vivo nonclinical pharmacology of CAN103 shows similar specific activity and uptake ability with Velaglucerase alfa. Animal data with a mouse model of GD has shown that CAN103 has the efficacy on reduction the storage cells in liver, the decreasing levels of Lyso-GL-1 and glucocerebroside were also observed even in the low dose. The single dose toxicity study in rats and monkeys revealed no specific toxicity up to the highest dose at 20 mg/kg, and no test substance related changes in the 4-w repeated dose toxicity study in rats and monkeys.

We obtained the IND approval for CAN103 from the NMPA in October 2021. We are in preparation of a Phase 1 trial in adult and adolescent GD patients and plan to initiate patient enrollment in the first half of 2022. Our clinical trials will evaluate the efficacy and safety of CAN103 for adult and adolescent patients with GD1 or GD3.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN103 SUCCESSFULLY.

Our Preclinical Candidates

CAN107

CAN107 is a recombinant humanized anti-FGF23 mAb for X-linked hypophosphatemia (XLH) being developed in China currently at CMC stage in preparation to initiate IND-enabling studies. XLH is an inherited disease of phosphate metabolism where mutations inactivating the Phosphate Regulating Endopeptidase Homolog, X-Linked (PHEX) gene lead to inactivation of the PHEX protein. The lack of PHEX protein/activity prevent it from correctly regulating fibroblast growth factor 23 (FGF23), resulting in overactivity of FGF-23 that reduces vitamin D1 α -hydroxylation and phosphate reabsorption by the kidneys, leading to hypophosphatemia and the related features of hereditary hypophosphatemic rickets, local

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and systemic effects including impaired growth, rickets, bone abnormalities and muscular dysfunction. The prevalence of the disease is estimated at 1 in 20,000 in 2020 and the prevalence of such inherited genetic disorder remains relatively stable over time, according to Frost & Sullivan.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN107 SUCCESSFULLY.

CAN104

CAN104 is an ERT being developed in China for the treatment of Fabry disease (FD). FD is an inherited lysosomal storage disorder of glycosphingolipid metabolism due to the absence or deficiency of α -Gal A which can lead to life-threatening heart and kidney problems. CAN104 is a recombinant humanized α -galactosidase A enzyme (α -Gal A). Its mechanism of action is through internalization of cells by first binding to the mannose-6-phosphate receptors (M6PRs) and then transporting to the lysosome. In the lysosome, CAN104 catalyses the hydrolysis of globotriaosylceramide (GL-3) and other α -galactyl-terminated neutral glycosphingolipids. We are accelerating CAN104’s preclinical development and it is currently under cell line development for IND-enabling studies. FD is one of the most common LSDs which usually starts in childhood and is more common in men than women. China has a relatively large number of patients with FD, accounting for about one-fifth of patients in the world. For more information on the competitive landscape of treatments for FD, see “Industry – Gene Therapy – Gene Therapy Application to LSDs”.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN104 SUCCESSFULLY.

CAN105

CAN105 is a treatment being developed for the treatment of Hemophilia A with massive market potential. It is a recombinant, humanized, bispecific antibody that bridges activated factor IX and factor X to restore the function of the missing activated factor VIII, which is not expected to be affected by existing factor VIII inhibitors or induce new development of such inhibitors. There were over 120,000 Hemophilia A patients in China in 2020 with an expected growth at a CAGR of 0.5% from 2020 to 2025 and 0.1% from 2025 to 2030. CAN105 is expected to enter preclinical research phase in the first half of 2022.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN105 SUCCESSFULLY.

Gene Therapy – CAN201 and CAN202

sL65 is a next generation liver-tropic AAV capsid platform for use in gene editing and gene therapy. At the American Society of Gene & Cell Therapy (“ASGCT”) conference in May 2020, data was presented showing that the capsids delivered highly efficient functional

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transduction of human hepatocytes in a humanized mouse model and non-human primates. The data also showed the capsids exhibited improved manufacturability and more resistance to pre-existing neutralizing antibodies in human serum samples. We are devising preclinical strategies on CAN201 as we and LogicBio, our collaboration partner, conduct preclinical evaluations of this drug candidate. Our development plan on CAN202 is subject to the development status of CAN201 to de-risk the process.

We obtained exclusive worldwide license rights in sL65 from LogicBio Therapeutics through a license agreement dated April 27, 2021 to develop and commercialize four gene therapy products in sL65, and an option to an exclusive license for LB-001 for the treatment of methylmalonic acidemia (MMA) in designated areas pursuant to the license agreement. LB-001 is an investigational in-vivo gene editing technology based on GeneRide™ platform, which is designed to precisely integrate corrective genes into albumin locus of the hepatocytes of patients to provide a durable therapeutic effect. For details, please refer to “– Collaboration and Licensing Arrangements.”

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN201 AND CAN202 SUCCESSFULLY.

Collaboration and Licensing Arrangements

As of the Latest Practicable Date, all of our license partners are Independent Third Parties. We discuss and negotiate each license and/or collaboration arrangement on a case-by-case basis; therefore, the terms under each arrangement are customized. However, based on our understanding of the industry, and as advised by Frost & Sullivan, we also believe the overall arrangement under our collaboration agreements is consistent with general industry practice for similar kinds of products. As part of the global collaboration with our license partners, when applicable, we may participate in our license partners’ global clinical studies by joining in the clinical studies with us taking the operational lead by conducting the screening, enrollment and treatment of patients and coordinating development, registration and commercialization in China and other specified territories where we have exclusive development and commercialization rights. Please see “Business” for detailed discussion on our products and late-stage clinical drug candidates and collaboration with our business partners. We plan to spend a portion of the [REDACTED] from this [REDACTED] on relevant milestone fees under the collaboration arrangements.

Development and License Agreement with Apogenix

On June 26, 2015, we entered into a development and license agreement with Apogenix AG (previously known as Apogenix GmbH) (“Apogenix”) as amended in December 2015, May 2021 and August 2021, respectively (the “Apogenix Agreement”) concerning our exclusive right to develop, manufacture and commercialize the compound known as APG101 (CAN008) and pharmaceutical products containing APG101 (“Apogenix Licensed Products”) in mainland China, Hong Kong, Macau and Taiwan (the “Greater China”).

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Pursuant to the Apogenix Agreement, Apogenix granted us an exclusive, royalty-bearing, license under specified Apogenix patent rights, materials and know-how to develop (not including any modification to the compound), manufacture and commercialize, including to market, promote, label, package, distribute, import, export, offer to sell and sell the Apogenix Licensed Products in Greater China for the treatment of patients with glioblastoma disease (the “GBM”) and/or other indications. Any sublicense to a third party by us (excluding to affiliates of us and Apogenix) requires the prior written consent of Apogenix. Pursuant to the Apogenix Agreement, should we, our affiliates or sublicensees outside the scope of the agreement commence clinical trials or commercialize any CD95 ligand inhibitor for the treatment of GBM within Greater China, then Apogenix may terminate and convert our exclusive license into a non-exclusive license and may independently exploit the Apogenix Licensed Products in Greater China, and we must grant to Apogenix a non-exclusive license to our development data.

In consideration of granting us such license under the Apogenix Agreement, we shall pay to Apogenix upfront aggregate payments of US\$6 million, which were paid in full by March 2018, and in consideration for the amendment in December 2015 to add Taiwan, we must pay Apogenix 50% of the profits generated by us, our affiliates or our permitted sublicensees from the sale or other disposition of any Apogenix Licensed Products in Taiwan⁽¹⁾. In consideration for the expansion of our exclusive license to indications other than GBM, we shall pay to Apogenix an upfront payment of EUR1 million, which was paid in October 2021. Apogenix is eligible to receive up to an additional aggregate amount of EUR6 million in regulatory milestone payments in mainland China for GBM, an aggregate amount of US\$30 million plus EUR4 million in sales milestone payments in Greater China for GBM and/or other indications, and up to US\$5 million in regulatory milestone payments in Taiwan, as well as up to an aggregate of EUR8 million for clinical development milestones other than GBM. We also must pay to Apogenix tiered low teens percentage royalties based on net sales of the Apogenix Licensed Products in Greater China, including for indications other than GBM, if so agreed upon by the parties. Such royalties may be subject to certain reductions for lack of a valid patent claim in mainland China or competing generic products in Greater China.

Under the Apogenix Agreement, we are responsible for the development, manufacturing and commercialization of APG101 for the treatment of GBM in Greater China. We must use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize the Apogenix Licensed Products in Greater China, and we are responsible for all costs and expenses incurred by us, or by Apogenix under the development plan and technology transfer as specified in the Apogenix Agreement associated with such activities.

(1) The Directors are of the view that the profit sharing arrangement was entered into in normal commercial terms, which was dated back to 2015 when we tried to expand the Apogenix licensing territory to Taiwan. Although Taiwan was not considered as a big market, we plan to conduct Phase I clinical trial there in the hope of accelerating the relative clinical development in mainland China. According to Frost & Sullivan, the arrangement is in line with the market practice as such arrangements are purely based on commercial negotiations.

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Subject to the terms of the Apogenix Agreement, in the development of the Apogenix Licensed Products, we and Apogenix will each solely own the entire right, title and interest in and to all inventions and discoveries related to Apogenix technology first developed, made or discovered solely by us or Apogenix, respectively. However, we possess the licensed rights within Greater China and Apogenix possesses such rights outside Greater China. In addition, we and Apogenix will jointly own an individual equal interest in certain inventions, patent rights and know-how based on jointly conceived intellectual property that relates to the Apogenix Licensed Products. We have the responsibility to file and prosecute our own patent rights and the jointly developed intellectual property in Greater China and Apogenix has the responsibility to file and prosecute our patent rights that relate to Apogenix technology and the jointly developed intellectual property outside Greater China.

Subject to the terms of the Apogenix Agreement, upon completion of the biomarker study to analyze CD95L expression and methylation patterns in the Chinese glioblastoma patient population Apogenix shall use its commercially reasonable efforts to transfer all data and information controlled by then to the extent necessary or useful for manufacturing and provide all relevant support. The manufacturing shall be conducted by a third party CMO or entity controlled by us.

The Apogenix Agreement may be terminated by us without cause upon 90 days' prior written notice to Apogenix, and by either us or Apogenix for cause in the event that (1) the biomarker study under the Apogenix Agreement is unsuccessful⁽¹⁾ or (2) the other party commits a material uncured breach or default of its obligations under the Apogenix Agreement. Any material breach which only affects Taiwan will only terminate the amendment granting license rights in Taiwan but not the entire Apogenix Agreement. Apogenix may terminate the Apogenix Agreement in the event that we, any of our affiliates, or a permitted sublicensee directly or indirectly challenges, or supports a third party to challenge, the validity of any Apogenix patent rights in a legal proceeding. Unless terminated earlier, the Apogenix Agreement will expire upon the fulfillment of relevant payment pursuant to the payment term, after which the license granted under the Apogenix Agreement shall survive and become non-exclusive, perpetual and royalty-free. Under the Apogenix Agreement, such royalty term with respect to an Apogenix Licensed Product expires on the later of (i) the expiry of the last-to-expire Apogenix patent with claims covering such Apogenix Licensed Product in mainland China, (ii) the expiry of major data or regulatory exclusivity for such Apogenix Licensed Product in mainland China, and (iii) the twelfth anniversary of the first commercial launch of such Apogenix Licensed Product in mainland China.

Apogenix is a private company based in Germany developing innovative immunotherapeutics for the treatment of cancer and viral infections. Since its inception in 2005, Apogenix has developed a promising portfolio of innovative immuno-oncology

(1) From July 2015 to January 2016, we completed a biomarker study for expression of CD95L in China. We solely own the entire right, title and interest in the data obtained in the biomarker study under the Apogenix Agreement.

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therapeutics for the treatment of cancer and viral infections. Apogenix’ drug candidates target different TNFSF-dependent signaling pathways, thereby restoring the anti-tumor immune response in cancer patients and reducing lymphopenia and inflammatory cell death in patients with viral infections.

As of the Latest Practicable Date, Apogenix is an Independent Third Party.

We paid a total of approximately US\$6 million to Apogenix under the Apogenix Agreement before the Track Record Period. During the Track Record Period, we did not make any additional payment. We are obligated to pay another upfront payment of EUR1 million which was paid in October 2021, and up to an additional aggregate amount of EUR6 million in regulatory milestone payments, an aggregate amount of US\$30 million plus EUR4 million in sales milestone payments, and up to US\$5 million in regulatory milestone payments, as well as up to an aggregate of EUR8 million for clinical development milestones other than GBM as discussed above under the Apogenix Agreement after the Track Record Period, which have not been paid yet.

Exclusive License Agreement with GC Pharma

On January 3, 2019, we entered into a license agreement (the “GC Pharma Agreement”) with Green Cross Corporation (“GC Pharma”) concerning the exclusive right to develop and commercialize any biopharmaceutical products containing the compound Idursulfase- β developed by GC Pharma as an active pharmaceutical ingredient that is formulated for intravenous administration in the treatment of Mucopolysaccharidosis Type II (also known as Hunter Syndrome) (the “GC Pharma Licensed Products”) in all indications except for the indication specifically for CNS symptoms (the “GC Pharma Licensed Field”). The GC Pharma Licensed Products include the product currently marketed by or on behalf of GC Pharma outside Greater China under the product name Hunterase[®].

Pursuant to the GC Pharma Agreement, GC Pharma granted to us an exclusive, sublicensable (subject to certain conditions), royalty-bearing right and license under certain patent rights, know-how and product names and trademarks relating to the GC Pharma Licensed Products to develop and commercialize (excluding manufacturing activities) the GC Pharma Licensed Products in the GC Pharma Licensed Field in Greater China. We elected under the GC Pharma Agreement not to commercialize in the following provinces: Shanxi, Guizhou, Gansu, Qinghai, Xizang, Jilin and Yunnan, and are required, upon written request of GC Pharma, to enter into a sublicense agreement licensing our commercialization rights under the GC Pharma Agreement to a designated GC Pharma affiliate in one or more of such provinces. GC Pharma has granted to us a right of first negotiation with respect to collaborations in the licensed territory regarding development and commercialization of the GC Pharma Licensed Products for treatment of Mucopolysaccharidosis Type II in the CNS indication. GC Pharma has also granted to us a right of first refusal with respect to GC Pharma granting to, or obtaining an offer from, a third party to develop or commercialize the GC Pharma Licensed Products in the licensed territory for treatment of Mucopolysaccharidosis Type II in the CNS indication.

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Under the GC Pharma Agreement, we are responsible, and must use commercially reasonable efforts, to develop, obtain regulatory approval for and commercialize the GC Pharma Licensed Products, and we are responsible for all costs and expenses incurred by us or on behalf of us associated with such activities. Unless separately agreed, we agree to purchase and GC Pharma agrees to supply to us GC Pharma Licensed Products at a fixed price as set forth in the GC Pharma Agreement and supply samples to us for regulatory approval at no charge. We also agreed not to directly or indirectly develop, manufacture or commercialize any product indicated for the treatment of Mucopolysaccharidosis Type II in China, other than the GC Pharma Licensed Products.

Subject to the terms of the GC Pharma Agreement, in the development of the GC Pharma Licensed Products, GC Pharma will own the entire right, title and interest in and to all intellectual property rights relating to the GC Pharma Licensed Products or the licensed rights under the GC Pharma Agreement, whether solely created by GC Pharma or by us or jointly created, and GC Pharma shall grant a royalty-free license to CANbridge under such rights to develop, commercialize the licensed products in the field. We will own any intellectual property rights created solely by us not related to the GC Pharma Licensed Products or the licensed rights, but grant to GC Pharma a perpetual, irrevocable, royalty-free, worldwide, sublicensable license under such intellectual property rights for GC Pharma to research, develop, manufacture, use, and commercialize the GC Pharma Licensed Products. Each party has rights for prosecution of its intellectual property rights, subject to a step-in right by us should GC Pharma choose not to prosecute a licensed patent. GC Pharma has the first right, but not the obligation, to enforce licensed patents in the licensed territory, subject to our step-in right should GC Pharma not diligently pursue an infringement action.

Pursuant to the GC Pharma Agreement, we paid GC Pharma a non-refundable, non-creditable upfront payment of US\$5 million in March 2019, and are further obligated to pay GC Pharma up to US\$5 million in the aggregate upon the occurrence of specified development milestones of achieving regulatory approval in mainland China and receiving pricing and reimbursement approval in mainland China. In addition, we are obligated to pay GC Pharma a fixed double digit percentage royalty on net sales of GC Pharma Licensed Products generated in each of Greater China. Such royalties are subject to a reduction in the event of generic competition. The royalty term with respect to a GC Pharma Licensed Product in any region expires on the later of (i) the expiry of the last-to-expire valid claim of a licensed patent covering such GC Pharma Licensed Product in such region, and (ii) the fifteenth anniversary of the first commercial sale of such GC Pharma Licensed Product in such region.

The GC Pharma Agreement may be terminated by us, without cause, upon prior written notice. GC Pharma may terminate the agreement upon certain conditions such as our failure to meet certain development timeline as agreed. In addition, either party may terminate the GC Pharma Agreement upon bankruptcy, a change of control, or material uncured breach of the agreement of or by the other party.

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GC Pharma is a biopharmaceutical company headquartered and listed in South Korea (stock code: 006280.KS) that delivers protein therapeutics and vaccines. It is a leading global protein products manufacturers and has been dedicated to quality healthcare solutions more than half a century.

As of the Latest Practicable Date, GC Pharma is an Independent Third Party.

During the Track Record Period, we paid a total of approximately US\$7.5 million to GC Pharma under the GC Pharma Agreement. We are obligated to pay up to US\$2.5 million for certain development milestones as discussed above under the GC Pharma Agreement after the Track Record Period.

Exclusive License Agreement with WuXi Biologics

On January 7, 2019, we entered into a license agreement (the “WuXi Biologics Agreement”) with WuXi Biologics Ireland Limited (“WuXi Biologics”), wherein WuXi Biologics granted to us (i) an exclusive, transferable (subject to certain conditions), royalty-bearing license under (a) all patents and patent applications controlled by WuXi Biologics or its affiliates during the term of agreement in Greater China that claim any aspect of the anti-C5 antibody that binds specifically to the C5 protein or a pharmaceutical composition containing the anti-C5 antibody (the “WuXi Biologics Licensed Product”) and (b) know-how solely pertaining to the WuXi Biologics Licensed Product, and (ii) a non-exclusive, royalty-bearing license under certain know-how that relates to both the WuXi Biologics Licensed Product and other products, in each case of (i) and (ii), with the right to sublicense through multiple tiers (subject to certain conditions), and to make, have made, use, register, sell, offer to sell, have sold, import, export, exploit, research, improve, develop and commercialize the WuXi Biologics Licensed Product (including all improvements and/or modifications) in Greater China for all indications related to the anti-C5 antibody. We granted back to WuXi Biologics a co-exclusive, irrevocable, fully paid, royalty-free license under all patent rights and know-how controlled by us, our affiliates or sublicensees at any time during the term of the agreement that is solely related to the WuXi Biologics Licensed Product or anti-C5 antibody or the research, development, manufacture, commercialization, sale or use thereof. WuXi Biologics has granted to us a right of first negotiation with respect to a global license for the WuXi Biologics Licensed Product and a right of first refusal with respect to a third party granting to or receiving from WuXi Biologics a global license, in each case outside of Greater China.

Under the WuXi Biologics Agreement, we will be responsible for the development and commercialization of the WuXi Biologics Licensed Product. We must use commercially reasonable efforts to develop, obtain regulatory approval and commercialize the WuXi Biologics Licensed Product, and we are responsible for all costs and expenses incurred by us or on behalf of us associated with such activities. Unless separately agreed, WuXi Biologics is our exclusive clinical supplier and primary commercial supplier for the WuXi Biologics

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Licensed Product. The supply price of the the WuXi Biologics Licensed Product is based on manufacturing cost at a specified fixed rate, plus a bonus payment of US\$500,000 for completion of clinical trial application and clinical batches.

Subject to the terms and conditions of the WuXi Biologics Agreement, we paid WuXi Biologics an upfront payment of US\$0.1 million in August 2019, and are obligated to pay up to an aggregate of US\$15.5 million in pre-clinical, clinical development and regulatory milestone payments upon events such as preclinical candidate selection, dosage of first patient in Phase 1 study and first BLA approval in mainland China, and up to an aggregate of US\$65 million in commercial milestone payments when annual net sales exceed certain amounts of sales in the certain territories. In addition, we are obligated to pay WuXi Biologics a tiered mid-single digit royalty on total aggregate net sales of the WuXi Biologics Licensed Product. Such royalties are subject to a reduction in the event of blocking third-party intellectual property and/or biosimilar competition. The royalty term for the WuXi Biologics Licensed Product in a specific country or region commences upon the first commercial sale in such country or region and expires on the later of (i) the expiry of the last-to-expire valid claim of a licensed patent covering the WuXi Biologics Licensed Product in such country or region, and (ii) the tenth anniversary of the first commercial sale of the WuXi Biologics Licensed Product in such country or region.

Subject to the terms of the WuXi Biologics Agreement, we and WuXi Biologics will each solely own the entire right, title and interest in and to all inventions and discoveries first made or discovered solely by us or WuXi Biologics, respectively, and will jointly own all inventions or discoveries jointly made or discovered. We have the sole right, at our expense, for the prosecution and maintenance of the licensed patent rights. We also have the first right, but not the obligation, to enforce the licensed patent rights.

Unless terminated earlier, the WuXi Biologics Agreement will expire, for each WuXi Biologics Licensed Product, upon the expiration of the royalty term on a country-by-country or region-by-region basis. The WuXi Biologics Agreement may be terminated by us, without cause, upon 90 days' prior written notice to WuXi Biologics. WuXi Biologics may terminate the WuXi Biologics Agreement if we directly or indirectly challenge any of the licensed patent rights. Either party may terminate the WuXi Biologics Agreement upon the insolvency of, or material uncured breach of the agreement by, the other party.

WuXi Biologics Ireland Limited is a subsidiary of WuXi Biologics (Cayman) Inc., a Hong Kong-listed company (stock code: 2269.HK) with an open-access biologics technology platform offering end-to-end solutions to empower organizations to discover, develop and manufacture biologics since 2000.

As of the Latest Practicable Date, WuXi Biologics Ireland Limited is an Independent Third Party.

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During the Track Record Period, we paid a total of approximately US\$0.6 million to WuXi Biologics under the WuXi Biologics Agreement. We are obligated to pay up to US\$15 million for pre-clinical, clinical development and regulatory development milestones and US\$65 million for commercial milestones as discussed above under the WuXi Biologics Agreement after the Track Record Period.

Exclusive License Agreement with Privus

On May 9, 2020, we entered into a license agreement (the “Privus Agreement”) with Privus Biologics, LLC (“Privus”), wherein Privus granted to us (i) an exclusive, transferable (subject to certain conditions), royalty-bearing license under (a) all patents and patent applications controlled by Privus or its affiliates during the term of agreement in worldwide except for Greater China with regard to a terminal complement inhibitor of the C5a and C5b proteins, and all other terminal complement inhibitors of the C5a and C5b proteins controlled by Privus (the “Privus Licensed Product”) and (b) know-how solely pertaining to the Privus Licensed Product, and the right to sublicense through multiple tiers in worldwide except for Greater China for all Privus Licensed Product.

Under the Privus Agreement, we will have sole control over and responsibility and decision-making authority for, at our sole cost and expenses, all development and commercialization of the Privus Licensed Product. We must use commercially reasonable efforts to develop, seek regulatory approval and commercialize the Privus Licensed Product, and we are responsible for all costs and expenses incurred by us or on behalf of us associated with such activities.

Subject to the terms and conditions of the Privus Agreement, we shall pay Privus an upfront payment of US\$6.0 million, which was paid in full by March 2021. We are further obligated to pay up to an aggregate of US\$73.0 million for regulatory milestones of first regulatory approvals in certain jurisdictions, clinical development milestones upon first dosage of a patient with a licensed product in a pivotal trial, and additional indication milestones if we achieve further regulatory approvals for licensed products in certain territories, as well as up to an aggregate of US\$118.0 million in commercial milestone payments when net sales exceed certain designated amounts. In addition, we are obligated to pay Privus a tiered mid-single digit royalty on total aggregate net sales of the Privus Licensed Product. Such royalties are subject to a reduction in the event of blocking third-party intellectual property and/or biosimilar competition.

Subject to the terms of the Privus Agreement, we and Privus will each solely own the entire right, title and interest in and to all inventions and discoveries first made or discovered solely by us or Privus, respectively, and will jointly own all inventions or discoveries jointly made or discovered. We have the sole right, at our expense, for the prosecution and maintenance of the licensed patent rights. We also have the first right, but not the obligation, to enforce the licensed patent rights.

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Unless terminated earlier, the Privus Agreement will expire, for each Privus Licensed Product, upon the expiration of the royalty term on a country-by-country or region-by-region basis. The Privus Agreement may be terminated by us, without cause, upon 90 days' prior written notice to Privus. Privus may terminate the Privus Agreement if we (i) cease all development activities prior to receipt of regulatory approval for the Privus Licensed Product in any of the U.S, E.U. or Japan for a period of six consecutive months and does not cure such cessation within 90 days or receiving written notice thereof from Privus or (ii) directly or indirectly challenge any of the licensed patent rights. Either party may terminate the Privus Agreement upon the insolvency of, or material uncured breach of the agreement by, the other party.

Privus is a limited liability company organized under the law of the State of Delaware, U.S., focusing on the business of discovering, manufacturing and developing biologics to treat rare diseases and conditions.

As of the Latest Practicable Date, Privus is an Independent Third Party.

During the Track Record Period, we paid a total of approximately US\$6 million to Privus under the Privus Agreement. We are obligated to pay up to US\$73 million for regulatory development milestones and US\$118.0 million for commercial milestones as discussed above under the Privus Agreement after the Track Record Period.

Collaboration with UMass

On June 1, 2020, we entered into a sponsored research agreement with The University of Massachusetts as represented by and solely on behalf of its medical school ("UMass"), pursuant to which we were granted an exclusive option to obtain a worldwide, royalty-bearing, exclusive license (with the right to sublicense through multiple tiers) under certain of UMass' patent rights and future patent rights related thereto, to use and practice such rights for the prevention, treatment, cure or control of conditions relating to certain neuromuscular disorders. Our exercise of the exclusive option obligates us and UMass to negotiate in good faith a license agreement containing reasonable terms. In consideration of the performance of research projects and the rights granted, we are obligated to provide financial support to UMass in periodic advance biannual payments as set forth in the sponsored research agreement. Pursuant to the sponsored research agreement, UMass granted to us a royalty-free, fully paid-up, perpetual, non-exclusive, worldwide license, without the right to grant sublicenses, under all of UMass' patent rights arising from the sponsored research project to make, have made, use, lease, sell, have sold, offer for sale and import products and otherwise practice such patent rights, provided that we agree to (a) demonstrate reasonable efforts to commercialize such products in the public interest and (b) pay a pro rata portion (in equal portions with each other non-exclusive licensee) of patent prosecution and maintenance costs in all countries, including the United States, in which we are granted a non-exclusive license right. Unless terminated earlier, the sponsored research agreement remains in effect until the later of two years from June 1, 2020 or completion of the research project. We may terminate the sponsored research agreement upon 30 days' prior notice if (i) a principal investigator leave UMass and no

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acceptable substitute is identified within 60 days or otherwise terminated his or her involvement in the research project, or (ii) parties are unable to reach agreement on the update of the research project pursuant to relevant provisions of the sponsored research agreement. Either party may terminate the sponsored research agreement upon the material uncured breach of the agreement by the other party.

On September 1, 2020, we entered into another sponsored research agreement with UMass, as represented by and solely on behalf of its medical school, for a research project on engineering AAV capsids with lower sensitivity to antibody neutralization and enhanced CNS and muscle tropism, pursuant to which we were granted an exclusive option to obtain a worldwide, royalty-bearing, exclusive license (with the right to sublicense through multiple tiers) under certain of UMass' patent rights and future patent rights related to the sponsored research project, to use and practice such rights for the prevention, treatment, cure or control of human indications, disease, disorder or conditions. Our exercise of the exclusive option obligates us and UMass to negotiate in good faith a license agreement containing reasonable terms. In consideration of the performance of research projects and the rights granted, we are obligated to provide financial support (including, material, reagents, consumables, supply and personnel costs) to UMass in periodic advance biannual payments as set forth in the sponsored research agreement. In turn, we and UMass have joint, undivided ownership of all patent rights which is conceived or reduced to practice jointly by us and UMass. Unless terminated earlier, the sponsored research agreement remains in effect until the later of two years from June 1, 2020 or completion of the research project. We may terminate the sponsored research agreement upon 30 days' prior notice if (i) a principal investigator leave UMass without acceptable substitute is identified within 60 days or otherwise terminated his or her involvement in the research project, or (ii) parties are unable to reach agreement on the update of the research project pursuant to relevant provisions of the sponsored research agreement. Either party may terminate the sponsored research agreement upon the material uncured breach of the agreement by the other party.

Located in Worcester, Massachusetts, U.S., UMass was founded in 1962 and is consistently ranked by U.S. News & World Report as one of the leading medical schools in the U.S. for primary care education. Its mission is to advance the health and well-being of the people of the Commonwealth and the world through pioneering education, research, public service and health care delivery.

As of the Latest Practicable Date, UMass is an Independent Third Party located in Worcester, Massachusetts.

Collaboration with LogicBio

On April 26, 2021, we entered into a strategic collaboration and licensing agreement with LogicBio Therapeutics, Inc. ("LogicBio"), wherein LogicBio granted to us (i) a worldwide, royalty-bearing, sublicensable through multiple tiers (subject to certain conditions), exclusive license to certain LogicBio patents and know-how to develop, manufacture and commercialize gene therapy candidates for two targets for the treatment of Fabry and Pompe diseases, such

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LogicBio patents and know-how being inclusive of LogicBio’s adeno-associated virus (AAV) sL65, a capsid produced from the LogicBio sAAVy™ platform; (ii) options for the development of AAV sL65-based treatments for two additional targets; and (iii) an option to obtain an exclusive, royalty-bearing, sublicensable through multiple tiers (subject to certain conditions) license to LogicBio patents and know-how to LB-001, an investigational in-vivo gene editing technology based on GeneRide™ platform for the potential treatment of methylmalonic acidemia (MMA), in Greater China (collectively, the “LogicBio Licensed Products”). Pursuant to the agreement, we granted to LogicBio a royalty-free, non-exclusive, sublicensable, license for LogicBio to perform its obligations under the agreement.

We are required to use commercially reasonable efforts to develop and seek regulatory approval for LogicBio Licensed Product directed against each target corresponding to each licensed indication in certain countries, and upon approval of the applicable biologics license application in such country, we are obligated to use commercially reasonable efforts to obtain regulatory approval and commercialize such product in such country. Similarly, if we exercise the LB-001 option, we are required to use commercially reasonable efforts in Greater China to develop, seek regulatory approval and commercialize LogicBio Licensed Product for LB-001. Except as otherwise provided in the agreement, we are solely responsible for, and will have sole control over, preparing, filing, and maintaining regulatory submissions and communicating with regulatory authorities in Greater China with respect to LogicBio Licensed Products.

Subject to the terms of the agreement, LogicBio will have an option, on a target-by-target basis with respect to certain targets, to enter into a separate worldwide, co-exclusive (with us) co-development and co-commercialization agreement with us with regard to products that are directed to the applicable target in certain time period. We and LogicBio will have sole responsibility for the conduct of the activities allocated to us or LogicBio, respectively.

Subject to the terms of the agreement, on a product-by-product basis for products other than LB-001, during an initial LogicBio manufacturing period, LogicBio has sole responsibility for all manufacturing activities. Following the initial LogicBio manufacturing period, we will have sole responsibility for and sole decision-making authority with respect to all manufacturing activities.

The agreement contains intellectual property provisions customary for this type of agreement.

Under the agreement, we paid a one-time, non-refundable upfront payment of US\$10 million in May 2021. Upon exercising the option for LB-001, we would assume responsibility and costs for all future development of LB-001 in Greater China, including regulatory and commercial activities and, potentially, manufacturing. The agreement also includes payments, including opt-in fees triggered upon the exercise of these options, as well as up to US\$591 million for clinical development milestones at initiations of clinical trials, regulatory

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milestones for receiving regulatory approval in certain designated territories, and commercial milestones for achieving net sales of the product at certain amounts in a calendar year, and up to a tiered double-digit royalties on net sales.

The royalty term for the LogicBio Licensed Product in a specific country commences upon the first sale in such country and expires on a licensed product-by-licensed product and country-by-country basis on the later of (i) the expiration of the last-to-expire valid claim of a licensed patent covering the LogicBio Licensed Product in such country, (ii) the expiration of all regulatory exclusivity for such LogicBio Licensed Product in such country, and (iii) the tenth anniversary of the first sale of the LogicBio Licensed Product in such country. In addition, LogicBio may enter into new license agreements with third parties during the term of the agreement and should we opt to receive a sublicense to patents, know-how or LB-001 technology under such agreements, we will be responsible for certain payments, subject to the terms of the agreement.

Unless terminated earlier, the agreement will expire, for each LogicBio Licensed Product, upon the expiration of the royalty term on a country-by-country or region-by-region basis. The agreement may be terminated by us, without cause, subject to a notice period. LogicBio may terminate the agreement if we (i) directly or indirectly challenge the validity, enforceability or scope of any licensed rights; or (ii) on a target-by-target basis cease development and commercialization activities regarding the LogicBio Licensed Products. In addition, either party may terminate the agreement upon insolvency of, or material uncured breach of the agreement by, the other party.

LogicBio is based in Lexington, Massachusetts, U.S., and listed on the NASDAQ stock exchange (Stock Symbol: LOGC). LogicBio is a clinical-stage genetic medicine company pioneering gene delivery and gene editing platforms to address rare and serious diseases from infancy through adulthood.

As of the Latest Practicable Date, LogicBio is an Independent Third Party.

During the Track Record Period, we paid a total of US\$10.0 million to LogicBio. We are obligated to pay up to US\$591 million for clinical development milestones at initiations of clinical trials, regulatory milestones for receiving regulatory approval in certain designated territories, and certain commercial milestones as discussed above to LogicBio after the Track Record Period.

Collaboration with Mirum

On April 28, 2021, we entered into a license agreement with Mirum Pharmaceuticals, Inc. (“Mirum”), wherein Mirum granted to us an exclusive, royalty-bearing, sublicensable (subject to certain conditions) license to certain Mirum licensed know-how and patents to develop, manufacture and commercialize maralixibat, an investigational, orally administered medication, and pharmaceutical products containing maralixibat (“Mirum Licensed Products”), which is being evaluated in several indications including Alagille syndrome (ALGS),

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progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA), within the licensed territory of Greater China for ALGS, PFIC, and BA. The licenses granted to us constitute sublicenses of upstream license agreements to Mirum which Mirum may not amend or terminate without our prior written consent.

Under the terms of the licensing agreement, we have obtained the exclusive right to develop and commercialize maralixibat within the Greater China regions for ALGS, PFIC, and BA. In exchange, Mirum received an \$11.0 million upfront payment in May 2021, and is further entitled to receive R&D funding and up to \$109.0 million for the achievement of future regulatory milestones for obtaining NMPA approval for designated indications and commercial milestones for achieving net sales at designated amounts, with significant double-digit tiered royalties based on product net sales. The royalty term for the Mirum Licensed Product in a specific country commences upon the first sale in such country and expires on a licensed product-by-licensed product and region-by-region basis on the later of (i) the expiration of the last-to-expire valid claim of a licensed patent covering the Mirum Licensed Product in such region, or expiration of the applicable upstream license agreement royalty term, (ii) the expiration of regulatory exclusivity for such Mirum Licensed Product in such region, or (iii) the twelve (12) anniversary of the first sale of the Mirum Licensed Product in such region.

In collaboration with Mirum, we have agreed to oversee Mirum's clinical study sites in China, with the goal of accelerating enrollment of the global Phase 2b EMBARK study, which was recently initiated for patients with BA. We also have the right to manufacture maralixibat in Greater China under certain conditions. We are required to use commercially reasonable efforts, at our sole cost and expense, to develop and commercialize the Mirum Licensed Products in Greater China and are responsible for obtaining regulatory approval for Mirum Licensed Products in the licensed territory.

Subject to the terms of the agreement, we and Mirum will each solely own the entire right, title and interest in and to all inventions and discoveries first made or discovered solely by us or Mirum, respectively, and will jointly own all inventions or discoveries jointly made or discovered in connection with the performance of activities under this agreement. Mirum has the first right, at its expense, for the prosecution and maintenance of the licensed patent rights in the licensed territory. We have the first right, but not the obligation, to enforce the licensed patent rights in the licensed territory.

Mirum is based in Foster City, California, U.S. and listed on the NASDAQ stock exchange (Stock Symbol: MIRM). Mirum is a clinical-stage biopharmaceutical company focused on the development and commercialization of a late-stage pipeline of novel therapies for debilitating liver diseases.

As of the Latest Practicable Date, Mirum is an Independent Third Party.

During the Track Record Period, we paid a total of US\$11.0 million to Mirum. We are obligated to pay up to US\$109.0 million for the achievement of future regulatory milestones as discussed above to Mirum after the Track Record Period.

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OUR PLATFORM

We have developed a fully-integrated platform for the research, development, and commercialization of rare disease therapies. The integration of our platform enables smooth collaboration among different functional groups at key points in the lifecycle of a product candidate with the goal of increasing the speed of development and likelihood of success while at the same time reducing the cost of development. In addition, our platform has been stress tested throughout the development of our product candidates by requiring each functional group to improve their process, approach and collaboration skills.

RESEARCH AND DEVELOPMENT

We believe that R&D is key to driving our therapies strategy and maintaining our competitiveness in the biopharmaceutical industry. We are dedicated to enhancing our rare disease drugs portfolio by leveraging our strong in-house R&D capabilities, which span from preclinical research to clinical development.

Our R&D Team

Our R&D team members have extensive early research, preclinical and clinical development experience, including a proven track record in the development of drugs for the treatment of different types of rare diseases. As of the Latest Practicable Date, we had a total of 173 employees, among whom 22 have a Ph.D. and/or M.D. degree, and more than 80% of our employees had experience working at multinational biopharmaceutical companies. Our R&D team members have an average of approximately 10 years of relevant industry experience.

Our R&D team is led by our founder Dr. Xue (Ph.D., M.B.A.), a veteran entrepreneur with over 22 years of experience in medical and pharmaceutical companies. Serving as the founding general manager of Genzyme China, he had successfully managed the launch of several life-saving drugs for the treatment of hematologic cancer and rare metabolic diseases in China, including but not limited to Thymoglobulin and Cerezyme. He is also the Deputy Director General at CHARD, Vice Chair of R&D Committee of China Pharmaceutical Innovation and Research Development Association (PhIRDA) and a member of Leadership and Development Committee of Joint Institute of Peking University Health Science Center and University of Michigan Medical School.

To leverage the capabilities of our R&D team, we promote company-wide cross-function collaboration to identify and mitigate inherent risks early in the development of innovative therapies with massive market potential. For example, in implementing such approach, our senior R&D members serve across different functional teams, and our medical team will be involved from the project inception and throughout the preclinical development of our research projects. This enables our team to be familiar with the assets at an early stage so that they can formulate development ideas early on and provide feedback to the internal R&D team.

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In addition, to empower our R&D team, achieve a lean operation and optimize the effectiveness and efficiency the drug development efforts for our innovative pipeline assets, we strategically combine internal research and global collaborations with top biotechnology institutions worldwide. See “Our Strengths – Extensive strategic partnerships to source innovative therapies globally” and “– Collaboration with CROs.” In particular, we continue to invest in gene therapy as our next-generation technology development and expand our in-house R&D activity to generate promising leads for treatment of rare diseases. See “Our Strategies – Maximize value creation through partnership and collaboration.” Our R&D efforts are also supported by a scientific advisory board with reputable key opinion leaders in the pharmaceutical industry, covering rare disease and gene therapy.

For the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, our R&D expenses were RMB55.4 million, RMB109.6 million and RMB274.8 million, respectively. For our Core Product CAN008, our R&D expenses were RMB11.9 million, RMB4.3 million and RMB17.9 million for the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, accounting for 21.5%, 3.9% and 6.5% of our total R&D expenses, respectively.

Preclinical Research

Our preclinical research effort is led by Dr. Yunxiang Zhu (PhD), our Vice President and Head of Global Research. Dr. Zhu has nearly 20 years of R&D leadership experience in the biotechnology industry, during which time he designed more than five first-in-class bispecific and trifunctional antibody lead candidates, and contributed greatly to the invention of the second-generation ERT. Our R&D teams currently base in Shanghai, China and Greater Boston area.

We have a streamlined our preclinical research process in identifying and validating potential therapeutic compounds. Our R&D team makes proposals on the drug target and modality for further investigation. Then, the R&D leaders from our preclinical research, clinical development and medical research teams review the proposals to assess the proposed therapeutic targets based on unmet clinical needs, competitive landscape and their fit with our corporate strategy. Our senior management will then approve the further investigation/in-house development, acquisition or in-licensing after such feasibility assessment.

In addition to biologics and small molecules, we are internally developing an AAV delivery platform targeting different tissues such as central nervous system (CNS) and muscles. We have also entered into collaborations with top medical companies and institutions including LogicBio Therapeutics and UMass to explore the gene therapy solutions for treatment of LSDs, MMA, and certain neuromuscular disorders based on novel AAV capsids. We are building gene therapy CMC operations with AAV research process development laboratory and pilot plants enabling translational studies in the Greater Boston area. We believe our full-fledged platform and collaboration partnerships also afford us with opportunities to pursue rare disease drug development in neglected diseases and quickly generate clinical proof-of-concept and data for global development. As we grow and scale up our infrastructure, we expect to enjoy a cost advantage which enables us to optimize our pricing and bring our rare disease therapies to as many overseas markets as possible.

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Clinical Development

Our clinical development team is led by Dr. Gerald Cox (MD, PhD), our Chief Development Strategist and interim CMO. Each of our clinical development projects involves a joint and collaborative process involving clinical development, science and pipeline strategy teams and is initiated only after a comprehensive study on product profile, clinical/preclinical data, existing and anticipated treatment and competitive landscape, as well as commercial potential. For each proposed clinical development project, a feasibility assessment led by our medical team is conducted. A feasibility report is generated in the process and submitted to our review committee (composed of functional representatives from medical, clinical operations, CMC, preclinical, regulatory affairs and our project leadership teams), and a clinical development project meeting will be organized to assess factors such as the project’s compatibility with our strategy, project feasibility, filing strategy, execution timetable, market and commercialization prospects and R&D resources available to either approve or reject the project. After approval, we assign a project lead for each of our clinical development project who formulates the study timetable and budget, and a medical lead who develops a detailed study protocol based on the compound’s MoA and oversees the trial execution. All of our trials are operated under the regulation set by Human Genetic Resources Administration of China (HGRAC) and ethics committees of the sites. Our clinical development team do not share any information with our licensing partners, and the communications with licensing partner are monitored and managed by our business development team. We also have internal standard operating procedures in place to regulate the activities related to human genetic information management.

Collaboration with CROs

To efficiently and effectively achieve our R&D targets, we adopt a distributed drug development model, where we select the most suitable partners to optimize the effectiveness and efficiency of our drug development efforts, including working with industry-leading CROs to manage, conduct and support our preclinical research and clinical trials. For example, we engaged PAREXEL China Co., Ltd., a leading clinical CRO in China, to conduct pharmacovigilance, data management, regulatory management, biometric analysis, project management and center reading for the Phase 1 trial of CAN008, and PPC China Corporation Limited, another leading clinical CRO in China, to provide pharmacovigilance, data management, regulatory management, biometric analysis and project management for the ongoing Phase 1 trial of CAN106. During the Track Record Period, we engaged ten and five CROs in the years ended December 31, 2019 and 2020 respectively, and seven CROs in the six months ended June 30, 2021. We select each CRO based on their expertise in specific products and indications, as well as the stages of development. According to Frost & Sullivan, engagement of more than 10 CROs is in line with market practice given the difficulty of clinical trial enrollment for rare diseases. We conduct competitive bidding to ensure we get the best value from our CRO partners. As we are actively expanding our R&D team, we plan to adequately staff each project based on the stages of the development and will increase resources as the project matures into the later stages. We have also established a full-function

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commercial team covering sales, marketing, medical affairs, market access, patient value & communications, channel management and etc., and we plan to add additional resources for health economics pricing or access as we have additional products enter into the commercialization stage.

We select CROs based on various factors, such as their professional qualifications, research experience, therapeutic area experience, industry reputation, project specialty, project track record and data management system. In addition, we consider their ability to facilitate site selection, timely recruit patients and conduct complex clinical trials efficiently with high quality. We typically enter into a general service agreement with a CRO for clinical trial management services under which we execute separate work orders for each clinical development project. The bases of determination of CRO fees include the services provided, number of work orders, and specialty of services. The prices we pay are consistent with market practice and comparable to those of similar companies. We closely supervise these CROs to ensure their performance in a manner that complies with our protocols and applicable laws, which in turn protects the integrity and authenticity of the data from our trials and studies.

Below is a summary of the key terms of an agreement that we typically enter into with our CROs:

- **Services.** The CRO provides us with services such as the implementation and management of a clinical research project as specified in the master agreement or a work order.
- **Term.** The CRO is required to perform its services within the prescribed time limit set out in each work order and in accordance with the KPIs agreed by both parties.
- **Payments.** We are required to make payments to the CRO in accordance with the payment schedule agreed by the parties.
- **Risk allocation.** Each party should indemnify the other party for losses caused by its negligence, recklessness, intentional misconduct or material breach of the master agreement or the work order.

MANUFACTURING

We currently outsource the production of drug candidates to a limited number of highly reputable CDMOs. For example, WuXi Biologics is the CDMOs we have engaged to provide small and large molecule manufacturing services. We have adopted procedures to ensure that the production qualifications, facilities and processes of our CDMOs comply with the relevant regulatory requirements and our internal guidelines. We select our CDMOs by reviewing a number of factors, including their qualifications, relevant expertise, production capacity, geographic proximity, reputation, track record, product quality, reliability in meeting delivery schedules, and the financial terms offered by them. We commission these CDMOs to develop and manufacture active pharmaceutical ingredients to support our clinical development. To

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monitor and evaluate the services performed by our CDMOs, we set a series of predefined specifications on in-process control and release tests, and review manufacturing related documents, including batch records and quality control test results, to ensure specifications are met. In addition, we conduct annual audits and when there is deviation from process protocol, ad hoc special audits, on our CDMOs.

In an effort to scale up our gene therapy development, we are in the process of building our AAV process development lab in Greater Boston area, which is expected to be opened in 2022, primarily for the manufacturing our gene therapy products. In addition, we are also establishing our manufacturing facilities in Suzhou, which is designed to comply with cGMP with several production lines. The Suzhou facilities are expected to be opened in 2023, which are mainly for supporting the production of CAN008 and other pipeline products.

SALES AND MARKETING

Our Sales Capabilities

As of the Latest Practicable Date, we had commercialized three products, Caphosol™ (CAN002) in mainland China since October 2018, Nerlynx® (CAN030) in Greater China since December 2019, and Hunterase® (CAN101) in mainland China since May 2021. We use a combination of our in-house sales and marketing team and a network of independent distributors to sell our products in Greater China. Our management team has a track record of successfully commercializing rare disease therapies across various key markets including China, Southeast Asia, the United States, Latin America and Europe. Led by them, we have assembled an experienced commercial team to ensure the successful commercialization of our drug candidates upon approval. As of the Latest Practicable Date, we had established a commercial team jointly led by Mr. Yijun Lu, our China General Manager and Mr. Marcelo Cheresky, our Chief Business Officer, consisting of 81 members.

As we successfully received the marketing approval from China’s NMPA and commercially launched Hunterase® (CAN101) in China in May 2021, we are currently building a dedicated in-house commercialization team to support its initial launch and expect to expand to a team of over 300 members in the next five years, comprising three major functions including marketing and sales, medical affairs and patient advocacy and assistance, with the mission to execute medical engagement plan for KOL development, promote entire community awareness and explore industry insights for better drug development strategy.

With our late-stage drug candidates entering into the commercialization stage, we have established our key operation hubs, where a majority of our business operations are conducted, in both Beijing and Shanghai, with offices in other locations in Great China, and plan to expand to each of the key target provinces with local offices. See “Our Strategies – Drive commercialization of our late-stage assets in Greater China.”

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Our Marketing Model and Sales Arrangements

We employ a strategic marketing model to promote and sell our products. Under this model, we promote our products to hospitals and physicians in Greater China through academic marketing, establishing center of excellence and referral network, and providing trainings to physicians.

Distribution and Direct Sales

In line with industry practice, we distributed a significant portion of our products to distributors during the Track Record Period, who then sold the products to hospitals, physicians, pharmacies or medical centers. We do not rely on the distributors to develop or expand our sales network, but benefit from their established nationwide or regional resources. During the Track Record Period, we distributed Caphosol™ (CAN002) in mainland China and Nerlynx® (CAN030) in Greater China. We also started commercialization of Hunterase® (CAN101) in mainland China in May 2021. We engaged one distributor for the sales of Caphosol™ (CAN002) and one distributor for the sales of Nerlynx® (CAN030) respectively in mainland China, each of which is an Independent Third Party. During the Track Record Period, we also sold Caphosol™ (CAN002) in mainland China directly to a healthcare company and sold Nerlynx® (CAN030) directly to hospitals, private clinics run by individual physicians⁽¹⁾, pharmacies and medical centers in Hong Kong and Taiwan via a sales and marketing service provider. We promote our products to hospitals and physicians in Greater China through academic marketing, establishing center of excellence and referral network, and providing trainings to physicians.

Caphosol™ (CAN002) is a mouth rinse indicated for temporary or persistent dryness of the mouth and throat used as an adjunct to standard oral care for the prevention and treatment of oral mucositis caused by radiotherapy or high dose chemotherapy. Nerlynx® (CAN030) is an anti-HER2 treatment as extended adjuvant therapy for early-stage HER2-positive breast cancer. As we strategically shift our business focus to rare disease and rare oncology, we have simplified our sales arrangements for Caphosol™ (CAN002) and Nerlynx® (CAN030).

Our collaboration with the distributor for Caphosol™ (CAN002) expired by the end of 2019 and we simplified our sales arrangements by adjusting the distribution model of Caphosol™ (CAN002) to sell directly to a healthcare company that conducts its own promotional activities in order to focus more on rare diseases in our business. In February 2020, we entered into an agreement with a healthcare company for the direct sales of Caphosol™ (CAN002), with a term of seven years since the first commercial order in mainland China, with an automatic renewal of a further period of three years unless otherwise agreed by the parties. Such healthcare company is a pharmaceutical wholesaling and

(1) According to Frost & Sullivan, it is a market practice for biotech companies to sell drugs directly to private clinics run by physicians where the invoice is directly billed to such physicians in Hong Kong and Taiwan. To the Company’s best knowledge, such physicians were Independent Third Parties as of the Latest Practicable Date.

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distribution company which onells CaphosolTM (CAN002) to sub-distributors. We do not require such healthcare company to report back to us to whom it onells CaphosolTM (CAN002). Such healthcare company was an Independent Third Party as of the Latest Practicable Date.

Our collaboration with the distributor for Nerlynx[®] (CAN030) expired by the end of March 2021. Our commercialization right of Nerlynx[®] (CAN030) in Greater China was granted by Puma Biotechnology, Inc. (Nasdaq: PBYI) (“Puma”) under a collaboration and license agreement in January 2018. In February 2021, we have reached an agreement with Puma to terminate such license agreement and Puma has agreed with Pierre Fabre Médicament SAS (“Pierre Fabre”) to transfer the exclusive commercialization right of Nerlynx[®] (CAN030) in Greater China to Pierre Fabre. We have simultaneously entered into a distribution agreement with Pierre Fabre pursuant to which Pierre Fabre appointed us as its distributor with exclusive rights to sell Nerlynx[®] (CAN030) for Pierre Fabre in Hong Kong, Macau, and Taiwan until December 31, 2022, with an option to renew. For details, please see “Business – Legal Proceedings and Compliance”.

For the commercialization of Hunterase[®] (CAN101) in mainland China, we entered into a distribution agreement in September 2020 with a distributor who, to the best of our Directors’ knowledge, is an Independent Third Party, for the distribution of Hunterase[®] (CAN101) in mainland China, for a term of two years commencing from the date of the agreement with an automatic renewal of a further period of three years unless otherwise agreed by the parties.

For the sales of Nerlynx[®] (CAN030) in Hong Kong and Taiwan, we do not enter into any sales agreements directly with any hospitals, physicians, pharmacies or medical centers. Instead, we enter into arrangements with a sales and marketing service provider, pursuant to which the title to the products we deliver to such provider remains with us until these products are sold to end consumers. Such provider provides us with services, including among others, product storage, delivery/transportation and invoicing, and pays us the purchase price of the underlying products within 90 days after the products are invoiced and delivered to the end customers, but they have the right to return to us for a full refund any product that is returned by end consumers, any stock of products expire, or the remaining stock upon termination of the agreement. We have not experienced any material sales return of Nerlynx[®] (CAN030) since its commercialization.

Revenue under the above arrangements is recognized when a sale is made to the end customer and control is transferred to the end customer upon their acceptance in accordance with the sales report provided by the service provider. Such revenues reflect the consideration paid by end consumers and do not take into account the sales commissions we pay to the service provider, which are recorded as sales and marketing expenses. Except for CAN002 which we sell directly to a healthcare company that conducts its own promotional activities, the daily market promotion activities of our other products including CAN030 and CAN101 are conducted by our own commercialization team.

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We have not experienced in the past nor expect in the future any material operational impediments in the transition of our sales arrangement to the healthcare company for Caphosol™ (CAN002) and the sales and marketing service provider for Nerlynx® (CAN030).

During the Track Record Period, the Two-Invoice System is not applicable to our arrangements of CAN030 and CAN002 with sub-distributors pursuant to the Notice on Opinions on the Implementation of the “Two-Invoice System” in Drug Procurement by Public Medical Institutions (for Trial Implementation) (the “2016 Notice”) and the Notice on Consolidating the Achievements of Cancelling Drug Markups and Deepening Comprehensive Reforms in Public Hospitals (the “2018 Notice”). The 2016 Notice and the 2018 Notice only regulate sales to public hospitals. Since such distribution of CAN002 and CAN030 was not distributed to any public hospital, it did not fall into the governing scope of the above-mentioned notices and thus would not be regarded as a breach of the Two-Invoice System, as advised by our PRC Legal Advisor. In addition, the distribution of Hunterase® (CAN101) through our distributor during the Track Record Period was not to any public hospitals. Therefore, it did not fall into the governing scope of the abovementioned notices either and would not be regarded as a breach of the Two-Invoice System, as advised by our PRC Legal Advisor. To ensure our continuous compliance with the Two-Invoice System going forward, we have various measures in place. For instance, we check the qualification of the distributors before we establish collaboration with them, and are able to monitor the distribution channel of our product sales to avoid any deviations from applicable laws and rules.

Our distributors are required to comply with all applicable laws and regulations, including, among other things, the anti-bribery and anti-kickback laws and regulations. We require each of our distributors to comply with our internal anti-bribery policies. We also require our distributors to monitor the compliance of sub-distributors with relevant anti-corruption and anti-bribery laws and regulations as applicable.

Goods Return Policy

We generally do not accept product returns or exchanges except for products with quality defects, or in the situation that the distributor has obtained our written consent for such return or exchange. Our distributors are required to inspect the quality and package of products on delivery. We sell the goods to our distributors in their entirety and our distributors have the responsibility to monitor stock shelf-life and manage any expired stocks on their end.

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Pricing

As of the Latest Practicable Date, we had three commercialized products in the market. We distributed products to our distributors, directly to a healthcare company in mainland China and directly to hospitals, private clinics run by individual physicians, pharmacies and medical centers in Hong Kong and Taiwan via a sales and marketing service provider at the price determined by us from time to time. When determining the price of our products distributed, we consider factors such as clinical value, current unmet medical needs, product quality, production costs, health economics in the country to market in, patient affordability and competitors’ pricing strategies. The list price of Hunterase[®] (CAN101) in China is similar to its reimbursement price in South Korea, where it was previously approved and commercialized in, taking the afore-mentioned key factors into account. We have initiated a Hunterase[®] (CAN101) patient assistance program in collaboration with a medical payment services provider to improve patients’ access to Hunterase[®] (CAN101) in China. We expect to follow similar pricing strategies when CAN008 enters the commercialization stage. We believe our pricing strategy can strike a balance between the affordability of patients and a sustainable return on these products.

As of the Latest Practicable Date, there was only general policies on the price control of drugs to prevent exorbitant profits, price monopoly, and price fraud, among others. For regulatory policies related to the pricing of our products, see “Regulation Environment – Price Controls.” However, there is no price guidance set by the PRC government on the specific therapies with indications targeted by our Core Product and commercialized products.

As of the Latest Practicable Date, CAN008, our Core Product was still in clinical stage, and our three commercialized products, CAN101, CAN002 and CAN030, had not been included under the national or provincial public medical insurance program in China or other relevant regions. In light of current circumstances, we believe that the likelihood that our products will be included in the national public medical insurance program in China in the near future remains relatively low. However, we observed that over the years of China’s exploration in insurance mechanism of rare diseases at the local level, an aggregate of 29 provinces have implemented insurance policies for certain rare disease with various reimbursement models. If our commercialized products or Core Product upon commercialization are included in public medical insurance programs, we may face downward pricing pressure. Nevertheless, it will also increase the sales volume and therefore further promote the market growth of our products. For details on other factors related to the pricing of our products, see “Industry Overview – Rare Disease Therapies Reimbursement and Pricing”.

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CUSTOMERS

For the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, the aggregate sales to our five largest customers were RMB1.5 million, RMB9.4 million and RMB6.4 million, representing 100.0%, 77.7% and 52.4% of our revenue, respectively. Sales to our largest customer for the same periods were RMB1.1 million, RMB5.3 million and RMB2.2 million, representing 72.2%, 44.2% and 17.7% of our revenue, respectively. Please see below a summary of the sales to our five largest customers for the periods indicated:

Five Largest Customers for the year ended December 31, 2019	Background	Covered Region	Sales Amount RMB'000	Percentage of Revenue
Customer A	Distributor	Mainland China	1,061	72.2%
Customer B	Physician	Hong Kong	408	27.8%
–	–		–	–
–	–		–	–
–	–		–	–
Total:			<u>1,460</u>	<u>100.0%</u>

Five Largest Customers for the year ended December 31, 2020	Background	Covered Region	Sales Amount RMB'000	Percentage of Revenue
Customer C	Distributor	Mainland China	5,324	44.2%
Customer D	Physician	Hong Kong	2,173	18.1%
Customer E	Hospital	Hong Kong	854	7.1%
Customer F	Hospital	Hong Kong	512	4.3%
Customer B	Physician	Hong Kong	491	4.1%
Total:			<u>9,354</u>	<u>77.7%</u>

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Five Largest Customers for the six months ended June 30, 2021	Background	Covered Region	Sales Amount <i>RMB'000</i>	Percentage of Revenue
Customer C	Distributor	Mainland China	2,162	17.7%
Customer G	Hospital	Taiwan	2,138	17.5%
Customer H	Healthcare company	Mainland China	841	6.9%
Customer I	Distributor	Mainland China	667	5.5%
Customer E	Hospital	Hong Kong	576	4.7%
Total:			<u>6,384</u>	<u>52.4%</u>

RAW MATERIALS AND SUPPLIERS

Suppliers

During the Track Record Period, our suppliers primarily consisted of (i) licensors from which we obtained intellectual property rights in respect of our in-licensed drug candidates and (ii) CROs and CDMOs, who provide third-party contracting services for research and development. We select our suppliers by considering their product quality, industry reputation and compliance with relevant regulations and industry standards.

For the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, purchases from our five largest suppliers in aggregate accounted for 63.1%, 83.7% and 69.3% of our total purchases (including value added tax), respectively, and purchases from our largest supplier accounted for 42.8%, 55.6% and 23.3% of our total purchases for the same periods (including value added tax), respectively.

Five Largest Suppliers for the year ended December 31, 2019	Purchases	Purchase Amount <i>(RMB'000)</i>	Percentage of Total Purchases
Supplier A	License agreement	34,881	42.8%
Supplier B	License agreement	6,209	7.6%
Supplier C	Research and development services	4,403	5.4%
Supplier D	Medical device products	3,153	3.9%
Supplier E	Research and development services	2,742	3.4%
Total		<u>51,388</u>	<u>63.1%</u>

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Five Largest Suppliers for the year ended December 31, 2020	Purchases	Purchase Amount (RMB'000)	Percentage of Total Purchases
Supplier F	License agreement and finished drug products	131,236	55.6%
Supplier G	Research and development services	34,560	14.6%
Supplier A	License agreement	16,312	6.9%
Supplier B	License agreement	8,622	3.7%
Supplier H	License agreement	6,898	2.9%
Total		197,628	83.7%

Five Largest Suppliers for the six months ended June 30, 2021	Purchases	Purchase Amount RMB'000	Percentage of Total Purchases
Supplier I	License agreement	71,500	23.3%
Supplier J	License agreement	70,704	23.1%
Supplier H	License agreement	37,375	12.2%
Supplier G	Research and development services	25,844	8.4%
Supplier K	Research and development services	7,136	2.3%
Total:		212,559	69.3%

Raw Materials

During the Track Record Period, we have not procured raw materials or equipment for commercial manufacturing.

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INVENTORY

Our inventories consist of finished goods. We currently store all our inventories in warehouses in Beijing, Guangzhou, Taipei, and Hong Kong.

All our products are subject to expiry. Our finished products generally have an effective period of approximately 36 months. We regularly monitor our inventories to reduce the risk of overstocking. We have in place internal policies which require a physical count of all our finished goods once every 12 months to identify products that are damaged, expired or soon-to-be expired.

Our Directors confirm that our inventory control policies have been effective and we did not experience any material shortage in supply or overstocking of inventories during the Track Record Period and up to the Latest Practicable Date.

As of December 31, 2019 and 2020, and 31 March 2021, our inventories amounted to RMB1.4 million, RMB0.6 million and 1.8 million, respectively.

COMPETITION

The pharmaceutical and biopharmaceutical industries are characterized by rapidly advancing technologies, competition and a strong emphasis on proprietary drugs. While we believe that our development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biopharmaceutical companies, academic institutions and public and private research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future.

We operate in the segments of the pharmaceutical, biotechnology and other related markets that address rare diseases. There are other companies working to develop similar therapies in these fields. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. Many of the companies we are competing against or with which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. 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 or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies or products complementary to, or necessary for, our research and development.

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Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer or more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain NMPA or other regulatory approval for their drugs earlier than we obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their efficacy, safety, convenience and price.

In addition, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our drug candidates that are in clinical trials for the same or similar cancer indications.

To maintain our market competitiveness and increase our market awareness, we will continue to expand our sales and marketing team, establish center of excellence and referral network, provide trainings to physicians, and attend or organize educational symposia, conferences, seminars, and other activities at national, regional and local levels in both China and the U.S..

For the competitive landscape of our specific drug candidates, please refer to “– Our Portfolio.”

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our insurance policies cover adverse events in our clinical trials, and we also maintain product liability insurance, property loss insurance, business interruption insurance and public liability insurance. We expect our employer liability insurance to be effective upon [REDACTED]. We maintain social welfare insurance for our employees in accordance with relevant PRC laws and regulations.

EMPLOYEES

As of the Latest Practicable Date, we had 173 employees in total. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Function	Number	% of Total
Commercialization	81	46.8%
Product Development (R&D, clinical, regulatory, IP)	54	31.2%
Quality Control	4	2.3%
General	34	19.7%
Total	<u>173</u>	<u>100%</u>

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We plan to further expand our commercialization team to have over 300 full time employees in the next five years. See the sub-section headed “Commercialization” in this section for more details.

We require all of our employees, especially those involved in sales and marketing and business development activities, to abide by our anti-bribery and anti-corruption compliance requirements and applicable laws and regulations to eliminate bribery and corruption risks. We closely monitor our employees’ compliance with anti-bribery and anti-corruption policies.

Employment Agreements with Key Management and Research Staff

We enter into standard confidentiality and non-compete and employment agreements with our key management and research staff. Our standard confidentiality and non-compete agreement prohibits the employee from competing with us, directly or indirectly, during his or her employment and for up to 24 months after the termination of his or her employment. The standard confidentiality and non-compete agreement also includes undertakings regarding the assignment of inventions and discoveries made during the course of the employee’s employment. For further details regarding the terms of the confidentiality and non-compete and employment agreements with our key management, please refer to the section headed “Directors and Senior Management” in this document.

We believe that we maintain a good working relationship with our employees. We have not experienced any material labor disputes or any significant difficulty in recruiting staff for our operations.

Training and Development

We conduct new staff training regularly to guide new employees and help them adapt to the new working environment. In addition, we provide on-line and in-person formal and comprehensive company-level and department-level training to our employees on a quarterly basis in addition to on-the-job training. We also encourage our employees to attend external seminars and workshops to enrich their technical knowledge and develop competencies and skills. We also provide training and development programs to our employees and external training sessions from time to time to improve their technical skills and ensure their awareness and compliance with our various policies and procedures.

Employee Benefits

Our employees’ remuneration consists of salaries, bonuses, share-based incentive plans, an employees’ provident fund, and social security contributions and other welfare payments. In accordance with applicable laws in China and other relevant jurisdictions, we have made contributions to social security insurance funds (including pension plans, unemployment insurance, work-related injury insurance, medical insurance and maternity insurance) and housing funds for our employees. For more information, please refer to the section headed

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“Risk Factors – Risks Relating to Extensive Government Regulations – Failure to comply with relevant regulations relating to social insurance and the housing provident fund may subject us to penalties and adversely affect our business, financial condition, results of operations and prospects.”

LAND AND PROPERTIES

As of the latest Practicable Date, we had a total of approximately 4,300 sq.m leased office space as our clinical and business development center in Greater China. We also have leased offices in the United States, which are used as our overseas offices in Greater Boston. The relevant lease agreements generally provide a duration of up to five years.

We do not have any property interest with a carrying amount of 15% or more of our consolidated total assets as of June 30, 2021. 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 38(1) 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 Group’s interests in land or buildings.

We do not own any real property for our operations. Upon expiration of our leases, we will need to negotiate for renewal of the leases or relocate if our landlords failed to provide valid title certificates with respect to some of our leased properties. There are plenty of alternative locations with valid titles for us to choose from, but we will incur additional costs in relation to the potential relocation. During the Track Record Period, we did not experience any dispute arising out of our leased properties. For details of risks relating to our leased properties, see the section headed “Risk Factors – Risks Relating to Our Operations – We do not own the real property for our current major operation sites and may be subject to risks relating to leased properties.” in this document.

INTELLECTUAL PROPERTY

Intellectual property rights are important to the success of our business. Our success depends, in part, on our ability to obtain and maintain patent and other intellectual property and proprietary protections for commercially important technologies, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

As of the Latest Practicable Date, we own or otherwise have exclusive rights to 17 granted patents and 47 pending patent applications worldwide. For CAN008, we are currently conducting R&D works in China, including the Phase 2 trial and pre-clinical research for other

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indications beyond GBM, which may be the subject of additional patent filings by ourselves in the short to mid-term. We believe there is no material legal impediment for us to obtain the approvals for these pending patents and trademarks.

The table below lists the portfolio of patent applications material to our business operations as of the Latest Practicable Date:

Summary of patents and patent applications of our product candidates

Product	Scope of Patent Protection	Patent Applicant/ Holder	Jurisdiction	Status	Patent Expiration*
CAN008	CD95-Fc Variants	Apogenix	China, Hong Kong	Granted	2033
	Reagents and methods of detecting cancer	Apogenix	China	Granted	2033
	CD95-Fc isoforms	Apogenix	China, Hong Kong	Pending	N/A
Hunterase® (CAN101)	Human iduronate-2-sulfatase and preparation method thereof	GC Pharma	China, Hong Kong	Granted	2032
CAN108	Pediatric compositions for cholestatic liver disease, Use of composition for treatment	Shire HGT	China	Granted	2032
		Shire HGT	China, Hong Kong	Pending	N/A
	Genotype and Dose-Dependent Response to an Asbti in Patients with Bile Salt Export Pump Deficiency	Mirum	Worldwide (PCT stage)	Pending	N/A
	Methods for Treating Cholestasis	Mirum	Worldwide (PCT stage)	Pending	N/A
	Methods for Increasing Growth in Pediatric Subjects Having Cholestatic Liver Disease	Mirum	Worldwide (PCT stage)	Pending	N/A
CAN106	Antibody Molecules to Complement Component 5 and Uses Thereof	Atarga	AE, AU, BR, CA, CL, CN, CO, EP, ID, IL, IN, JP, KR, MX, NZ, PE, PH, RU, SA, SG, TW, ZA**	Pending	2039

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- * Patent expiration does not include any applicable patent term extensions
- ** Australia, Brazil, Canada, Chile, China, Colombia, Europe, Indonesia, Israel, India, Japan, South Korea, Mexico, New Zealand, Peru, Philippines, Russia, Saudi Arabia, Singapore, South Africa, Taiwan, United Arab Emirates

LEGAL PROCEEDINGS AND COMPLIANCE

We entered into a collaboration and license agreement (the “2018 License Agreement”) with Puma Biotechnology, Inc. (Nasdaq: PBYI) (“Puma”), a biopharmaceutical company, in January 2018, in which Puma granted us exclusive rights to develop and commercialize neratinib in Greater China. Neratinib is a drug developed by Puma and approved for marketing in the U.S. for both the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and HER2-positive metastatic breast cancer. Neratinib is marketed in the U.S. as NERLYNX[®] (neratinib) tablets.

Pierre Fabre Médicament SAS (“Pierre Fabre”), a global pharmaceutical and healthcare products company, entered into a license agreement (the “2019 License Agreement”) with Puma in March 2019, pursuant to which Puma granted Pierre Fabre certain rights and licenses to develop and commercialize neratinib in Europe, Turkey, Middle East and Africa.

In July 2020, Puma initiated an arbitration proceeding against us in connection with the 2018 License Agreement (the “Arbitration”) before the International Chamber of Commerce. We filed a response in August 2020 and asserted counterclaims against Puma. To settle the Arbitration, we have reached an agreement with Puma in February 2021 to terminate the 2018 License Agreement. Simultaneous to the termination of the 2018 License Agreement, Puma has agreed with Pierre Fabre, to amend the terms of the 2019 License Agreement to extend Pierre Fabre exclusive rights to develop and commercialize neratinib to also include Greater China.

We have also simultaneously entered into a distribution agreement with Pierre Fabre (the “Distribution Agreement”) pursuant to which Pierre Fabre appoints us as its distributor with exclusive rights to register, import, market, distribute and sell neratinib for Pierre Fabre with commercially reasonable efforts in Hong Kong, Macau, and Taiwan until December 31, 2022, with an option to renew. Both parties reached this mutual agreement based on the benefits for transition derived from our established commercial presence in Hong Kong and Taiwan which can facilitate an optimal business transition for both parties over a two year distribution term with an option to extend.

Pursuant to the terms of the various agreements implementing this transaction among the three companies, Puma received an upfront payment of US\$50 million from Pierre Fabre in consideration for the amendment to their 2019 License Agreement, and we received a one-time US\$20 million termination fee from Puma to return all rights to neratinib in Greater China back to Puma. Finally, both parties have agreed to dismiss the Arbitration with prejudice, and not to pursue any further actions against the other party related to the claims asserted in the Arbitration. We recorded a net transaction gain out of the termination fee from Puma and as

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we strategically shift our business focus to rare disease and rare oncology, the termination of the 2018 License Agreement, the settlement with Puma and various agreements implementing this transaction are not expected to have any material adverse impact on our future business operations or financial results.

We do not foresee implications of the termination of the 2018 License Agreement with our ability to fulfill our role to develop and commercialize licensed products as a licensee.

We have developed internal control on partnership execution whereby we will (i) set the key milestones in the agreement with financial payments; (ii) create a joint steering committee with our partner with regular meetings to be every three to six months; (iii) designate responsible persons appointed by each party as alliance management contacts for managing communication; and (iv) hold regular project meetings internally across functional teams.

ENVIRONMENTAL MATTERS AND WORKPLACE SAFETY

We are currently at an early stage of laboratory operations and still rely on CDMOs for the manufacturing function and partially rely on CROs for our clinical development and other activities. As a result, the current nature of our business does not expose us to a substantial risk of environmental, health or work safety matters, and we do not expect the potential risks of such matters will have a material adverse impact on our business, strategy and financial performance.

We strive to operate our facilities in a manner that protects the environment and the health and safety of our employees, patients and communities. Our operations in the future, particularly after the completion and initiation of manufacturing in our manufacturing facility in Suzhou and Greater Boston, will involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. We will make preparations for environmental control and considerations in the design process, and we will follow regulatory rules and industry standards for the disposal of waste and hazardous materials. We will also designate personnel and staff to specifically monitor and enforce the compliance of our operations with environment, health and safety laws, and regulations.

We have implemented company-wide environmental, health and safety manuals, policies and standard operating procedures that include management systems and procedures relating to emissions of air, water and other media; waste water generation and treatment; process safety management; handling, use, storage, treatment and disposal of hazardous substances; worker health and safety requirements; third party safety management; emergency planning and response; and product stewardship.

We have not had any significant workplace accidents in our history.

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PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations. For more details, please see the section headed “Risk Factors – Risks Relating to Extensive Government Regulation – Our and/or others’ 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” in this document.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to the success of our business operations. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the PRC and global pharmaceutical markets, our ability to develop, manufacture and commercialize our drug candidates, and our ability to compete with other oncology pharmaceutical companies. See “Risk Factors.” We also face various market risks. In particular, we are exposed to credit, liquidity, interest rate and currency risks that arise in the normal course of our business. See “Financial Information – Market Risk Disclosure.”

We have adopted a comprehensive set of risk management policies, which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis. Our senior management, and ultimately our Directors, supervise the implementation of our risk management policies. 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.

The following key principles outline our Group’s approach to risk management and internal control:

- Our Audit Committee oversees and manages 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) monitoring the most significant risks associated with our business operations and our management’s handling of such risks; and (iii) ensuring the appropriate application of our risk management framework across our Group.
- The relevant departments, including but not limited to the business operations, finance and general administration departments, are responsible for developing and implementing our risk management policy and carrying out our day-to-day risk management practice, such as assessing risks on key business operations, advising risk responses and optimizing risk management policies. 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

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the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, evaluation, prioritization, and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operations or functions; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

Internal Control

Our Board of Directors is responsible for establishing and maintaining appropriate and effective internal control system to safeguard our Shareholders' investment at all times. Our internal control policies set out a framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis.

Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding our business operations, and we provide training about these measures and procedures to new employees. We also constantly monitor the implementation of these measures and procedures.
- We maintain strict anti-corruption policies on personnel with external communication functions. We will also ensure that our commercialization team complies with applicable promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.
- Our Directors (who are responsible for monitoring the corporate governance of our Group), with help from our Compliance Adviser, will also periodically review our compliance status with all relevant laws and regulations after the [REDACTED].
- We plan to establish an audit committee, which will (i) make recommendations to our Directors on the appointment and removal of external auditors; and (ii) review the financial statements and render advice in respect of financial reporting, as well as (iii) oversee the financial reporting system and internal control and risk management systems of our Group.

During the Track Record Period, we have regularly reviewed and enhanced our risk management and internal control systems. We believe 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.

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QUALITY CONTROL

We have a quality management department that devotes resources to quality management of our products. We have our own quality control system and devote significant attention to quality control for the designing, R&D manufacturing, testing and transportation of our products and product candidates. Our management team is actively involved in setting quality policies and managing our internal and external quality performance. We have established a strict quality control system in accordance with ICH Q10 and NMPA regulations.

As of the Latest Practicable Date, our quality assurance department consists of four employees. Our quality assurance team is responsible for ensuring raw materials, production process and the quality of finished goods and focuses on the establishment, implementation and maintenance of our quality management system, as well as monitoring our operation in real time throughout the entire development and production process to ensure its compliance with the applicable regulatory and industry requirements.

AWARDS AND RECOGNITIONS

The table below sets forth a summary of the major awards and projects for which we received government grants as of the Latest Practicable Date:

Award/Grant	Awardee	Award/ Completion Date	Award Authority
Key Overseas Chinese Entrepreneurial Team (重點華僑華人創業團隊)	CANbridge Life Sciences Limited	2015	State Council for Overseas Chinese Affairs Office
2018 Future Medicine 100 Forum	CANbridge Life Sciences Limited	2018	VCBeat Network and VCBeat Research Institute
China Future Healthcare Rankings 2019 – Top 100 Pharma & Biotech Companies	CANbridge Pharmaceuticals, Inc.	2019	VCBeat Network and VCBeat Research Institute
HSBC Pioneer Corporation Member	CANbridge Life Sciences Limited	2019	Hongkong and Shanghai Banking Corporation Limited

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Award/Grant	Awardee	Award/ Completion Date	Award Authority
Cancer Frontier Diagnosis and Treatment-Beijing International Science and Technology Cooperation Base (腫瘤前沿診治-北京市國際科技合作基地)	CANbridge Life Sciences Limited	2019-2020	Beijing Municipal Science and Technology Commission
Zhongguancun Science Part High and New Technology Enterprise (中關村高新技術企業)	CANbridge Life Sciences Limited	2019	Administrative Committee of Zhongguancun Science Part
Director member of China Pharmaceutical Innovation and Research Development Association	CANbridge Pharmaceuticals, Inc.	2019	China Pharmaceutical Innovation and Research Development Association
Member of China Alliance for Rare Disease	CANbridge Life Sciences Limited	2018	China Alliance for Rare Disease
Top 30 Most Growing Companies in China's New Economy of Chinese Venture	CANbridge Life Sciences Limited	2021	Chinese Venture Magazine

DIRECTORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

As of the date of this document, our Board of Directors consists of seven Directors, comprising one executive Director, three non-executive Directors and three independent non-executive Directors. Our executive Director, non-executive Directors and independent non-executive Directors will be subject to rotation and re-election at the annual general meetings of our Company in accordance with the Articles of Association.

The table below sets forth certain information in respect of the members of the Board of Directors of our Company:

Name	Age	Date of Joining our Group	Date of Appointment as Director	Position	Roles and Responsibilities
Dr. Xue	[52]	June 12, 2012	January 30, 2018	Chairman of the Board, Executive Director and Chief Executive Officer	Founder of the Company and overseeing the overall strategic business planning and operational management
Dr. Kan Chen (陳侃)	[39]	December 16, 2020	December 16, 2020	Non-executive Director	Participating in formulating our Company’s corporate and business strategies
Dr. Derek Paul Di Rocco	[41]	March 10, 2020	March 10, 2020	Non-executive Director	Participating in formulating our Company’s corporate and business strategies
Mr. Xiao Le (樂霄)	[32]	December 16, 2020	December 16, 2020	Non-executive Director	Participating in formulating our Company’s corporate and business strategies

DIRECTORS AND SENIOR MANAGEMENT

Name	Age	Date of Joining our Group	Date of Appointment as Director	Position	Roles and Responsibilities
Mr. James Arthur Geraghty	[67]	May 27, 2017	July 18, 2018	Independent non-executive Director	Supervising and providing independent judgment to our Board
Dr. Richard James Gregory	[63]	April 21, 2020	April 21, 2020	Independent non-executive Director	Supervising and providing independent judgment to our Board
Mr. Peng Kuan Chan (陳炳鈞)	[57]	June 11, 2021	June 11, 2021	Independent non-executive Director	Supervising and providing independent judgment to our Board

Executive Director

Dr. James Qun Xue, Ph.D., M.B.A., aged [52], has served as Chairman of the Board, Director and Chief Executive Officer since the inception of our Company in January 2018 and was re-designated as an executive Director on June 21, 2021. Dr. Xue is the founder of our Company and has been actively involved in the business, strategy and operational management of our Group since its establishment.

Dr. Xue has over 22 years of experience in medical and pharmaceutical companies. Dr. Xue began his career as a scientist at Kosan Biosciences, Inc. from May 1998 to August 2000, where he dedicated himself to research in bioengineering. In 2002, Dr. Xue joined Genzyme Corporation, where he served in various positions with increasing responsibilities including, among others, the general manager of Genzyme China and senior director of business excellence, and accumulated extensive management experience there until 2011. Since June 2012, Dr. Xue has served as venture partner at Tullis Health Investors where he was principally responsible for providing advice on portfolio company investments and maintaining and enhancing company’s brand and market position.

DIRECTORS AND SENIOR MANAGEMENT

Dr. Xue is deputy director general of the China Alliance for Rare Disease (中國罕見病聯盟), deputy director of the Shanghai Foundation for Rare Disease. He has been the vice chair of the R&D committee of the China Pharmaceutical Innovation and Research Development Association (PhIRDA) since May 2016 and a member of the Leadership Council of the Joint Institute of Peking University Health Science Center and University of Michigan Medical School since August 2017. Dr. Xue has also been a member of BayHelix Group, a non-profit organization of business leaders with a mission to shape the growth of the life sciences and healthcare industry and a mentor of the Termeer Foundation, a nonprofit organization focused on connecting life science innovators and catalyzing the creation of new medicines.

Dr. Xue obtained his Bachelor of Science degree in pharmaceutical chemistry from Peking University School of Pharmacy in July 1992. He further obtained his Ph.D. in bioorganic chemistry from Brown University in April 1997. In addition, Dr. Xue received his postdoctoral degree in pharmaceutical chemistry and biochemistry from University of California in April 1998 and his Master of Business Administration from Darden School of Business, University of Virginia in May 2002.

Non-executive Directors

Dr. Kan Chen (陳侃), Ph.D., aged [39], was appointed as a Director in December 2020 and re-designated as a non-executive Director on June 21, 2021. Dr. Chen has served as director of CANbridge Life Sciences, our wholly-owned subsidiary, since January 2021. Dr. Chen is responsible for participating in formulating our Company’s corporate and business strategies.

Dr. Chen has been as a non-executive director of Antengene Corporation Limited (HKEX: 6996) since March 2021 and a non-executive director of Connect Biopharma Holdings Limited (NASDAQ: CNTB) since December 2020. Dr. Chen has also been serving as a director of Jiangsu Yahong Pharmaceutical Technology Co., Ltd. (江蘇亞虹醫藥科技有限公司), a company principally engaged in drug innovation with a focus on urinary system tumors and other serious diseases, and Abbisko Cayman Limited, a company principally engaged in research of small molecule new drugs, since October 2020 and from February 2020 to June 2021, respectively. Dr. Chen has also been serving as associate and vice president and then as principal of Qiming Venture Partners, focusing on healthcare management, since February 2016. From September 2014 to January 2016, Dr. Chen had been the senior scientist of Janssen, Pharmaceutical Companies of Johnson & Johnson, responsible for drug discovery. From November 2012 to August 2014, he served as group leader of Jiangsu Hengrui Medicine Co., Ltd. (SHA: 600276) responsible for drug discovery. From September 2009 to October 2012, he served as research fellow of immunology research at Brigham and Women’s Hospital of Harvard Medical School.

Dr. Chen received his Bachelor of Science degree in biological sciences from Fudan University in July 2004 and his Ph. D. degree in cell biology from Case Western Reserve University in January 2009.

DIRECTORS AND SENIOR MANAGEMENT

Dr. Derek Paul Di Rocco, Ph.D., aged [41], was appointed as a Director in March 2020 and was re-designated as a non-executive Director on June 21, 2021. Dr. Di Rocco is responsible for participating in formulating our Company’s corporate and business strategies.

Dr. Di Rocco has served as the partner of RA Capital Management, L.P., or RA Capital, a multi-stage investment manager dedicated to evidence-based investing in healthcare and life sciences, since 2020 and was previously a principal from 2017 to 2020 and joined RA Capital in 2013. As representative of RA Capital, Dr. Di Rocco has served as a non-executive director for Achilles Therapeutics plc (NASDAQ: ACHL) since September 2019, Werewolf Therapeutics, Inc. (NASDAQ: HOWL) since December 2020, Connect Biopharma Holdings Limited (NASDAQ: CNTB) since August 2020, iTeos Therapeutics, Inc. (NASDAQ: ITOS) since March 2020 and of 89bio, Inc. (NASDAQ: ETNB) since March 2018, respectively.

Dr. Di Rocco received his bachelor’s degree in biology from College of the Holy Cross in May 2002 and his Ph.D. degree in pharmacology from University of Washington in August 2009.

Mr. Xiao Le (樂霄), aged [32], was appointed as a Director on December 2020 and was re-designated as a non-executive Director on June 21, 2021. Mr. Le is responsible for participating in formulating our Company’s corporate and business strategies.

Mr. Le currently has been serving as non-executive director of Ambrx Biopharma Inc. (NYSE: AMAM) since November 2020 and as director of corporate development and investment at WuXi AppTec (HKEX: 2359). Prior to that, Mr. Le served at 6 Dimensions Capital (previously known as Frontline BioVentures), a company whose principal business is equity investment, as an investment professional since May 2016.

Mr. Le received his bachelor’s degree in chemical and biomolecular engineering from Johns Hopkins University in May 2013 and his masters’ degree in finance from the Massachusetts Institute of Technology in June 2015.

Independent Non-executive Directors

Mr. James Arthur Geraghty, aged [67], was appointed as an independent non-executive Director on July 18, 2018. Mr. Geraghty has served as an independent non-executive director of CANbridge Life Sciences, our wholly-owned subsidiary, since May 2017. Mr. Geraghty is responsible for supervising and providing independent judgment to our Board.

Mr. Geraghty has approximately 30 years’ management experience in business development, strategy and operations. Mr. Geraghty was an entrepreneur in residence of Third Rock Ventures from May 2013 to December 2016, where he was responsible for company formation and governance. Prior to this, Mr. Geraghty served as the senior vice president responsible for strategy and business development at Sanofi S.A. between April 2011 and December 2012. Mr. Geraghty worked with Genzyme Corporation from 1992 to 2011, with his last position being the senior vice president responsible for international development. From

DIRECTORS AND SENIOR MANAGEMENT

1993 to 2007, Mr. Geraghty served as the chairman of board and the chief executive officer for Genzyme Transgenics Corporation. Prior to that, Mr. Geraghty started his career at Bain Capital, responsible for healthcare strategy consulting. Mr. Geraghty has been the chairman of the board of Orchard Therapeutics (NASDAQ: ORTX) and Pieris Pharmaceuticals (NASDAQ: PIRS) since May 2018 and since November 2017, respectively. Mr. Geraghty has also served as an independent non-employee Director of Fulcrum Therapeutics (NASDAQ: PIRS) since October 2016, Voyager Therapeutics (NASDAQ: VYGR) since January 2014 and Idera Pharmaceuticals (NASDAQ: IDRA) since July 2013, respectively.

Mr. Geraghty received his bachelor’s degree in psychology from Georgetown University and received his Juris Doctor degree from Yale University Law School in May 1980.

Dr. Richard James Gregory, Ph.D., aged [63], was appointed as an independent non-executive Director in April 2020. Dr. Gregory is responsible for supervising and providing independent judgment to our Board.

Dr. Gregory has over 30 years’ experience in research and development. Dr. Gregory has served as an independent non-employee director of Homology Medicines (NASDAQ: FIXX) since 2015 and is currently an independent director of ProMIS Neurosciences (TSX: PMN). Dr. Gregory was the executive vice president and the chief scientific officer of ImmunoGen Inc. from January 2015 to August 2019. Prior to that, since February 1989, Dr. Gregory had spent 25 years at Genzyme Corporation (NASDAQ: GENZ) in roles of increasing responsibility, including Vice President and senior Vice President, with his last position being the Head of Research and Development for Genzyme Sanofi. In early 1990s, he also worked with Canji, Inc., focusing on the field of molecular biology. In 1989, Dr. Gregory served as a postdoctoral fellow of the Worcester Foundation for Experimental Biology.

Dr. Gregory received his bachelor’s degree in Science in Biochemistry from Virginia Polytechnic Institute and State University in June 1980 and his Ph.D. degree from University of Massachusetts Amherst in January 1986. Dr. Gregory has been a fellow of the American Institute for Medical and Biological Engineering since February 2010.

Mr. Peng Kuan Chan (陳炳鈞), aged [57], was appointed as an independent non-executive Director of the Company on June 11, 2021. Mr. Chan is responsible for supervising and providing independent judgment to our Board.

Mr. Chan has over 25 years of experience in corporate financing, investment banking, initial public offering, mergers and acquisitions as well as financial management. Mr. Chan has been serving as an independent non-executive director of Yincheng International Holding Co., Ltd. (HKEX: 1902) since February 2019.

DIRECTORS AND SENIOR MANAGEMENT

From October 2017 to May 2019, Mr. Chan was the chief financial officer of Elegance Optical International Holdings Ltd (HKEX: 0907), where he was responsible for corporate finance and financial management. Prior to this, from January 2012 to September 2017, Mr. Chan served as the chief operating officer of CITIC Merchant Co., Limited, responsible for formulating business strategies and executing business plans of the company.

Between January 2011 and November 2011, Mr. Chan served as Head of Asia CIG and Cleantech of Piper Jaffray Asia Limited. Mr. Chan served as the managing director of corporate finance – Great China coverage department, and an executive director of corporate finance department of BNP Paribas Capital (Asia Pacific) Limited from July 2006 to January 2011 and from March 2005 to June 2006, respectively. Between August 2000 and December 2004, Mr. Chan served as an executive director of Sanyuan Group Limited (三元集團有限公司), a company delisted from the Stock Exchange in December 2009 (stock code: 140) which principally engaged in property investment and bio-pharmaceuticals, with the mission of restructuring its business activities and materialising its debt restructuring plan. He served BNP Prime Peregrine Capital Limited from May 1994 to August 2000 where his last position was an executive director.

Mr. Chan received his bachelor’s degree in commerce from University of Canterbury in May 1989 and received his master’s degree in applied finance from Macquarie University in November 1998. He has been a Chartered Accountant of Chartered Accountants Australia and New Zealand since November 1992. He has been a Certified Public Accountant of the Hong Kong Institute of Certified Public Accountants (“HKICPA”) since July 1993.

Mr. Chan was a director of the following companies, which were involuntarily wound up:

Name of Company	Place of incorporation	Principal business activity immediately before being voluntarily wound up or struck off	Voluntarily wound up or being struck off	Reason (if struck off)
Pacific Engineering Limited	Hong Kong	a company principally engaged in the trading of the sea sand	involuntarily wound up on May 11, 2006 due to winding up order	This company had been making loss and a creditor filed a petition to wind up this company which was subsequently dissolved by compulsory winding up.

DIRECTORS AND SENIOR MANAGEMENT

Name of Company	Place of incorporation	Principal business activity immediately before being voluntarily wound up or struck off	Voluntarily wound up or being struck off	Reason (if struck off)
Infinity Properties Limited	Hong Kong	a property holding company	involuntarily wound up on January 31, 2007 due to winding up order	This company was wound up as a result of the debt restructuring agreement reached between Sanyuan Group Limited (a then listed company on the Stock Exchange and the holding company of this company) and the relevant lending bank. This company was dissolved by compulsory winding up as a result thereof.
Propland Limited	Hong Kong	a property holding company	involuntarily wound up on October 6, 2006 due to winding up order	same as above
V & O Company Limited	Hong Kong	a property holding company	involuntarily wound up on October 6, 2006 due to winding up order	same as above

Mr. Chan was appointed on August 31, 2000 as a director of each of Pacific Engineering Limited, Infinity Properties Limited, Propland Limited and V&O Company Limited (collectively, the “Relevant Companies”), all of which were incorporated in Hong Kong and wholly-owned subsidiaries of Sanyuan Group Limited (三元集團有限公司).

As a result of the debt restructuring agreement reached between Sanyuan Group Limited (三元集團有限公司) and the relevant lending bank, winding up petitions were filed to wind up Infinity Properties Limited, Propland Limited and V&O Company Limited on December 23, 2004 and the respective winding-up orders were granted against those companies on February 23, 2005.

DIRECTORS AND SENIOR MANAGEMENT

There was no wrongful act on the part of Mr. Chan leading to the winding up of the Relevant Companies. Mr. Chan has confirmed that, (i) he was not involved in the daily operations of the Relevant Companies at any time; and (ii) during the course of the liquidation of the Relevant Companies, there was no allegation of fraud or other impropriety, judgment debt or disqualification order made against him.

SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management of our business. The table below shows certain information in respect of the senior management of our Company:

Name	Age	Date of Joining our Group	Date of Appointment as Senior Management	Position	Roles and Responsibilities
Dr. Xue	[52]	June 12, 2012	January 30, 2018	Chairman of the Board, Executive Director, and Chief Executive Officer	Founder of the Company and overseeing the overall strategic business planning and operational management
Mr. Glenn Hassan	[43]	April 2, 2019	April 2, 2019	Chief Financial Officer	Overseeing the management of the Group’s finances
Dr. Yunxiang Zhu (朱雲祥)	[57]	September 15, 2020	September 15, 2020	Vice President, Head of Global Research	Overseeing global research operations
Mr. Yijun Lu (陸義駿)	[47]	November 9, 2020	November 9, 2020	General Manager of CANbridge China	Overseeing commercial business operations in the PRC

Dr. James Qun Xue, aged [52], has served as Chairman of the Board, Director and Chief Executive Officer since the inception of our Company in January 2018 and was re-designated as an executive Director on June 21, 2021. Please see his biography under the paragraphs headed “Board of Directors – Executive Director” in this section.

Mr. Glenn Hassan, aged [43], was appointed as our Chief Financial Officer in April 2019. Mr. Hassan is responsible for overseeing the management of the Group’s finances.

DIRECTORS AND SENIOR MANAGEMENT

Before joining our Company, Mr. Hassan served as director, healthcare investment banking at China Renaissance Securities Inc. since August 2018, where he advised various cross-border healthcare investments and capital raising activities. Prior to this, he was a public market healthcare investor, serving as portfolio manager and senior analyst at Leerink Capital Partners from March 2016 to January 2018 and working at Citadel LLC’s Surveyor Capital from June 2014 to February 2016. Mr Hassan started his investing career at Fidelity Management & Research Company where he served with increasing responsibilities from April 2008 to May 2014.

Mr. Hassan received his bachelor’s degree of science in business with finance concentration from Indiana University in May 2002. Mr. Hassan further obtained his master’s degree of science in global financial analysis and graduated with high distinction from McCallum Graduate School of Business, Bentley College in May 2004.

Dr. Yunxiang Zhu (朱雲祥), Ph.D., aged [57], was appointed as Vice President and Head of Global Research in September 2020. Dr. Zhu is responsible for overseeing overall business operations and company-wide budgeting and expense for R&D.

From May 2018 to September 2020, Dr. Zhu served as senior vice president at Shenogen Pharma Group, responsible for company strategy in drug discovery and development. Prior to that, from February 2001 to May 2018, he served over 17 years at Sanofi Genzyme, progressing through various positions including staff scientist (level II), senior scientist, principal scientist, fellow, distinguished fellow, and senior director in charge of muscle disease research. During this period, he was responsible for scientific research in specialty care. From August 1988 to August 1990, Dr. Zhu served as research associate at Fudan University.

Dr. Zhu received his bachelor’s degree of science in chemistry from Zhejiang University in June 1984. Dr. Zhu further received his master of science in biochemistry from Shanghai Institute of Materia Medica in July 1988. He obtained his Ph.D. in cell biology from University of Miami School of Medicine in February 1996 and conducted his post-doctorate training in cell biology at Washington University School of Medicine from February 1996 to February 2001.

Mr. Yijun Lu (陸義駿), aged [47], was appointed as General Manager of CANbridge China in November 2020. Mr. Lu is responsible for overseeing our commercial business operations in the PRC.

Before joining our Company, from April 2020 to November 2020, Mr. Lu served as head of hemophilia and rare disease at Takeda (China) Holdings Co. Ltd, where he led the launch and development of certain products related to rare diseases, such as Replagal, Vpriv, Takhzyro and Firazyf. From July 2018 and April 2019, Mr. Lu was the franchise head of hematology at Shire Bioscience (Shanghai) Co. Ltd., where he led the hemophilia business development in China. From April 2017 to July 2018, he served as head of value demonstration and access at Shire Bioscience (Shanghai) Co. Ltd., during which he received the CEO Award and the APAC Best Value Demonstration and Access Award. Mr. Lu also served as national sales head at

DIRECTORS AND SENIOR MANAGEMENT

Baxalta Bioscience (Shanghai) Co. Ltd. from January 2016 to April 2017 and as marketing manager at Baxter China Investment Co. Ltd. from February 2014 to December 2015. From October 2012 to February 2014, he served as associate marketing manager at Celgene Pharmaceutical (Shanghai) Co. Ltd. Since July 2011, he served as senior regional sales manager at Bayer Healthcare Company Ltd. Mr. Lu served at Beijing Novartis Pharma Ltd. as senior regional sales manager and regional sales manager from July 2006 to July 2011 and as senior district sales manager from February 2005 to July 2006. Before that, he served in the sales team at the Shanghai Representative Office of Eli Lilly Asia Inc. in 2002. From July 1996 to February 2000, Mr. Lu served as oncologist at Shanghai No.1 People’s Hospital.

Mr. Lu obtained his bachelor’s degree in clinical medicine from Shanghai Jiaotong University School of Medicine in August 1996. He received his certificate of Beijing International MBA Course from Peking University in April 2009.

Directors’ and Senior Management’s Interests

Save as disclosed above in this section, none of our Directors or senior management has been a director of any public company the securities of which are listed on any securities market in Hong Kong or overseas in the three years immediately preceding the date of this document. Save as disclosed above in this section, 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 our 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. As of the Latest Practicable Date, save for the interests in the Shares of our Company beneficially held by Dr. Xue under his own name and held indirectly through CTX Pharma and the Family Trust and the interests in the Shares of our Company beneficially held by Mr. James Arthur Geraghty, which are disclosed in the section headed “Appendix IV – Statutory and General Information – C. Further Information about our Directors” in this document, none of our Directors held any interest in the securities within the meaning of Part XV of the SFO. Save as disclosed above in this section, as of the Latest Practicable Date, none of our Directors or senior management is related to other Directors or senior management of our Company.

JOINT COMPANY SECRETARIES

Ms. Qian Ma was appointed as one of our joint company secretaries on June 21, 2021. Ms. Ma has worked with King & Wood Mallesons since July 2015 and has supported the Company as designated external legal counsel since 2017, where she has facilitated legal and compliance of the Company. Ms. Ma is expected to be formally engaged as Head of Legal and Compliance of our Company prior to the [REDACTED]. Ms. Ma has obtained the PRC legal professional qualification since 2014. Ms. Ma obtained her bachelor’s degree in history and international studies (double major) and her Juris Master degree from Peking University in July 2013 and July 2016, respectively.

DIRECTORS AND SENIOR MANAGEMENT

Mr. Keith Shing Cheung Wong was appointed as one of our joint company secretaries on June 21, 2021. Mr. Wong has been a senior manager of SWCS Corporate Services Group (Hong Kong) Limited since March 2020, mainly responsible for managing the company secretarial and compliance work for companies listed on the Stock Exchange. Prior to that, Mr. Wong worked at the international accounting firm KPMG, China Huajun Group Limited (formerly known as Huajun Holdings Limited), a company listed on the Stock Exchange (stock code: 0377), and the Listing Division of the Stock Exchange. Mr. Wong obtained a bachelor’s degree in finance, accounting and management from University of Nottingham in July 2009. He is currently a member of the Hong Kong Institute of Certified Public Accountants.

KEY TERMS OF EMPLOYMENT CONTRACTS

Employment Arrangements of Senior Management

We normally enter into (i) an employment contract and (ii) a confidentiality and non-compete agreement with our senior management members and other key personnel. Below sets forth the key terms of these contracts we enter into with our senior management members and other key personnel.

- *Terms:* We normally enter into an employment contract with our senior management members and other key personnel with a term of five years.
- *No conflict:* During the term of the employment, the employee shall work on a full-time basis for us and shall not, without our express prior written approval, work as an employee or consultant of any other company which competes with our Group.

Confidentiality

- *Confidential information:* The employee shall keep confidential information (i) that is not known to the public and of commercial value obtained from our Group during the term of his or her employment and (ii) in relation to the intellectual property rights created, applied for or held by our Group, including but not limited to trade secrets, written documents entered into with business partners, sales data and analysis, business plans and objectives, list of business partners, client data, human resource matters, financial information, technical information and intellectual property information.
- *Obligation and duration:* Except for legitimate business purposes, the employee shall not, for the term of his or her employment and thereafter, disclose, divulge, copy or use for profit any confidential information. In addition, the employee shall return to the relevant personnel of our Group or otherwise properly deal with any documents, materials or information concerning our Group immediately upon the occurrence of job change, termination of employment or when any “need-to-know” circumstance ceases to exist.

DIRECTORS AND SENIOR MANAGEMENT

Intellectual Property Rights

- *Acknowledgement:* The employee agrees that we shall have all rights in all inventions, creations, improvements, original works, designs, researches and other results (i) that the employee completes during the term of his or her employment in order to perform duties, complete tasks or with the use of our Group’s resources; (ii) that is closely related to our Group’s business and completed in the employee’s spare time during the term of his or her employment or within one year after termination of his or her employment and is not for specific tasks and without the use of our Group’s resources; or (iii) that the employee completes or assists in completing by referring to or using our confidential information, provided that the employee shall have the right of authorship in cases of (i) and (ii) above.
- *Indemnification and assignment:* The employee agrees to indemnify us for all direct and indirect losses suffered by us in cases of (i) to (iii) above and assist us to acquire the relevant intellectual rights pursuant to the terms of the confidentiality and non-compete agreement.

Non-competition and Non-solicitation

- *Non-competition obligation:* Unless otherwise waived by our Group, the employee shall not invest, own, manage, engage in, operate, advise, provide service, participate in or take office in any entity that competes with our business, nor shall the employee carry out, engage in or participate in any competing business in any other manner.
- *Non-solicitation obligation:* Unless otherwise waived by our Group, the employee shall not (i) solicit or attempt to induce any of our customers, suppliers, agents, traders, distributors, clients or any persons, partners or companies who are used to deal with our Group to terminate its engagement with us; or (ii) solicit or attempt to induce any person who is employed by our Group and in charge of technical or management work to leave our Group, or to hire such person or provide him or her with employment opportunity or service contract.
- *Duration:* The non-competition and non-solicitation obligations shall subsist throughout the employee’s term of employment and, where applicable, up to 24 months after termination of employment for whatever reason.

REMUNERATION OF DIRECTORS AND SENIOR MANAGEMENT

Our Directors receive compensation in the form of fees, salaries, bonuses, other allowances, benefits in kind, contribution to the pension scheme and other share-based compensation. We determine the compensation of our Directors based on each Director’s responsibilities, qualification, position and seniority. Each of our independent non-executive Directors [has] signed an appointment letter with our Company for a term of three years effective upon the date of this document. For more information on the appointment letters, please refer to the section headed “Appendix IV – Statutory and General Information – C. Further Information about our Directors – 1. Particulars of Directors’ Service Contracts and Appointment Letters” in this document.

DIRECTORS AND SENIOR MANAGEMENT

For more information on the Directors’ remuneration during the Track Record Period as well as information on the highest paid individuals, please see Notes 8 and 9 of the Accountants’ Report set out in Appendix I to this document.

Save as disclosed above in this section and the sections headed “Financial Information”, “Accountants’ Report” and “Statutory and General Information” in this document, no other payments have been paid or are payable during the Track Record Period to our Directors or senior management by our Group.

CORPORATE GOVERNANCE

We have established the following committees in our Board of Directors: an Audit Committee, a Remuneration Committee and a Nomination and Corporate Governance Committee. The committees operate in accordance with terms of reference established by our Board of Directors.

Audit Committee

Our Company has established the Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code. The Audit Committee consists of two independent non-executive directors, namely, Dr. Richard James Gregory and Mr. Peng Kuan Chan, and one non-executive director, namely, Dr. Kan Chen. Mr. Peng Kuan Chan, being the chairman of the Audit Committee, 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 of Directors by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of our Group, overseeing the audit process and performing other duties and responsibilities assigned by our Board of Directors.

Remuneration Committee

Our Company has established the Remuneration Committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and the Corporate Governance Code. The Remuneration Committee consists of one non-executive director, namely, Mr. Xiao Le and two independent non-executive directors, namely, Dr. Richard James Gregory and Mr. James Arthur Geraghty. Dr. Richard James Gregory is the chairman of the Remuneration Committee. The primary duties of the Remuneration Committee include, without limitation, making recommendations to the Board of Directors on our policy and structure for the remuneration of all Directors and senior management and on the establishment of a formal and transparent procedure for developing the policy on such remuneration, determining with delegated responsibility, or making recommendations to the Board of Directors on the specific remuneration packages of individual executive Directors and senior management and reviewing and approving management’s remuneration proposals by reference to corporate goals and objectives resolved by the Board of Directors from time to time.

DIRECTORS AND SENIOR MANAGEMENT

Nomination and Corporate Governance Committee

Our Company has established the Nomination and Corporate Governance Committee with written terms of reference in compliance with the Corporate Governance Code. The Nomination and Corporate Governance Committee consists of one executive Director, namely, Dr. Xue, one non-executive directors, namely, Dr. Derek Paul Di Rocco and three independent non-executive Directors, namely, Dr. Richard James Gregory, Mr. James Arthur Geraghty and Mr. Peng Kuan Chan. Dr. Xue is the chairman of the Nomination and Corporate Governance Committee. The primary duties of the Nomination and Corporate Governance Committee include, without limitation, reviewing the structure, size and composition of the Board of Directors, assessing the independence of the independent non-executive Directors, making recommendations to the Board of Directors on matters relating to the appointment or re-appointment of Directors, developing, reviewing and assessing the adequacy of our Company’s policies and practices on corporate governance and reviewing our Company’s compliance with the Corporate Governance Code and disclosure in the corporate governance report.

Corporate Governance Code

Pursuant to code provision A.2.1 of the Corporate Governance Code, companies listed on the Stock Exchange are expected to comply with, but may choose to deviate from the requirement that the roles of chairman and chief executive should be separate and should not be performed by the same individual.

Dr. Xue has served as chairman of the board and general manager of CANbridge Life Sciences since June 2012 and as Chairman of the Board, Director and Chief Executive Officer since the inception of our Company in January 2018. Dr. Xue is the founder of the Group and has extensive experience in the business operations and management of our Group. Our Board believes that, in view of his experience, personal profile and his roles in our Company as mentioned in this section, Dr. Xue is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our Chief Executive Officer. Our Board also believes that the combined role of Chairman of the Board and Chief Executive Officer can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board. Our Directors consider that the balance of power and authority will not be impaired due to this arrangement. In addition, all major decisions are made in consultation with members of the Board, including the relevant Board committees, and three independent non-executive Directors. Save as disclosed above, our Directors consider that upon [REDACTED], we will comply with all applicable code provisions of the Corporate Governance Code as set out in Appendix 14 to the Listing Rules.

DIRECTORS AND SENIOR MANAGEMENT

Board Diversity Policy

We are committed to promote diversity in our Company to the extent practicable by taking into consideration a number of factors in respect of our corporate governance structure.

We [have adopted] a board diversity policy which sets out the objective and approach to achieve and maintain diversity of our Board in order to enhance the effectiveness of our Board. Pursuant to the board diversity policy, we seek to achieve board diversity through the consideration of a number of factors, including but not limited to professional experience, skills, knowledge, gender, age, nationality, cultural and education background, ethnicity and length of service. Our Directors have a balanced mix of knowledge and skills, including knowledge and experience in the areas of biotechnology, clinical research, life science, business management, finance, investment and accounting. They obtained degrees in various areas including pharmaceutical chemistry and biochemistry, chemical and biomolecular engineering, life science, clinical research, business administration and accounting. Our board diversity policy is well implemented as evidenced by the fact that there are Directors ranging from [32] years old to [67] years old with different nationalities and experience from different industries and sectors. Our Board believes that based on our existing business model and specific needs, the background of our Directors and the composition of our Board satisfies the principles under the Board Diversity Policy. Nevertheless, in recognizing the particular importance of gender diversity, our Company is committed to provide career development opportunities for female staff and we confirms that our Nomination Committee will use its best efforts to identify and recommend female candidates to our Board for consideration on the appointment as Director of our Company. Our Nomination Committee will aim to recommend at least one female Director candidate to the Board for its consideration at least once per year, with the aim of adding at least one female Director to the Board within one year after [REDACTED].

We are also committed to adopting a similar approach to promote diversity within the management (including but not limited to the senior management) of our Company to enhance the effectiveness of corporate governance of our Company as a whole.

Our Nomination and Corporate Governance Committee is delegated by our Board to be responsible for compliance with relevant codes governing board diversity under the Corporate Governance Code. Subsequent to the [REDACTED], our Nomination and Corporate Governance Committee will review the board diversity policy from time to time to ensure its continued effectiveness and we will disclose in our corporate governance report about the implementation of the board diversity policy on an annual basis.

DIRECTORS AND SENIOR MANAGEMENT

Compliance Adviser

We have appointed Somerley Capital Limited as our Compliance Adviser pursuant to Rule 3A.19 of the Listing Rules. Our Compliance Adviser will provide us with guidance and advice as to compliance with the Listing Rules and applicable Hong Kong laws. Pursuant to Rule 3A.23 of the Listing Rules, our Compliance Adviser will advise our Company in certain circumstances including: (a) before the publication of any regulatory announcement, circular, or financial report; (b) where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues and share repurchases; (c) where we propose to use the [REDACTED] of the [REDACTED] in a manner different from that detailed in this document or where the business activities, development or results of our Group deviate from any forecast, estimate or other information in this document; and (d) where the Stock Exchange makes an inquiry to our Company under Rule 13.10 of the Listing Rules.

The term of appointment of our Compliance Adviser shall commence on the [REDACTED] and is expected to end on the date on which we comply with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED].

COMPETITION

Each of our Directors confirms that as of the Latest Practicable Date, he or she did not have any interest in a business which competes or is likely to compete, directly or indirectly, with our business and requires disclosure under Rule 8.10 of the Listing Rules.

From time to time our non-executive Directors may serve on the boards of both private and public companies within the broader healthcare and biopharmaceutical industries. However, as these non-executive Directors are not members of our executive management team, we do not believe that their interests in such companies as directors would render us incapable of carrying on our business independently from the other companies in which these non-executive Directors may hold directorships from time to time.

SUBSTANTIAL SHAREHOLDERS

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the Share Subdivision, Conversion and [REDACTED] and assuming the Share Options outstanding as at the Latest Practicable Date, the following persons will have interests or short positions in our Shares or our 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, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group:

Name of Shareholder	Capacity/ Nature of Interest	Number of Shares as of the Latest Practicable Date ⁽¹⁾	Approximate percentage of interest in our Company upon the completion of the [REDACTED] (assuming the [REDACTED] is not exercised)	Approximate percentage of interest in our Company upon the completion of the [REDACTED]
CTX Pharma ⁽²⁾	Beneficial interest	2,604,238	[REDACTED]	[REDACTED]
Dr. Xue ⁽²⁾⁽³⁾⁽⁴⁾	Interest in controlled corporation	2,604,238	[REDACTED]	[REDACTED]
	Founder of a discretionary trust	1,500,000	[REDACTED]	[REDACTED]
	Beneficial interest	73,305	[REDACTED]	[REDACTED]
WuXi AppTec ⁽⁵⁾	Interest in controlled corporation	4,034,696	[REDACTED]	[REDACTED]
RA Capital Management, L.P. ⁽⁶⁾	Interest in controlled corporation	3,654,959	[REDACTED]	[REDACTED]
Qiming Corporate GP IV, Ltd. ⁽⁷⁾	Interest in controlled corporation	3,282,933	[REDACTED]	[REDACTED]
Qiming Venture Partners IV, L.P. ⁽⁷⁾	Beneficial interest	3,182,449	[REDACTED]	[REDACTED]

Notes:

- (1) The number of Shares held assuming that all of the Preferred Shares have been converted into the Shares on a one-to-one basis. The number of shares held are subject to adjustments as a result of the Share Subdivision.
- (2) CTX Pharma is an exempted company with limited liability incorporated in the British Virgin Islands and holds 2,604,238 Shares in our Company. CTX Pharma is wholly-owned by Dr. Xue. Pursuant to a voting rights proxy agreement dated February 9, 2020, each of Xiangyun Holdings Limited, Apollo China Holdings Limited, Sea&Sky Holdings Limited, Clear Stone Holdings Limited, Hongweix Holdings Limited, Medkelvin Holdings Limited, Chengzhang Holdings Limited, Dingkai Holdings Limited, Merrifield Holdings Limited and Flemingddf Holdings Limited (the “Entrusters”), who in aggregate hold 2,790,416 Shares in our Company, voluntarily entrusted all of the voting rights of their Shares directly held in our Company to CTX Pharma. Accordingly, each of CTX Pharma and Dr. Xue is deemed interested in the Shares held by the Entrusters. Such voting rights proxy agreement will terminate upon [REDACTED].

SUBSTANTIAL SHAREHOLDERS

- (3) Dr. Xue beneficially holds 73,305 Shares of our Company under his own name.
- (4) 1,500,000 Shares of our Company are held by the Family Trust. Under the terms of the Family Trust, Dr. Xu has the power to exercise all the voting rights attached to the Shares of our Company. Accordingly, Dr. Xue is deemed interested in the Shares held by the Family Trust.
- (5) WuXi AppTec (HongKong) Limited, company incorporated in Hong Kong on March 26, 2012 holding 2,055,486 Shares of our Company, is a wholly-owned subsidiary of WuXi AppTec. Moreover, WuXi PharmaTech Healthcare Fund I L.P. is an exempted limited partnership established in the Cayman Islands directly holding 1,979,210 Shares in our Company. All limited partnership interests of WuXi PharmaTech Healthcare Fund I L.P. are held by Wuxi Apptec and the general partner of WuXi PharmaTech Healthcare Fund I L.P. is a wholly-owned subsidiary of WuXi AppTec. Accordingly, Wuxi Apptec is deemed interested in the Shares held by each of WuXi AppTec (HongKong) Limited and WuXi PharmaTech Healthcare Fund I L.P..
- (6) RA Capital Management, L.P., a limited partnership formed in Delaware, United States, serves as investment manager of RA Capital Healthcare Fund, L.P., an exempted limited partnership established in Delaware, United States, directly holding 2,349,914 Shares in our Company, RA Capital Nexus Fund, L.P., an exempted limited partnership established in the Delaware, United States, directly holding 913,740 Shares in our Company, and Blackwell Partners LLC – Series A, a series limited liability company incorporated in Delaware, United States, holds 391,305 Shares in our Company. The general partner of RA Capital Healthcare Fund, LP is RA Capital Healthcare Fund GP, LLC and the general partner of RA Capital Nexus Fund, LP is RA Capital Nexus Fund GP, LLC. Each of RA Capital Healthcare Fund, L.P. and RA Capital Nexus Fund, L.P. is an affiliate of RA Capital Management, L.P.. Accordingly, RA Capital Management, L.P. is deemed interested in the Shares held by each of RA Capital Healthcare Fund, L.P., RA Capital Nexus Fund, L.P. and Blackwell Partners LLC.
- (7) Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P. are venture capital funds operated under Qiming Venture Partners and registered as exempted limited partnerships in the Cayman Islands. Qiming GP IV, L.P. is the general partner of Qiming Venture Partners IV, L.P., and Qiming Corporate GP IV, Ltd. is the general partner of Qiming GP IV, L.P. Accordingly, each of Qiming GP IV, L.P. and Qiming Corporate GP IV, Ltd. is deemed to be interested in the Shares held by Qiming Venture Partners IV, L.P. Moreover, Qiming Managing Directors Fund IV, L.P. holds 100,484 Shares of our Company. Qiming Corporate GP IV, Ltd. is the general partner of Qiming Managing Directors Fund IV, L.P. and is deemed to be interested in the Shares held by Qiming Managing Directors Fund IV, L.P..

Except as disclosed above, our Directors are not aware of any other person who will, immediately following the completion of the [REDACTED] (assuming the Share Options outstanding as at the Latest Practicable Date and the [REDACTED] are not exercised), 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 5% 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. Our Directors are not aware of any arrangement which may at a subsequent date result in a change of control of our Company or any other member of our Group.

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 or credited as fully paid immediately following completion of the [REDACTED].

As of the Latest Practicable Date, our authorized share capital was USD50,000.00 divided into 500,000,000 shares of a nominal or par value of USD0.0001 each, of which (i) 469,111,025 are designated as Ordinary Shares; (ii) 1,761,145 are designated as Series A-1 Preferred Shares; (iii) 2,748,067 are designated as Series A-2 Preferred Shares; (iv) 4,305,847 are designated as Series B-1 Preferred Shares; (v) 3,624,926 are designated as Series B-2 Preferred Shares; (vi) 3,283,518 are designated as Series C-1 Preferred Shares; (vii) 641,940 are designated as Series C-2 Preferred Shares; (viii) 577,745 are designated as Series C-3 Preferred Share; (ix) 481,232 are designated as Series C-4 Preferred Shares; (x) 7,868,126 are designated as Series D-1 Preferred Shares; (xi) 1,538,482 are designated as Series D-2 Preferred Shares; (xii) 115,496 are designated as Series D-3 Preferred Shares; and (xiii) 3,942,451 are designated as Series E Preferred Shares.

Effective upon the conditions of the [REDACTED] being fulfilled, each share in our then issued and unissued share capital shall be split into 10 shares of the corresponding class with par value of US0.0001 each. The Preferred Shares will be converted into ordinary shares of our Company on a one-to-one basis by way of re-designation, and our authorised share capital will be USD50,000.00 divided into 5,000,000,000 ordinary shares of a nominal or par value of USD0.00001 each, immediately before the completion of the [REDACTED].

Assuming the Share Options outstanding as at the Latest Practicable Date and the [REDACTED] are not exercised and no shares are issued pursuant to the [REDACTED] RSU Scheme and the [REDACTED] Share Option Scheme, the share capital of our Company immediately following completion of the Share Subdivision, Conversion and [REDACTED] will be as follows:

Description of Shares	Number of Shares	Aggregate nominal value of Shares (US\$)
Shares in issue (including the Shares upon re-designation of the Preferred Shares)	367,940,920	3,679.4092
Shares to be issued under the [REDACTED]	<u>[REDACTED]</u>	<u>[REDACTED]</u>
Total	<u><u>[REDACTED]</u></u>	<u><u>[REDACTED]</u></u>

SHARE CAPITAL

Assuming the [REDACTED] is exercised in full and no Share Option outstanding as at the Latest Practicable Date is exercised and no shares are issued pursuant to the [REDACTED] RSU Scheme and the [REDACTED] Share Option Scheme, the share capital of our Company immediately following completion of the [REDACTED] will be as follows:

Description of Shares	Number of Shares	Aggregate nominal value of Shares (US\$)
Shares in issue (including the Shares upon re-designation of the Preferred Shares)	367,940,920	3,679.4092
Shares to be issued under the [REDACTED]	<u>[REDACTED]</u>	<u>[REDACTED]</u>
Total	<u>[REDACTED]</u>	<u>[REDACTED]</u>

ASSUMPTIONS

The above tables assume that the [REDACTED] becomes unconditional, that Shares are issued pursuant to the [REDACTED], and that the [REDACTED] are converted into ordinary shares on a one-to-one basis.

RANKING

The [REDACTED] are Shares in the share capital of our Company and rank equally with all Shares currently in issue or to be issued (including all Preferred Shares re-designated into Shares upon completion of the [REDACTED]) and, in particular, will rank equally for all dividends or other distributions declared, made or paid on the Shares in respect of a record date which falls after the date of this document.

CIRCUMSTANCES UNDER WHICH GENERAL MEETINGS ARE REQUIRED

Pursuant to the Cayman Companies Act and the terms of the Articles of Association, our Company may from time to time by ordinary resolution of Shareholders: (i) increase its share capital; (ii) consolidate and divide its share capital into Shares of larger amount; (iii) divide its Shares into several classes; and (iv) cancel any Shares which have not been taken or agreed to be taken. In addition, our Company may, subject to the provisions of the Cayman Companies Act, reduce its share capital or undistributable reserve by its Shareholders passing a special resolution. See the section headed “Appendix III – Summary of the Constitution of Our Company and Cayman Companies Act – Articles of Association – Alteration of capital” in this document for further details.

SHARE CAPITAL

[REDACTED] EQUITY INCENTIVE PLAN

We adopted the **[REDACTED]** Equity Incentive Plan. For further details, please see the section headed “Appendix IV – Statutory and General Information – D. **[REDACTED]** Equity Incentive Plan” in this document.

[REDACTED] RSU SCHEME

We [adopted] the **[REDACTED]** RSU Scheme. For further details, please see the section headed “Statutory and General Information – E. **[REDACTED]** RSU Scheme” in this document.

[REDACTED] SHARE OPTION SCHEME

We [adopted] the **[REDACTED]** Share Option Scheme. For further details, please see the section headed “Statutory and General Information – F. **[REDACTED]** Share Option Scheme” 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 with a total nominal value of not more than the sum of:

- 20% of the aggregate nominal value of the Shares in issue immediately following completion of the Share Subdivision and the **[REDACTED]**; and
- the aggregate nominal value of the Shares repurchased by us under the authority referred to in the sub-section headed “General Mandate to Repurchase Shares” in this section.

This general mandate to issue Shares will expire at the earliest of:

- the conclusion of the next annual general meeting of our Company;
- the expiration of the period within which the next annual general meeting of our Company is required to be held by any applicable law or the Articles of Association; or
- the time when it is varied or revoked by an ordinary resolution of our Shareholders in a general meeting.

See the section headed “Appendix IV – Statutory and General Information – A. Further Information about our Group – 4. Resolutions of our Shareholders” in this document for further details of the general mandate to allot, issue and deal with Shares.

SHARE CAPITAL

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 our own securities with nominal value of up to 10% of the aggregate nominal value of our Shares in issue immediately following completion of the Share Subdivision and the [REDACTED].

The repurchase mandate only relates to repurchases made on the Stock Exchange, or on any other stock exchange on which our Shares are listed (and which are recognized by the SFC and the Stock Exchange for this purpose), and which are in accordance with 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 – 5. Repurchases of our Own Securities” in this document.

The general mandate to repurchase Shares will expire at the earliest of:

- the conclusion of the next annual general meeting of our Company;
- the expiration of the period within which the next annual general meeting of our Company is required to be held by any applicable law or the Articles of Association; or
- the time when it is varied or revoked by an ordinary resolution of our Shareholders in a general meeting.

See the section headed “Appendix IV – Statutory and General Information – A. Further Information about our Group – 4. Resolutions of our Shareholders” in this document for further details of the general mandate to repurchase Shares.

FINANCIAL INFORMATION

You should read the following discussion and analysis with our audited consolidated financial information, including the notes thereto, included in the Accountants’ Report in Appendix I to this document. Our consolidated financial information has been prepared in accordance with IFRS, which may differ in material aspects from generally accepted accounting principles in other jurisdictions, including the United States.

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance. These statements are based on our assumptions and analysis in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. However, whether actual outcomes and developments will meet our expectations and predictions depends on a number of risks and uncertainties. In evaluating our business, you should carefully consider the information provided in the section headed “Risk Factors” in this document.

For the purpose of this section, unless the context otherwise requires, references to 2019 and 2020 refer to our financial year ended December 31 of such year. Unless the context otherwise requires, financial information described in this section is described on a consolidated basis.

OVERVIEW

We are a China-based, rare disease-focused biopharmaceutical company committed to the research, development and commercialization of biotech therapies. As of the Latest Practicable Date, we had developed a comprehensive pipeline of 13 drug assets with significant market potential targeting some of the most prevalent rare diseases as well as rare oncology indications, including three marketed products, four drug candidates at clinical stage, one at IND-enabling stage, two at preclinical stage, and three gene therapy programs at lead identification stage.

We are led by a management team with significant industry experience in rare diseases, spanning R&D, clinical development, regulatory affairs, business development and commercialization, supported by a pool of talent of 173 employees where more than 80% of our employees had experience working at multinational biopharmaceutical companies. Our management team collectively has a track record of successfully commercializing rare disease therapies across the key markets including China, the United States, Europe, Latin America, and Southeast Asia. Leveraging our management’s expertise, we play an active role in advancing the rare disease industry and shaping the rare disease ecosystem in China. For example, our founder Dr. Xue is currently serving as the Deputy Director General of China’s Alliance for Rare Disease (CHARD).

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Since our inception in 2012, we have built a comprehensive portfolio targeting diseases with validated mechanisms of action with significant market potential, consisting of biologics, small molecules, and gene therapy solutions. We have built our pipeline through, and will continue to enrich it via business partnerships and collaborations with academic institutions, together with in-house research and development.

During Track Record Period, our revenue primarily constituted of the sales of our approved medical products, namely, CaphosolTM(CAN002), Nerlynx[®](CAN030) and Hunterase[®](CAN101). In 2019, 2020 and for the six months ended June 30, 2020 and 2021, our revenue from sales of products amounted to RMB1.5 million, RMB12.0 million, RMB1.9 million and RMB12.2 million, respectively. During the Track Record Period, we incurred substantial amount of fair value changes of convertible redeemable preferred shares, research and development expenses, administrative expenses, selling and distribution expenses, and as a result, we recorded a total net loss of RMB217.7 million in 2019, RMB846.0 million in 2020 and RMB156.7 million and RMB344.2 million for the six months ended June 30, 2020 and 2021, respectively. Out of the net loss during the Track Record Period, we recognized fair value changes of convertible redeemable preferred shares of RMB73.7 million, RMB591.4 million and RMB21.8 million for the years ended 2019, 2020 and for the six months ended June 30, 2021, respectively. The convertible redeemable preferred shares will be converted into Shares upon [REDACTED], after which we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable preferred shares. We expect to incur an increased amount of operating expenses in the near term as we further our pre-clinical research, continue the clinical development of, and seek regulatory approval for and manufacturing of our product candidates, launch our pipeline products, and expand the commercialization of our approved products in China and overseas.

BASIS OF PREPARATION

Our Company was incorporated as an exempted company with limited liability in the Cayman Islands on 30 January 2018. Our Company is an investment holding company. During the Track Record Period, the subsidiaries of the Company were principally engaged in the research and development and commercialization of medical products. For more details, see the section headed “History, Reorganization and Corporate Structure.”

The consolidated financial information of our Group has been prepared in accordance with International Financial Reporting Standards (“IFRSs”) (which include all International Financial Reporting Standards, International Accounting Standards (“IASs”) and Interpretations) issued by the International Accounting Standards Board (“IASB”). All IFRSs effective for the accounting period commencing from 1 January 2021, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the consolidated financial information consistently throughout the Track Record Period and the six months ended June 30, 2020.

FINANCIAL INFORMATION

The consolidated financial information has been prepared under the historical cost convention, except for certain financial liabilities which have been measured at fair value through profit or loss, as explained in the respective accounting policies in the Accountants’ Report in Appendix I to this document. The consolidated financial information of our Group is presented in RMB and all values are rounded to the nearest thousand except when otherwise indicated. The preparation of consolidated financial information in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying our Company’s accounting policies.

SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations have been, and are expected to continue to be, affected by a number of factors, many of which may be beyond our control. A discussion of the key factors is set out below.

Our Ability to Commercialize and Develop Our Drug Candidates

Our business and results of operations depend on our ability to commercialize our drug candidates, if approved for marketing. Our pipeline consists of nine drug candidates ranging from pre-clinical to registrational stage for the treatment of rare diseases. Although we currently have three products approved for commercial sale and have generated revenue from the sales of two products in the Track Record Period, we expect to commercialize one or more of our drug candidates over the coming years as they move toward the final stages of development. We expect the commercial sales of these drugs to generate revenue for us in the near future. Our ability to do so is however dependent on the successful commercialization of such products. The commercialization may require significant marketing efforts before we generate any revenue from product sales. If they fail to achieve the degree of market acceptance, we may not be able to generate revenue as expected. See the section headed “Business” for more information on the development status of our various drug candidates and “Risk Factors – Risks Relating to Manufacturing and Commercialization of Our Drug Candidates” in this document.

Our business and results of operations also depend on our ability to successfully develop our drug candidates. As of the Latest Practicable Date, we had developed a comprehensive and differentiated pipeline of 13 drug assets with significant market potential targeting some of the most prevalent rare diseases as well as rare oncology indications, including three marketed products, four drug candidates at clinical stage, one at IND-enabling stage, two at preclinical stage and another three gene therapy programs at lead identification stage. For more information on the development status of our various drug candidates, see the section headed “Business – Our Portfolio” in this document. Our business and results of operations depend on our drug candidates demonstrating favorable safety and efficacy clinical trial results, and our ability to obtain the requisite regulatory approvals for our drug candidates.

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Cost Structure

Our results of operations are significantly affected by our cost structure, which primarily consists of research and development costs, administrative expenses and selling and distribution expenses.

Since our inception, we have focused our resources on our R&D activities, including conducting pre-clinical studies, clinical trials and activities related to regulatory filings for our drug candidates. Our research and development costs primarily consist of:

- staff costs that consists of salaries, bonuses, welfare, pension and shared-based compensation for our research and development employees;
- travel and business related expenses;
- technical service fees;
- testing and clinical trial expenses; and
- license fees, including upfront and milestone payments.

Research and development activities are central to our business. Our current research and development activities mainly relate to drug discovery, preclinical research, clinical trials and the clinical advancement of our drug candidates. See “Business – Research and Development.” Our research and development expenses primarily consist of staff costs, travel and business related expenses, technical service fees, testing and clinical trial expenses, license fees and other expenses. At this time, it is difficult to estimate or know for certain, the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our drug candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our drug candidates. This is due to the numerous risks and uncertainties associated with developing and commercializing such drug candidates. We expect research and development costs to increase significantly for the foreseeable future as our development programs progress, as we continue to support the clinical trials of our drug candidates and as we initiate additional clinical trials on these drug candidates.

Our administrative expenses primarily consist of staff costs for administrative personnel, depreciation expenses, travel costs, office expenses, professional service fees, and others. Staff costs consist of salaries, bonuses, welfare, pension and shared-based compensation for administrative personnel. Other administrative expenses include rental fees, taxes and bank charges.

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We also expect our administrative expenses to increase in future periods to support our drug and development efforts and support any commercialization activities with respect to our drug candidates, if approved. We also anticipate increased legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company in Hong Kong.

Our selling and distribution expenses primarily consist of marketing expenses, staff costs, travel costs, amortization expenses and others. Given our robust pipeline of drug candidates in clinical trials, especially our three products at commercial stage, we are in the process of expanding our sales and marketing team in anticipation of current products and potential product launches in the coming years.

Funding for Our Operations

For the years ended December 31, 2019 and 2020 and for the six months ended June 30, 2021, we funded our operations primarily through equity and debt financing. Going forward, after successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with revenue generated from sales of our drug products. However, with the continuing expansion of our business and development of new drug candidates, we may require further funding through public or private equity offerings, debt financing and other sources. Any changes in our ability to fund our operations will affect our cash flow and results of operation.

SIGNIFICANT ACCOUNTING POLICIES AND ESTIMATES

We have identified certain accounting policies that are significant to the preparation of our consolidated financial statements. Some of our accounting policies involve subjective assumptions and estimates, as well as complex judgments relating to accounting items. Estimates and judgments are continually re-evaluated and are based on historical experience and other factors, including industry practices and expectations of future events that we believe to be reasonable under the circumstances. We have not changed our assumptions or estimates in the past and have not noticed any material errors regarding our assumptions or estimates. Under current circumstances, we do not expect that our assumptions or estimates are likely to change significantly in the future. When reviewing our consolidated financial statements, you should consider (i) our critical accounting policies, (ii) the judgments and other uncertainties affecting the application of such policies, and (iii) the sensitivity of reported results to changes in conditions and assumptions.

We set forth below those accounting policies that we believe are of critical importance to us or involve the most significant estimates and judgments used in the preparation of our consolidated financial statements. Our significant accounting policies and estimates, which are important for an understanding of our financial condition and results of operations, are set forth in detail in Notes 2.4 and 3 to the Accountants' Report in Appendix I to this document.

FINANCIAL INFORMATION

Significant Accounting Policies

Revenue Recognition

Revenue from contracts with customers

We recognised revenue from contracts with customers 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 the associated uncertainty with the variable consideration is subsequently resolved, and it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognised will not occur.

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 the Group and the customer at contract inception. When the contract contains a financing component which provides the Group with a significant financial benefit for more than one year, revenue recognised 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.

Other income

We recognised interest income 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.

Inventories

Inventories are stated at the lower of cost and net realizable value. Cost is determined on the weighted average basis and comprises all cost of purchase and other costs incurred in bringing the inventories to their present location and condition. Net realizable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

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Intangible Assets (Other Than Goodwill)

We measured intangible assets acquired separately 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 each financial year end.

Intangible assets not yet available for use are tested for impairment annually either individually or at the cash-generating unit level. Such intangible assets are not amortized.

Intellectual Properties

Purchased patents and licenses are stated at cost less any impairment losses and are amortized on the straight-line basis over their estimated useful lives of 10 years, based on the remaining patent protection period.

Research and development expenditures

All research costs are charged to the statement of profit or loss as incurred. Expenditure incurred on projects to develop new products is capitalized 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. Deferred development costs are stated at cost less any impairment losses and are amortized using the straight-line basis over the commercial lives of the underlying products not exceeding ten years, commencing from the date when the products are put into commercial production.

Fair Value Measurement

We measure our financial derivatives 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 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, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the Accountants’ Report 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 Accountants’ Report on a recurring basis, we determine 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.

As of December 31, 2019 and 2020 and June 30, 2021, our Level 3 financial instruments included our convertible redeemable preferred shares, convertible loans and derivative financial instruments at fair value through profit or loss, which 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. See “– Description of Selected Components of Statements of Profit or Loss – Fair Value Changes”.

In relation to the valuation of our convertible redeemable preferred shares, convertible loans and derivative financial instruments during the Track Record Period, our Directors adopted the following procedures: (1) reviewed the terms of the relevant agreements; (2) reviewed the relevant fair value measurement assessment presented by our finance personnel and carefully considered all information available and considered various applicable valuation techniques in determining the valuation of the convertible redeemable preferred shares, convertible loans and derivative financial instruments; (3) engaged an independent third-party valuer for the valuation of the convertible redeemable preferred shares, convertible loans and derivative financial instruments, and provided all material documents and information to the valuer which were true, accurate and complete that were likely to affect the valuation to ensure

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that the valuation took into account all relevant matters; and (4) reviewed the valuation results prepared by the valuer. Based on the above procedures, our Directors are of the view that the valuation analysis performed by the valuer is fair and reasonable, and the financial statements of our Group are properly prepared.

Details of the fair value measurement of the Level 3 financial instruments, particularly the fair value hierarchy, the valuation techniques, significant unobservable inputs and the relationship of unobservable inputs to fair value, are disclosed in note 33 to the Accountants’ Report in Appendix I. The Reporting Accountant has carried out necessary audit works in accordance with Hong Kong Standard on Investment Circular Reporting Engagement 200 “Accountants’ Reports on Historical Financial Information in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants for the purpose of expressing an opinion on our historical financial information for the Track Record Period as a whole in Appendix I to this document. The Reporting Accountant’s opinion on our historical financial information for the Track Record Period as a whole is set out on page I-1 to I-3 of Appendix I to this document.

The Joint Sponsors have conducted, among others, the following due diligence work in respect of the valuation analysis on level 3 financial instruments performed by the valuer: (1) discussed with the Company to understand the nature and details of the financial instruments; (2) obtained and reviewed the relevant subscription agreements regarding the financial instruments; (3) discussed with the Company and the Reporting Accountants about the key basis and assumptions for the valuation of the financial instruments; (4) conducted interviews with the valuer to understand the assumptions and methodology used in the valuation report; (5) reviewed the relevant notes in the Accountants’ Report as contained in Appendix I; (6) reviewed relevant documents provided by valuer, including the valuer’s credentials and the valuation reports, which set forth the valuation approaches, selection of approach, assumptions, key inputs and sources of information. Having considered the work done by the Company and the Reporting Accountants, and the relevant due diligence work conducted as stated above, nothing has come to the Joint Sponsors’ attention that would cause the Joint Sponsors to question the valuation analysis performed by the valuer on the level 3 financial instruments.

Share-based Payments

We operate a share option scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. 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**”). We measured the cost of equity-settled transactions with employees for grants by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by an external valuer using a binomial model, further details of which are given in note 30 to the Accountants’ Report.

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The cost of equity-settled transactions is recognized 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 each of the relevant periods 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 the statement of 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 our 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.

No expense is recognized for awards that do not ultimately vest because non-market performance and/or service conditions have not been met. 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 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.

The dilutive effect of outstanding options is reflected as additional share dilution in the computation of earnings per share.

Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress, 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.

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Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to the statement of 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:

Electronic equipment	32%
Furniture and fixtures	19%
Motor vehicles	24%
Leasehold improvements	Over the shorter of the lease terms and 20%

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 each financial year end.

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 the statement of 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 property, plant and equipment under construction, which is stated at cost less any impairment losses, and are not depreciated. Cost comprises the direct costs of construction and capitalised borrowing costs on related borrowed funds during the period of construction. Construction in progress is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

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.

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Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases. The Group recognizes 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 recognized at the commencement date of the lease (that is 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. 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:

Categories	Estimated useful lives
Leasehold office	1.2 to 8 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 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 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 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, 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

The Group applies the short-term lease recognition exemption to its short-term leases of equipment (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).

Lease payments on short-term leases are recognized 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 amortized cost, fair value through other comprehensive income, and fair value through profit or loss.

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 accordance with the policies set out for “Revenue recognition” below.

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 amortized 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.

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All regular way purchases and sales of financial assets are recognized 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.

Financial assets at amortized cost (debt instruments)

Financial assets at amortized cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognized in the statement of profit or loss when the asset is derecognized, modified or impaired.

Government Grants

We recognized 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, it is recognized as income on a systematic basis over the periods that the costs, which it is intended to compensate, are expensed. Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to the statement of 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 the statement of profit or loss by way of a reduced depreciation charge.

Impairment testing of the patents and licenses

We performed annual impairment testing during the Track Record Period for the patents and technology know-how which were not yet available for use. For impairment testing, the development cost is allocated to the cash generating unit (the “CGU”) at the product pipeline level, which is supposed to be able to generate cash flows independently from those of the other products.

As at 31 December 2019, the intangible asset is related to the capitalisation of the license expense and clinical trial expenses of Hunterase® (CAN101), which has been available for use from 2020.

The recoverable amount of the CGU is determined based on a value-in-use calculation using cash flow projections from financial budgets approved by senior management of the Group covering a 5-year period based on the remaining valid term of the patent related to the CAN101.

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Key assumptions used in the calculation are as follows:

	As at 31 December 2019
CAN101	
Gross margin (% of revenue)	57.4%
The pre-tax discount rate	19.6%

Assumptions were used in the value-in-use calculation of the CGU as at 31 December 2019. The following describes each key assumption on which management has based its cash flow projections to undertake impairment testing of the development cost:

Gross margin – The basis used to determine the value assigned to the budgeted gross margin is the average gross margin expected to achieve since the year when the CAN101 products launched.

The pre-tax discount rate used is before tax and reflects specific risks relating to the unit.

The following tables set forth the impact of reasonably possible changes in each of the key assumptions, with all other variables held constant, on impairment testing of the development cost as of the dates indicated.

	Recoverable amount of the development cost exceeds its carrying amount decrease by As at 31 December 2019 RMB'000
CAN101	
Possible changes of key assumptions	
The gross margin rate decreased by 5.0%	(7,045)
Pre-tax discount rate increased by 1.0%	(3,002)

Considering that there was sufficient headroom based on the assessment, we believe that any reasonably possible change in any of the key assumptions would not cause the carrying amount of the CGU to exceed its recoverable amount.

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Details of the headroom measured by excess of the recoverable amounts over the carrying amounts of the CGU as at 31 December 2019 is set out as follows:

	As at 31 December 2019
	<i>RMB'000</i>
CAN101	
Recoverable amounts	51,356
Less: carrying amounts	<u>(41,633)</u>
	<u><u>9,723</u></u>

The directors of the Company determined that there was no impairment of its CGU at the end of each of the Track Record Period.

Critical Accounting Estimates

The preparation of financial statements requires the use of accounting estimates which, by definition, will seldom equal the actual results. Management also needs to exercise judgement in applying our Group’s accounting policies.

Estimates and judgements are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the entity and that are believed to be reasonable under the circumstances.

Estimation of the fair value of financial liabilities

We measured certain financial liabilities at fair value at the end of each of the relevant periods as disclosed in note 33 to the Accountants’ Report. The convertible redeemable preferred shares and warrants issued by us are not traded in an active market and the respective fair value is determined by using valuation techniques. We applied the backsolve approach to determine the underlying equity value of the Company and adopted the option-pricing method and equity allocation model to determine the fair value of the convertible redeemable preferred shares and warrants. Key assumptions such as the timing of the liquidation, redemption or the event as well as the probability of the various scenarios were based on our best estimates. Further details are included in notes 25, 26 and 33 to the Accountants’ Report.

The convertible loans borrowed by the Company exhibits the characteristics of an embedded derivative and we have designated the entire instrument as a financial liability at fair value through profit or loss. As it is not traded in an active market, we applied the backsolve approach to determine its fair value. Key assumptions such as conversion possibility were based on our best estimates. Further details are included in notes 24 and 33 to the Accountants’ Report.

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Impairment of non-financial assets (other than goodwill)

We assess whether there are any indicators of impairment for all non-financial assets at the end of each of the reporting period. Intangible assets not yet available for intended use are tested for impairment annually and at other times when such an indicator exists. Other 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.

Fair value measurement of share-based payments

The Group has set up the 2019 Equity Incentive Plan and granted options to the Company’s directors, the Group’s employees and consultants. The fair value of the options is determined by the binomial option-pricing model at the grant dates for options granted to directors and employees, and at the service provision dates for the consultants. Significant estimates on assumptions, including the underlying equity value, discount rate, expected volatility, and dividend yield, are made by management. Further details are included in note 30 to the Accountants’ Report.

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 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).

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Recognition of income taxes and deferred tax assets

Determining income tax provision involves judgment 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. We evaluate 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. Deferred tax assets are recognized in respect of deductible temporary differences and unused tax losses. As those deferred tax assets can only be recognized to the extent that it is probable that future taxable profits will be available against which the deductible temporary differences and the losses can be utilized, management's judgment is required to assess the probability of future taxable profits. Our assessment is revised as necessary and additional deferred tax assets are recognized if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered.

Provision for inventories

We review the carrying amounts of the inventories at the end of each of the reporting period to determine whether the inventories are carried at lower of cost and net realizable value. The net realizable value is estimated based on current market situation and historical experience. Any change in the assumptions would increase or decrease the amount of inventories written-down or the related reversals of write-down and affect the Group's financial position.

Useful lives of intangible assets

We amortized the intangible assets on the straight-line basis by taking into account the residual value. We review the estimated useful lives on an annual basis to determine the related amortization charges for its intangible assets. The estimation is based on the legal protection period, with consideration of market condition. Our management will increase the amortization charges when useful lives become shorter than previously estimated.

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DESCRIPTION OF SELECTED COMPONENTS OF STATEMENTS OF PROFIT OR LOSS

The table below sets forth our consolidated statements of profit or loss for the periods indicated derived from our consolidated statements of profit or loss set out in the Accountants’ Report included in Appendix I to this document:

	For the year		For the six months	
	ended December 31,		ended June 30,	
	2019	2020	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(unaudited)</i>	
Revenue	1,469	12,032	1,944	12,192
Cost of sales	(504)	(5,154)	(838)	(5,353)
Gross profit	965	6,878	1,106	6,839
Other income and gains	580	1,359	747	11,052
Selling and distribution expenses	(28,881)	(51,008)	(16,401)	(44,768)
Administrative expenses	(53,719)	(77,716)	(29,337)	(52,928)
Research and development expenses	(55,383)	(109,642)	(35,884)	(274,837)
Fair value changes of convertible redeemable preferred shares	(73,694)	(591,385)	(79,043)	(21,848)
Fair value changes of convertible loans	(1,584)	1,689	1,689	–
Fair value changes of derivative financial instruments	(17)	(20,746)	3,175	34,454
Other expenses	(3,667)	(1,599)	(663)	(609)
Finance costs	(2,275)	(3,873)	(2,119)	(1,558)
Loss before tax	(217,675)	(846,043)	(156,730)	(344,203)
Income tax expense	–	–	–	–
Loss for the year/period	(217,675)	(846,043)	(156,730)	(344,203)
Attributable to:				
Owners of the parent	(217,675)	(846,043)	(156,730)	(344,203)

Revenue

During the Track Record Period, our revenue was generated from sales of medical products, including our Caphosol™(CAN002), Nerlynx®(CAN030) and Hunterase®(CAN101) to three countries or regions. For the year ended 2019 and 2020 and the six months ended June 30, 2021, the revenue we generated from Caphosol™(CAN002) was RMB1.1 million, RMB0.4 million and RMB0.9 million, respectively. Caphosol™(CAN002) experienced a decreasing

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trend in its average selling price over the Track Record Period mainly due to a shift in our distribution model in 2020 to selling directly at a lower average selling price to a healthcare company that conducts its own promotional activities. The average selling price of Caphosol™ (CAN002) remains stable during the first half of 2021, and we expect its average selling price to continue to remain stable in the future during the term of the agreement between us and the healthcare company until 2027, with an automatic renewal of a further period of three years unless otherwise agreed by the parties.

For the year ended 2019 and 2020 and the six months ended June 30, 2021, the revenue we generated from Nerlynx® (CAN030) was RMB0.4 million, RMB11.7 million and RMB10.7 million, respectively. Nerlynx® (CAN030) experienced a decrease in its average selling price over the Track Record Period mainly due to (i) a planned price decrease in Hong Kong to expand market access, (ii) its introduction in mainland China, a region where the average selling price is lower, starting in the fourth quarter of 2020 and (iii) our active participation in the patient assistance programs to increase our sales volume during the Track Record Period. We did not experience a decrease in the average selling price of Nerlynx® (CAN030) as of June 30, 2021 as compared to March 31, 2021, and do not expect their average selling price to continue to decrease unless Nerlynx® (CAN030) is added to any reimbursement drug list in the future and we plan to actively participate in the reimbursement program to increase patient access to Nerlynx® (CAN030).

We launched Hunterase® (CAN101) in mainland China in May 2021. For the six months ended June 30, 2021, the revenue we generated from Hunterase® (CAN101) was RMB0.7 million. As our pipeline drug candidates are expected to launch into the market in the near future upon approval, we expect to continue to generate most of our revenue from sales of medical products.

Geographical information

	Year ended		Six months ended	
	December 31,		June 30,	
	2019	2020	2020	2021
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Mainland China	1,061	5,448	117	3,837
Taiwan	–	319	–	5,418
Hong Kong	408	6,265	1,827	2,937
	1,469	12,032	1,944	12,192
	1,469	12,032	1,944	12,192

The revenue information above is based on the locations of the customers.

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Cost of Sales

Our cost of sales primarily consists of costs of goods sold and royalties. Our costs of goods sold primarily consist of purchase costs of the medical products. Our royalties primarily include the royalties associated with Nerlynx[®](CAN030). Royalties are determined in accordance with respective royalty terms which is mainly based on, among others, the revenue generated by the respective products.

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. For the years ended December 31, 2019 and 2020, our gross profit was RMB1.1 million and RMB6.9 million, respectively, and our gross profit margin was 65.7% and 57.2%, respectively. For the six months ended June 30, 2020 and 2021, our gross profit was RMB1.0 million and RMB6.8 million, respectively, and our gross profit margin was 56.9% and 56.1%, respectively.

Other Income and Gains

Our other income and gains consist of bank interest income, government grants, interest income from financial assets measured at amortized cost, gain on disposal of an intangible asset and foreign exchange gains, net. The table below sets forth a breakdown of our other income and gains for the periods indicated:

	For the year		For the six months	
	ended December 31,		ended June 30,	
	2019	2020	2020	2021
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
	<i>(unaudited)</i>			
Other income and gains				
Bank interest income	120	964	454	1,124
Government grants	173	395	293	201
Interest income from financial				
assets measured at amortized cost	40	–	–	–
Gain on disposal of an intangible				
asset	–	–	–	9,727
Foreign exchange gains, net	247	–	–	–
	<u>580</u>	<u>1,359</u>	<u>747</u>	<u>11,052</u>
Total	<u>580</u>	<u>1,359</u>	<u>747</u>	<u>11,052</u>

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Bank interest income refers to the amount of interest we received from our deposits with commercial banks. Government grants mainly represent incentives we received from the local governments for the purpose of compensation for expenditure arising from research activities and clinical trial activities and awards for new product development and expenditure incurred on certain projects. For example, we received government grants from relevant government authorities for our construction of R&D facilities in China. Interest income from financial assets measured at amortized cost represents the interest derived from wealth management products and calculated by applying the effective interest rate to the gross carrying amount of our financial assets. Gain on disposal of an intangible asset represents the gain on disposal of our license rights in Nerlynx[®](CAN030) as we strategically shift our business focus to rare disease and rare oncology. For details, please refer to “Business – Legal Proceedings and Compliance”. Foreign exchange gains, net, primarily reflect the increased value of the foreign currency we hold resulting from fluctuated exchange rate.

Selling and Distribution Expenses

Our selling and distribution expenses primarily consist of marketing expenses, staff costs, travel and business related expenses, amortization expenses and others. The table below sets forth a breakdown of our selling and distribution expenses for the periods indicated:

	For the year		For the six months	
	ended December 31,		ended June 30,	
	2019	2020	2020	2021
	RMB'000	RMB'000	RMB'000	RMB'000
			<i>(unaudited)</i>	
Selling and Distribution Expenses				
Marketing expenses	8,930	8,066	1,462	14,244
Staff costs	16,641	29,206	12,135	25,044
Travel and business related expenses	1,346	1,676	222	1,393
Amortization expenses	–	10,679	2,345	3,764
Others	1,964	1,381	237	323
Total	28,881	51,008	16,401	44,768

Our marketing expenses primarily consist of expenses associated with our sales and marketing activities, such as product promotion expenses. Our staff costs include salaries, bonuses, welfare, pension and share-based compensation for our sales and marketing employees. Our travel and business related expenses include any travel expenses incurred for our sales and marketing activities. Our selling and distribution expenses include amortization expenses relating to certain of our intangible assets. Our license payment with regard to Hunterase[®](CAN101) and Nerlynx[®](CAN030) are closely related to our product commercialization and therefore the amortization expenses are recognized as selling and distribution expenses. Our other selling and distribution expenses are mainly comprised of office supplies as well as other expenses that are directly related to our marketing and promotion activities.

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Administrative Expenses

Our administrative expenses primarily consist of staff costs, depreciation expenses, travel and business related expenses, office expenses, professional service fees, [REDACTED] and others. The table below sets forth a breakdown of our administrative expenses for the periods indicated:

	For the year ended December 31,		For the six months ended June 30,	
	2019	2020	2020	2021
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
	<i>(unaudited)</i>			
Administrative Expenses				
Staff costs	28,454	29,300	15,509	19,353
Depreciation expenses	3,113	4,757	1,944	3,336
Travel and business related expenses	1,810	925	312	744
Office expenses	823	2,260	901	1,379
Professional service fees	15,716	29,323	9,153	18,747
[REDACTED]	293	7,671	400	7,538
Others	3,510	3,480	1,118	1,831
Total	<u>53,719</u>	<u>77,716</u>	<u>29,337</u>	<u>52,928</u>

Our staff costs include salaries, bonuses, welfare, pension and shared-based compensation for our administrative staff. Our depreciation expenses mainly include depreciation of property, plant and equipment and right-of-use assets. Travel and business related expenses include any travel expenses incurred during business trips of the administrative staff. Our office expenses include utility costs, communication expenses and other general office expenses. Our professional service fees primarily consist of the service fees paid to third-party professionals, such as tax advisors, legal advisors, auditors and intellectual property agents. Other administrative expenses primarily include rental fees, taxes and bank charges.

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Research and Development Expenses

Our research and development expenses primarily consist of staff costs, travel and business related expenses, technical service fees, testing and clinical trial expenses, license fees and other expenses. The table below sets forth a breakdown of our research and development expenses for the periods indicated:

	For the year ended December 31,		For the six months ended June 30,	
	2019	2020	2020	2021
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Research and development expenses				
Staff costs	20,326	29,006	10,220	20,984
Travel and business related expenses	2,711	1,257	86	739
Technical service fees	8,419	13,222	3,588	10,436
Testing and clinical trial expenses	14,090	39,249	1,661	67,022
License fees	6,209	24,030	19,224	173,283
Other expenses	3,628	2,878	1,105	2,373
Total	<u>55,383</u>	<u>109,642</u>	<u>35,884</u>	<u>274,837</u>

Our staff costs include salaries, bonuses, welfare, pension and shared-based compensation for our research and development employees. Travel and business related expenses include any travel expenses incurred during business trips for research and development activities. Our technical service fees refer to the service fees we paid to our third-party service providers for research and development strategy and technical advices. Testing and clinical trial expenses include CMC expenses, clinical trials expenses, expenses incurred in connection with our pre-clinical studies and other testing expenses. Our license fees include upfront and milestone payments. Other expenses are mainly comprised of registration fee, depreciation and amortization and other general expenses incurred for the purpose of research and development.

For our Core Product, CAN008, our research and development expenses were RMB11.9 million and RMB4.3 million for the years ended December 31, 2019 and 2020 respectively and RMB1.6 million and RMB17.9 million for the six months ended June 30, 2020 and 2021, respectively. Changes in the R&D expenses are related to the scope and size of R&D activities in CAN008.

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Fair Value Changes

Fair value changes of convertible redeemable preferred shares

Fair value changes of convertible redeemable preferred shares represent changes in fair value of the preferred shares issued by us. We designated the entire instrument of the convertible redeemable preferred shares as financial liabilities at fair value through profit or loss. Any directly attributable transaction costs are recognized as finance costs in profit or loss. Subsequent to initial recognition, the fair value change of preferred shares is recognized in profit or loss except for the portion attributable to credit risk change which will be recognized to other comprehensive income, if any. The convertible redeemable preferred shares will be converted into Shares upon [REDACTED], after which we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable preferred shares.

The convertible redeemable preferred shares issued by the Company are not traded in an active market and the respective fair value is determined by using valuation techniques. The Group applied the Backsolve Approach to determine the underlying equity value of the Company and adopted the option-pricing method and equity allocation model to determine the fair value of the convertible redeemable preferred shares. Key assumptions such as the risk-free interest rate, the lack of marketability discount as well as the volatility were based on the Group’s best estimates. The table below sets forth our fair value changes of convertible redeemable preferred shares for the years ended December 31, 2019 and 2020 and for the six months ended June 30, 2020 and 2021. Our fair value changes of convertible redeemable preferred shares changed from a loss of RMB73.7 million for 2019 to a loss of RMB591.4 million for 2020, primarily due to the increase in our Company’s valuation. Please see note 25 of the Accountants’ Report set out in Appendix I for further details.

	For the year		For the six months	
	ended December 31,		ended June 30,	
	2019	2020	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
	<i>(unaudited)</i>			
Fair value changes of convertible redeemable preferred shares	(73,694)	(591,385)	(79,043)	(21,848)

Fair value changes of convertible loans

In July 2019, the Company entered into a convertible loan agreement (the “**Convertible Loan Agreement**”) with Yuanming Healthcare Holdings Limited (“**Yuanming Healthcare**”). Yuanming Healthcare provided the Company with a convertible loan amounting to US\$5 million, which bears floating interest which depended on factors including the timing of the Company’s completion of future rounds of financing, the investment amount for such financing and the subscription price for Yuanming Healthcare to convert such loan to the Company’s

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convertible redeemable preferred shares. The Company has designated the convertible loan from Yuanming Healthcare as a financial liability at fair value through profit or loss. As of June 30, 2021, the convertible loan has been fully converted into convertible redeemable preferred shares, and the Company does not expect to record additional fair value changes from such convertible loan in the future.

The table below sets forth our fair value changes of convertible loans for the years ended December 31, 2019 and 2020 and for the six months ended June 30, 2020 and 2021. Please see note 24 of the Accountants’ Report set out in Appendix I for further details.

	For the year		For the six months	
	ended December 31,		ended June 30,	
	2019	2020	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
	<i>(unaudited)</i>			
Fair value changes of convertible loans	(1,584)	1,689	1,689	–

Our fair value changes of convertible loans changed from a loss of RMB1.6 million for 2019 to a gain of RMB1.7 million for 2020, primarily due to the decrease of the fair value of convertible loans in 2020. The decrease of the fair value of convertible loans was due to changes of fair value assumptions such as decrease in time to maturity of convertible loans and increase in the conversion probability to equity, as a result of Series D-1 preferred shares financing closed in March 2020.

Fair value changes of derivative financial instruments

The derivative financial instruments represented warrants issued by the Company to the holders who will be entitled to exercise the warrants in exchange for the Company’s convertible redeemable preferred shares. We measured warrants at fair value through profit and loss. The table below sets forth our fair value changes of derivative financial instruments for the years ended December 31, 2019 and 2020 and for the six months ended June 30, 2020 and 2021. Please see note 26 of the Accountants’ Report set out in Appendix I for further details.

	For the year		For the six months	
	ended December 31,		ended June 30,	
	2019	2020	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
	<i>(unaudited)</i>			
Fair value changes of derivative financial instruments	(17)	(20,746)	3,175	34,454

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Our fair value changes of derivative financial instruments increased significantly from a gain of RMB3.2 million for the six months ended June 30, 2020 to a gain of RMB34.5 million for the six months ended June 30, 2021, primarily due to the derecognition of derivative financial instruments in the six months ended June 30, 2021 and the decrease in the fair value of derivative financial instruments before its derecognition. As the expiration date of the derivative financial instruments approached during the six months ended June 30, 2021, the time value of the derivative financial instruments decreased, resulting in the decrease of the fair value of the derivative financial instrument by RMB15.1 million before its derecognition. As investors of Series D-1 Preferred Shares agreed to terminate their rights to exercise warrants in May 2021, the corresponding derivative financial instruments were derecognized, resulting in a decrease of the liability and a gain recorded in fair value changes of derivative financial instruments by RMB19.3 million.

Other Expenses

Our other expenses were RMB3.7 million, RMB1.6 million, RMB0.7 million and RMB0.6 million for the years ended December 31, 2019 and 2020 and for the six months ended June 30, 2020 and 2021, respectively. Our other expenses primarily consist of foreign exchange losses (net), write-down of inventories to net realizable value, impairment of other receivables, and other expenses.

	For the year ended December 31,		For the six months ended June 30,	
	2019 <i>RMB'000</i>	2020 <i>RMB'000</i>	2020 <i>RMB'000</i>	2021 <i>RMB'000</i>
			<i>(unaudited)</i>	
Foreign exchange loss, net	–	470	448	607
Write-down of inventories to net realizable value	3,504	1,117	215	–
Impairment of other receivables	163	–	–	–
Others	–	12	–	2
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total	<u> 3,667</u>	<u> 1,599</u>	<u> 663</u>	<u> 609</u>

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Finance Costs

Our finance costs were RMB2.3 million and RMB3.9 million for the years ended December 31, 2019 and 2020, and RMB2.1 million and RMB1.6 million for the six months ended June 30, 2020 and 2021, respectively. Our finance costs mainly consist of interest on bank loans, interest on lease liabilities and transaction cost for issuance of the Company’s convertible redeemable preferred shares. The table below sets forth a breakdown of our finance costs for the years ended December 31, 2019 and 2020 and for the six months ended June 30, 2020 and 2021:

	For the year ended		For the six months	
	December 31,		ended June 30,	
	2019	2020	2020	2021
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
	<i>(unaudited)</i>			
Finance costs				
Interest on bank loans	983	3,401	1,920	1,328
Interest on lease liabilities	366	393	160	230
Transaction cost for issuance of the Company’s convertible redeemable preferred shares	926	79	39	–
Total	<u>2,275</u>	<u>3,873</u>	<u>2,119</u>	<u>1,558</u>

Income Tax Expense

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

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains. In addition, the Cayman Islands does not impose withholding tax on dividend payments.

Hong Kong

The subsidiaries incorporated in Hong Kong are subject to income tax at the rate of 16.5% on the estimated assessable profits arising in Hong Kong during the Track Record Period.

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Taiwan

The subsidiary incorporated in Taiwan is subject to income tax at a rate of 20% on the estimated assessable profits arising in Taiwan during the Track Record Period.

Mainland China

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”), the subsidiaries which operate in Mainland China are subject to CIT at a rate of 25% on the taxable income.

United States of America

The subsidiary incorporated in Delaware, United States is subject to statutory United States federal corporate income tax at a rate of 21% during the Track Record Period.

During the Track Record Period and up to the Latest Practicable Date, we paid all relevant taxes in accordance with tax regulations and did not have any disputes or unresolved tax issues with the relevant tax authorities.

PERIOD TO PERIOD COMPARISON OF RESULTS OF OPERATIONS

Six months ended June 30, 2020 Compared to Six months ended June 30, 2021

Revenue

Our total revenue increased by 527.2% from RMB1.9 million for the six months ended June 30, 2020 to RMB12.2 million for the six months ended June 30, 2021, primarily attributable to the commercialization of Nerlynx[®](CAN030) in mainland China in November 2020 and in Taiwan in December 2020 and the increase of sales of Nerlynx[®](CAN030) since its launch in Hong Kong in December 2019. The revenue increase was also driven by the commercialization of Hunterase[®](CAN101) in mainland China in May 2021.

Cost of Sales

Our cost of sales increased by 538.8% from RMB0.8 million for the six months ended June 30, 2020 to RMB5.4 million for the six months ended June 30, 2021, primarily attributable to the increase in sales of commercialized products. Our cost of sales accounted for 43.1% and 43.9% of our revenue for the six months ended June 30, 2020 and 2021, respectively.

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Gross Profit and Gross Profit Margin

As a result of the changes in our revenue and cost of sales described above, our gross profit increased by 518.4% from RMB1.1 million for the six months ended June 30, 2020 to RMB6.8 million for the six months ended June 30, 2021. Our gross profit margin was 56.9% and 56.1% for the six months ended June 30, 2020 and 2021, respectively.

Other Income and Gains

Our other income and gains increased by 1,379.5% from RMB0.7 million for the six months ended June 30, 2020 to RMB11.1 million for the six months ended June 30, 2021. Such increase mainly resulted from the increase in gain on disposal of our license rights in Nerlynx[®](CAN030) as we strategically shift our business focus to rare disease and rare oncology. For details, please refer to “Business – Legal Proceedings and Compliance”.

Selling and Distribution Expenses

Our selling and distribution expenses increased by 173.0% from RMB16.4 million for the six months ended June 30, 2020 to RMB44.8 million for the six months ended June 30, 2021. Such increase was primarily attributable to (i) our increased staff costs from RMB12.1 million for the six months ended June 30, 2020 to RMB25.0 million for the six months ended June 30, 2021, as a result of our headcount increase in the commercial team in preparation of the launch of Hunterase[®](CAN101) in Greater China, and (ii) our increased marketing expenses from RMB1.5 million for the six months ended June 30, 2020 to RMB14.2 million for the six months ended June 30, 2021, as a result of increased market research and marketing activities for Hunterase[®](CAN101) and other pipeline candidates and products.

Administrative Expenses

Our administrative expenses increased by 80.5% from RMB29.3 million for the six months ended June 30, 2020 to RMB52.9 million for the six months ended June 30, 2021. Such increase was primarily attributable to (i) our increased professional service fees from RMB9.2 million for the six months ended June 30, 2020 to RMB18.7 million for the six months ended June 30, 2021 as a result of the increase in relevant professional service fees mainly including lawyer fees, audit fees, tax advisory fees with regard to our financing activities (excluding the [REDACTED]) and business development activities; and (ii) increased [REDACTED] from RMB0.4 million for the six months ended June 30, 2020 to RMB7.5 million for the six months ended June 30, 2021.

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Research and Development Expenses

Our research and development expenses increased by 665.5% from RMB35.9 million for the six months ended June 30, 2020 to RMB274.8 million six months ended June 30, 2021. Such increase was primarily due to (i) increased staff costs from RMB10.2 million for the six months ended June 30, 2020 to RMB21.0 million for the six months ended June 30, 2021, as a result of headcount increase and the increase of share option expenses, (ii) increased license fee from RMB19.2 million for the six months ended June 30, 2020 to RMB173.3 million for the six months ended June 30, 2021, and (iii) increased testing and clinical trial expenses from RMB1.7 million for the six months ended June 30, 2020 to RMB67.0 million for the six months ended June 30, 2021, due to more CRO and CMC activities carried out for our pipeline candidates in the six months ended June 30, 2021 as compared with those in the same period of 2020.

Fair Value Changes of Convertible Redeemable Preferred Shares

Our fair value changes of convertible redeemable preferred shares decreased by 72.4% from a loss of RMB79.0 million for the six months ended June 30, 2020 to a loss of RMB21.8 million for the six months ended June 30, 2021, which was in line with the changes in our Company’s valuation and we adopted the Back Solve Approach method and equity allocation model to determine the fair value of the convertible redeemable preferred shares.

Fair Value Changes of Convertible Loans

Our fair value changes of convertible loans changed from a gain of RMB1.7 million for the six months ended June 30, 2020 to nil for the six months ended June 30, 2021, primarily due to Yuanming Healthcare exercised its convertible rights and all the convertible loans were converted to the convertible redeemable preferred shares in March 2020.

Fair Value Changes of Derivative Financial Instruments

Our fair value changes of derivative financial instruments increased significantly from a gain of RMB3.2 million for the six months ended June 30, 2020 to a gain of RMB34.5 million for the six months ended June 30, 2021, primarily due to the derecognition of derivative financial instruments in the six months ended June 30, 2021 and the decrease in the fair value of derivative financial instruments before its derecognition. As the expiration date of the derivative financial instruments approached during the six months ended June 30, 2021, the time value of the derivative financial instruments decreased, resulting in the decrease of the fair value of the derivative financial instrument by RMB15.1 million before its derecognition. As investors of Series D-1 Preferred Shares agreed to terminate their rights to exercise warrants in May 2021, the corresponding derivative financial instruments were derecognized, resulting in a decrease of the liability and a gain recorded in fair value changes of derivative financial instruments by RMB19.3 million.

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Other Expenses

Our other expenses decreased from RMB0.7 million for the six months ended June 30, 2020 to RMB0.6 million for the six months ended June 30, 2021, primarily due to the decrease in write-down of inventories to net realizable value.

Finance Costs

Our finance costs decreased by 26.5% from RMB2.1 million for the six months ended June 30, 2020 to RMB1.6 million for the six months ended June 30, 2021, primarily in line with the decrease of loan balance with the repayment as well as the decrease of interest rate.

Year Ended December 31, 2019 Compared to Year Ended December 31, 2020

Revenue

Our total revenue increased by 719.1% from RMB1.5 million for 2019 to RMB12.0 million for 2020, primarily attributable to our sales in China, Hong Kong and Taiwan. Our revenue is primarily driven by medical products sales, mainly the increase in sales of our Nerlynx[®](CAN030) since its launch in Hong Kong in December 2019, in mainland China in November 2020 and in Taiwan in December 2020. During 2020, our medical products sales and marketing activities had not been obviously affected by the COVID-19 pandemic since we launched the first product in December 2019.

Cost of Sales

Our cost of sales increased by 922.6% from RMB0.5 million for 2019 to RMB5.2 million for 2020, primarily attributable to the increase in Nerlynx[®](CAN030) sales in 2020 since its commercialization in Hong Kong in December 2019, in mainland China in November 2020 and in Taiwan in December 2020. Our cost of sales accounted for 34.3% and 42.8% of our revenue for 2019 and 2020, respectively.

Gross Profit and Gross Profit Margin

As a result of the changes in our revenue and cost of sales described above, our gross profit increased by 612.7% from RMB1.0 million for 2019 to RMB6.9 million for 2020. Our gross profit margin decreased from 65.7% for 2019 to 57.2% for 2020, due to adjustments in business strategy and decreases in the average selling prices of our commercialized products. CAN002's gross profit margin decreased due to a shift in its distribution model in 2020 to selling directly at a lower average selling price to a healthcare company that conducts its own promotional activities. A decrease in CAN030's gross profit margin resulted from its lower average selling price due to a planned price decrease in Hong Kong during the Track Record Period to expand market access and its introduction in mainland China, a region where the average selling price is lower, in the fourth quarter of 2020.

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Other Income and Gains

Our other income and gains increased by 134.3% from RMB0.6 million for 2019 to RMB1.4 million for 2020. Such increase was mainly resulted from the increase in bank interest income, which is mainly due to the increase of cash and bank balance.

Selling and Distribution Expenses

Our selling and distribution expenses increased by 76.6% from RMB28.9 million for 2019 to RMB51.0 million for 2020. Such increase was primarily attributable to (i) our increased staff costs from RMB16.6 million for 2019 to RMB29.2 million for 2020, as a result of our headcount increase in the commercial team in preparation of the commercial sales of Nerlynx[®](CAN030) and launch of Hunterase[®](CAN101) in China, and (ii) our increased intangible assets amortization from nil for 2019 to RMB10.7 million for 2020, due to the patents and license of Nerlynx[®](CAN030) began to amortize in May 2020 and the patents and license of Hunterase[®](CAN101) began to amortize in September 2020 since they received respective marketing approval in China.

Administrative Expenses

Our administrative expenses increased by 44.7% from RMB53.7 million for 2019 to RMB77.7 million for 2020. Such increase was primarily attributable to (i) our increased professional service fees from RMB15.7 million for 2019 to RMB29.3 million for 2020 as a result of the increase in relevant professional service fees mainly including lawyer fee, audit fees, tax advisory fee with regard to our financing activities (excluding the [REDACTED]) and business development activities; and (ii) increased [REDACTED] from RMB0.3 million for 2019 to RMB7.7 million for 2020.

Research and Development Expenses

Our research and development expenses increased by 98.0%, from RMB55.4 million for 2019 to RMB109.6 million for 2020. Such change was primarily due to (i) increased staff costs from RMB20.3 million for 2019 to RMB29.0 million for 2020 mainly due to headcount increase of our R&D personnel and the increase of share option expenses, (ii) increased license fee from RMB6.2 million for 2019 to RMB24.0 million for 2020, and (iii) increased testing and clinical trial expenses from RMB14.1 million for 2019 to RMB39.2 million for 2020.

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Fair Value Changes of Convertible Redeemable Preferred Shares

Our fair value changes of convertible redeemable preferred shares changed from a loss of RMB73.7 million for 2019 to a loss of RMB591.4 million for 2020, primarily due to the increase in our Company’s valuation.

Fair Value Changes of Convertible Loans

Our fair value changes of convertible loans changed from a loss of RMB1.6 million for 2019 to a gain of RMB1.7 million for 2020, primarily due to the decrease of the fair value of convertible loans in 2020. The decrease of the fair value of convertible loans was due to changes of fair value assumptions such as decrease in time to maturity of convertible loans and increase in the conversion probability to equity, as a result of Series D-1 preferred shares financing closed in March 2020.

Fair Value Changes of Derivative Financial Instruments

Our fair value changes of derivative financial instruments changed from a loss of RMB17,000 for 2019 to a loss of RMB20.7 million for 2020, primarily due to our issuance of warrants to relevant investors.

Other Expenses

Our other expenses decreased from RMB3.7 million for 2019 to RMB1.6 million for 2020, primarily due to changes of provided inventory provision. RMB1.1 million inventory provision was provided in 2020, while RMB3.5 million inventory provision was provided in 2019 for the stocks of CaphosolTM(CAN002).

Finance Costs

Our finance costs increased by 70.2% from RMB2.3 million for 2019 to RMB3.9 million for 2020 primarily in line with the increase in our interest-bearing bank loans.

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DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The table below sets forth selected information from our consolidated statements of financial position as of the dates indicated, which have been extracted from the Accountants’ Report set out in Appendix I to this document:

	As of December 31,		As of
	2019	2020	June 30,
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Total non-current assets ⁽¹⁾	50,645	195,313	70,939
Total current assets	37,905	391,045	480,432
Total assets	88,550	586,358	551,371
Total current liabilities	43,749	108,103	100,925
Total non-current liabilities	1,035,447	2,224,111	2,515,244
Total liabilities	1,079,196	2,332,214	2,616,169
Net current (liabilities)/assets	(5,844)	282,942	379,507
Net liabilities	(990,646)	(1,745,856)	(2,064,798)
Share capital	5	5	5
Reserves	(990,651)	(1,745,861)	(2,064,803)
Total equity	(990,646)	(1,745,856)	(2,064,798)

Note:

- (1) We had non-current assets of RMB195.3 million as of December 31, 2020, compared to non-current assets of RMB50.6 million as of December 31, 2019. The change was primarily due to the increase of intangible assets of patent and license in 2020. The non-current assets decreased from RMB195.3 million as of December 31, 2020 to RMB70.9 million as of June 30, 2021, mainly due to the disposal of the license rights in Nerlynx®CAN030 in the first quarter of 2021. For details, please refer to “Business – Legal Proceedings and Compliance”.

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NET CURRENT ASSETS/LIABILITIES

The following table sets forth our current assets and current liabilities as of the dates indicated:

	As of December 31,		As of	As of
	2019	2020	June 30,	[August 31],
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(unaudited)</i>
Current assets				
Inventories	1,447	553	1,269	5,472
Trade receivables	593	7,040	7,128	6,369
Prepayments, other receivables and other assets	21,992	22,648	29,935	32,173
Cash and cash equivalents	13,873	360,804	442,100	381,458
Total current assets	37,905	391,045	480,432	425,472
Current liabilities				
Trade payables	6,576	46,713	42,108	49,894
Other payables and accruals	24,634	33,557	39,038	37,786
Interest-bearing bank and other borrowings	9,596	22,314	14,066	13,281
Leases liabilities	2,943	5,519	5,713	7,825
Total current liabilities	43,749	108,103	100,925	108,786
Net current (liabilities)/assets	(5,844)	282,942	379,507	316,686

We had net current assets of RMB316.7 million as of [August 31], 2021 being the latest practicable date for the purpose of liquidity disclosure in this document, compared to net current assets of RMB379.5 million as of June 30, 2021. The change was primarily due to the decrease in cash and bank balances of RMB60.6 million which was mainly spent on research and development activities as well as the staff payroll and welfare.

We had net current assets of RMB282.9 million as of December 31, 2020, compared to net current liabilities of RMB5.8 million as of December 31, 2019. The change was primarily due to an increase in cash and cash equivalents of RMB346.9 million, partially offset by (i) an increase in interest-bearing bank and other borrowings of RMB12.7 million, (ii) an increase in trade payables of RMB40.1 million, and (iii) an increase in other payables and accruals of RMB8.9 million. Among the above, the increase in cash and cash equivalents was primarily due to the completion of Series D and Series E financing.

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Our net current assets increased by 34.1% from RMB282.9 million as of December 31, 2020 to RMB379.5 million as of June 30, 2021, primarily due to an inflow of RMB334.9 million from the second completion of Series D-1 and tranche 2 of Series E financing activities and an inflow of US\$20.0 million from the disposal of our license rights in Nerlynx® (CAN030) in 2021 as we strategically shift our business focus to rare disease and rare oncology. For details, please refer to “Business – Legal Proceedings and Compliance”.

For changes in other key line items, see “– Inventories,” “– Trade Receivables,” “– Prepayments, Other Receivables and Other Assets” and “– Net Current Assets/Liabilities.”

Inventories

Our inventories merely consist of finished goods. We regularly monitor our inventories and endeavor to keep an optimal inventory level in line with the expected usages in the near term. For further details of our inventory management, see “Business – Inventory.”

Our inventory balance decreased from RMB1.4 million as of December 31, 2019 to RMB0.6 million as of December 31, 2020, which was as a result of RMB1.2 million of inventory provision provided in 2020 for the stocks of Caphosol™(CAN002). Our inventory balance increased from RMB0.6 million as of December 31, 2020 to RMB1.3 million as of June 30, 2021, primarily due to the increase of stocks of Hunterase®(CAN101) for its commercial launch in mainland China in May 2021.

The table below sets forth our inventory turnover days for the periods indicated:

	For the year ended		For the six
	December 31,		months ended
	2019	2020	June 30,
			2021
Inventory turnover days ⁽¹⁾	1,220	70	31

Note:

- (1) Inventory turnover days for a year/period is the arithmetic mean of the beginning and ending balances of inventory for the relevant year/period divided by the sum of cost of sales for the relevant year/period and multiplied by 360 or 180 days for the full-year period or relevant period.

For the years ended December 31, 2019 and 2020 and the six months ended June 30, 2021, our inventory turnover days were 1,220 days, 70 days and 31 days, respectively. The continuous decrease in inventory turnover days during the Track Record Period was primarily due to the normalization of commercialization and the improvement of our inventory control.

As of [September 30], 2021, RMB540 thousand, representing 42.5% of the inventory as of June 30, 2021 was subsequently utilized.

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Trade Receivables

Our trade receivables primarily represent the balances due from certain customers. We generally allow our customers for a credit period from 30 to 90 days. We set a maximum credit limit for each customer and consider a number of factors in determining the credit term of a customer, including its cash flow conditions and creditworthiness as well as the local medical care policy and market environment. For details, see “Business – Sales and Marketing – Our Marketing Model and Sales Arrangements.”

The table below sets forth our trade receivables as of the dates indicated:

	As of December 31,		As of
	2019	2020	June 30,
	<i>RMB'000</i>	<i>RMB'000</i>	2021
			<i>RMB'000</i>
Trade receivables	593	7,040	7,128
Impairment	—	—	—
	<u> </u>	<u> </u>	<u> </u>
Total	<u> 593</u>	<u> 7,040</u>	<u> 7,128</u>

Our trade receivables increased from RMB7.0 million as of December 31, 2020 to RMB7.1 million as of June 30, 2021, primarily due to increase of sales. Our trade receivables increased from RMB0.6 million as of December 31, 2019 to RMB7.0 million as of December 31, 2020, which was due to the commercialization of Nerlynx[®](CAN030) in Hong Kong in December 2019, in mainland China in November 2020 and in Taiwan in December 2020, which generated the trade receivable balance of RMB6.3 million. We do not hold any collateral or other credit enhancements over our trade receivables balance and such receivables are non-interest bearing.

In determining impairment of trade receivables, we conduct regular reviews of aging analysis and evaluate collectability, taking into account of the historical loss patterns of our customers and adjust for forward looking macroeconomic data in calculating the expected credit loss rate. We did not record provision for impairment of trade receivables during the Track Record Period.

As of [September 30], 2021, RMB6,264 thousand, representing 87.9% of the trade receivables as of June 30, 2021 was subsequently settled.

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The table below sets forth our trade receivables turnover days for the periods indicated:

	As of December 31,		As of
	2019	2020	June 30,
			2021
Average trade receivables turnover days ⁽¹⁾	122	114	105

Note:

- (1) Average trade receivables turnover days for a period equals the arithmetic mean of the beginning and ending trade receivable balances divided by revenue for that period and multiplied by 360 or 180 days for the full-year period or relevant period.

The average trade receivables turnover days were 122 days in 2019, while the average trade receivables turnover days were 114 days in 2020, which was primarily due to that the first sales of Nerlynx[®](CAN030) in Hong Kong occurred in December 2019, which increased the balance of trade receivable and caused the longer turnover days in the calculation. Our trade receivables turnover days decreased from 114 days in 2020 to 105 days for the six months ended June 30, 2021, primarily due to improvement of sales.

The following table sets forth an ageing analysis of the trade receivables as at the end of each of the relevant periods, based on the invoice date and net of loss allowance:

	As of December 31,		As of
	2019	2020	June 30,
	<i>RMB'000</i>	<i>RMB'000</i>	2021
			<i>RMB'000</i>
Trade receivables			
Within three months	593	7,040	4,966
Over three months	—	—	2,162
	593	7,040	7,128
	593	7,040	7,128

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Prepayments, Other Receivables and Other Assets

Our current prepayments, other receivables and other assets include prepayments, value-added tax recoverable, loans to a director and other receivables. Prepayments primarily include prepaid service fee, prepaid rental fees and prepayments for purchase of goods and services. The table below sets forth our prepayments, other receivables and other assets as of the dates indicated:

	As of December 31,		As of
	2019	2020	June 30,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Prepayments	278	4,683	19,769
Value-added tax recoverable	11,129	6,777	8,797
Loans to a director	8,965	9,198	–
Other receivables	1,620	1,990	1,369
	21,992	22,648	29,935
Non-current portion	–	–	–
Current portion	21,992	22,648	29,935

Our current prepayments, other receivables and other assets increased slightly from RMB22.0 million as of December 31, 2019 to RMB22.6 million as of December 31, 2020, which was primarily attributable to a decrease in value-added tax (“VAT”) recoverable of RMB4.4 million due to VAT refund, and substantially offset by an increase in prepayments of RMB4.4 million including increase in prepayment of purchase of goods, prepaid rental fees and other prepaid service fees. Our current prepayments, other receivables and other assets increased from RMB22.6 million as of December 31, 2020 to RMB29.9 million as of June 30, 2021, mainly due to the increase in prepayment to suppliers for purchase of goods and prepaid R&D expenses, partially offset by the repayment of a director loan.

Cash and Cash Equivalents

Cash and cash equivalents were RMB13.9 million, RMB360.8 million and RMB442.1 million as of December 31, 2019 and 2020, and as of June 30, 2021, respectively, primarily consisting of time deposits with original maturity of less than one year when acquired. The increase was mainly attributable from the funds we received from our financing activities.

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The table below sets forth our cash and cash equivalents as of the dates indicated:

	As of December 31,		As of
	2019	2020	June 30,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Cash and bank balances	13,873	99,808	248,297
Time deposits	—	260,996	193,803
	<u>13,873</u>	<u>360,804</u>	<u>442,100</u>
Denominated in:			
RMB	351	9,341	19,226
HK\$	56	1,392	1,942
US\$	13,325	349,494	417,426
TW\$	141	577	3,506
	<u>13,873</u>	<u>360,804</u>	<u>442,100</u>
Cash and cash equivalents	<u>13,873</u>	<u>360,804</u>	<u>442,100</u>

Trade Payables

Our trade payables primarily consist of the balances due to our suppliers for purchase of medical products and CRO and CDMO services. Our trading terms with suppliers vary depending on a number of factors, in particular the type of products and transaction volumes. Our trade payables increased from RMB6.6 million as of December 31, 2019 to RMB46.7 million as of December 31, 2020 primarily due to our increased use of CRO and CDMO services for research and development activities, and decreased to RMB42.1 million as of June 30, 2021, primarily due to our increased settlement of trade payables.

The following table sets forth an ageing analysis of the trade payables as of the dates indicated:

	As of December 31,		As of
	2019	2020	June 30,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables			
Within six months	<u>6,576</u>	<u>46,713</u>	<u>42,108</u>
Total	<u><u>6,576</u></u>	<u><u>46,713</u></u>	<u><u>42,108</u></u>

As of [September 30], 2021, RMB9.6 million, representing 22.8% of the trade payables as of June 30, 2021 was subsequently settled.

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Other Payables and Accruals

Our other payables and accruals refer to taxes payable other than corporate income tax, payroll payable, other payables, due to related parties and accruals, among which other payables including payables due to our third-party technical service providers, [REDACTED] costs and professional service fees. The table below sets forth our other payables and accruals as of the dates indicated:

	As of December 31,		As of
	2019	2020	June 30,
	<i>RMB'000</i>	<i>RMB'000</i>	2021
			<i>RMB'000</i>
Taxes other than income tax	710	995	1,115
Payroll payable	12,762	16,562	15,865
Other payables	7,692	13,692	21,192
Due to related parties	168	–	–
Accruals	3,302	2,308	866
	<u>3,302</u>	<u>2,308</u>	<u>866</u>
Total	<u>24,634</u>	<u>33,557</u>	<u>39,038</u>

The increase in our other payables and accruals as of December 31, 2020 compared to that as of December 31, 2019, was primarily attributable to the increase in payroll payable as a result of the increase in number of our employees, increase of other payables as a result of more technical service received and [REDACTED] occurred in 2020. Our other payables and accruals increased to RMB39.0 million as of June 30, 2021, which was primarily attributable to the increase in other payables due to increase in professional service fees.

Interest-Bearing Bank and Other Borrowings

Our interest-bearing bank and other borrowings consist primarily of loans and borrowings from third parties.

The bank loan agreements contain standard events of default such as the occurrence of a change of control, bankruptcy and an event that has a material adverse effect. Our Directors confirm that we had no material defaults in payment of interest-bearing bank and other borrowings and had not breached any finance covenants thereunder during the Track Record Period and up to the Latest Practicable Date. Our Directors also confirm that we are not subject to other material covenants under any agreements with respect to any bank loans or other borrowings.

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The table below sets forth the details of our interest-bearing bank and other borrowings as of the dates indicated:

	As at December 31,		As of
	2019	2020	June 30,
	<i>RMB'000</i>	<i>RMB'000</i>	2021
			<i>RMB'000</i>
Included in current liabilities			
Bank loans-secured	9,596	13,814	14,066
Bank loans-unsecured	—	8,500	—
Included in non-current liabilities			
Bank loans-secured	16,870	11,645	4,487
Total	26,466	33,959	18,553
Analyzed into:			
Bank loans:			
Within one year or on demand	9,596	22,314	14,066
In the second year	9,895	11,261	4,487
In the third to fifth years, inclusive	6,975	384	—
Beyond five years	—	—	—
	26,466	33,959	18,553

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 lease liabilities increased from RMB7.3 million as of December 31, 2019 to RMB12.9 million as of December 31, 2020, primarily due to our additional leased properties and expanded office area to support our expansion of business operations for launch of products. Our lease liabilities decreased from RMB12.9 million as of December 31, 2020 to RMB11.4 million as of June 30, 2021, primarily due to rental fee paid during the period. The table below sets forth our lease liabilities for the periods indicated:

	As of December 31,		As of
	2019	2020	June 30,
	<i>RMB'000</i>	<i>RMB'000</i>	2021
			<i>RMB'000</i>
Lease liabilities			
Current portion	2,943	5,519	5,713
Non-current portion	4,401	7,417	5,680

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Except as discussed above, we did not have any other material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of the Latest Practicable Date.

LIQUIDITY AND CAPITAL RESOURCES

Overview

During the Track Record Period, we relied on capital contributions by our shareholders and bank loans as the major sources of liquidity. We also generate cash from our revenue from our sales revenue of existing commercialized products, mainly including CaphosolTM(CAN002), Nerlynx[®](CAN030) and Hunterase[®](CAN101) in the Track Record Period. As our business develops and expands, we expect to generate more net cash from our operating activities, through increasing sales revenue of the existing commercialized products and by launching new products, as a result of the broader market acceptance of our existing products and our continued efforts in marketing and expansion, improving cost control and operating efficiency and accelerating the turnover of trade receivables by tightening our credit policy.

With respect to cash management, our objective is to optimize liquidity to gain a better return for Shareholders in a risk-averse manner. Specifically, we have policies in place to monitor and manage the settlement of trade receivables. When determining the credit term of a customer or a distributor, we consider a number of factors, including its cash flow conditions and creditworthiness. To monitor the settlement of our trade receivables and avoid credit losses, we conduct annual review of each customer's or distributor's financial performance, which is primarily based on the amount and aging of the trade receivables due from such customer or distributor in the respective period. Pursuant to our distribution agreement, when our distributor fails to make a payment within the credit term, we may, at our discretion, terminate the distribution arrangement or take certain other measures as appropriate.

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Cash Flows

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

	As of December 31,		As of June 30,	
	2019	2020	2020	2021
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>	
Cash outflow from operating activities				
before movements in working capital	(116,560)	(198,611)	(67,740)	(351,521)
Changes in working capital	(9,735)	45,999	(2,902)	(10,762)
Interest received	120	964	454	1,124
Net cash flows used in operating activities	(126,175)	(151,648)	(70,188)	(361,159)
Net cash flows from/(used in) investing				
activities	(42,420)	(153,483)	(146,104)	128,581
Net cash flows from financing activities	96,967	679,263	397,538	315,383
Net increase/(decrease) in cash and cash				
equivalents	(71,628)	374,132	181,246	82,805
Cash and cash equivalents at beginning				
of year/period	85,240	13,873	13,873	360,804
Effect of foreign exchange rate changes, net	261	(27,201)	(470)	(1,509)
Cash and cash equivalents at end of				
year/period	13,873	360,804	194,649	442,100

Net Cash Flows used in Operating Activities

Since the commencement of our business operation, we have incurred negative cash flows from our operations. Substantially all of our operating cash outflows have resulted from our R&D costs, selling and distribution expenses and administrative expenses. We plan to improve our net operating cash flow mainly through improving profitability and reducing net loss. In addition, we will continue to expand our business scale and generate additional source of revenue with our new products. As we further expand sales of our approved products, commercialize our pipeline products and increase our operational scale in the future, the cost of sales and operating expenses are expected to remain relatively stable due to optimization of our cost structure economies of scale, which would drive up our profitability and reduce our net loss, thus improving our net operating cash flow.

For the six months ended June 30, 2021, our net cash used in operating activities was RMB361.2 million, which was primarily attributable to our net loss before tax of RMB344.2 million, negatively adjusted by fair value changes of derivative financial instruments of RMB34.5 million, gain on disposal of an intangible asset of RMB9.7 million, decrease in trade payables of RMB4.6 million, partially offset by fair value changes of convertible redeemable preferred shares of RMB21.8 million.

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For the year ended December 31, 2020, our net cash used in operating activities was RMB151.6 million, which was primarily attributable to our net loss before tax of RMB846.0 million, positively adjusted by fair value changes of convertible redeemable preferred shares of RMB591.4 million, increase in trade payable of RMB40.6 million, fair value changes of derivative financial instruments of RMB20.7 million, increase in other payables and accruals of RMB10.1 million, partially offset by increase in trade receivables of RMB6.6 million.

For the year ended December 31, 2019, our net cash used in operating activities was RMB126.2 million, which was primarily attributable to our net loss before tax of RMB217.7 million, positively adjusted by fair value changes of convertible redeemable preferred shares of RMB73.7 million, share-based payment expenses of RMB16.7 million and increase in other payable and accruals of RMB9.7 million, partially offset by decrease in trade payables of RMB16.4 million.

Net Cash Flows From/(Used in) Investing Activities

For the six months ended June 30, 2021, our net cash from investing activities was RMB128.6 million, mainly attributable to proceeds from disposal of an intangible asset of RMB131.4 million.

For the year ended December 31, 2020, our net cash used in investing activities was RMB153.5 million, mainly attributable to (i) additions to other intangible assets of RMB150.9 million and (ii) purchases of items of property, plant and equipment of RMB2.6 million.

For the year ended December 31, 2019, our net cash used in investing activities was RMB42.4 million, mainly attributable to (i) additions to other intangible assets of RMB41.4 million, and (ii) purchases of financial assets measured at amortised cost of RMB12.0 million, which were partially offset by proceeds from disposal of financial assets measured at amortised at cost of RMB12.0 million.

Net Cash Flows From Financing Activities

During the Track Record Period, we derived our cash inflows from financing activities primarily from capital injections by our shareholders and bank loans.

For the six months ended June 30, 2021, we had RMB315.4 million of net cash flows from financing activities, primarily attributable to proceeds from issue of convertible redeemable preferred shares of RMB334.9 million, partially offset by repayment of bank and other borrowings of RMB15.8 million.

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For the year ended December 31, 2020, we had RMB679.3 million of net cash flows from financing activities, primarily attributable to (i) proceeds from issue of convertible redeemable preferred shares of RMB665.7 million, (ii) proceeds from bank and other borrowings of RMB21.5 million, and (iii) proceeds from issue of derivative financial instruments of RMB15.4 million, which were partially offset by (i) payment of lease liabilities of RMB3.8 million, (ii) repayment of bank and other borrowings of RMB14.2 million, and (iii) interest paid on bank loans and interest paid on convertible loans of RMB2.6 million and RMB2.4 million, respectively.

For the year ended December 31, 2019, we had RMB97.0 million of net cash flows from financing activities, primarily attributable to (i) proceeds from issue of convertible redeemable preferred shares of RMB40.4 million, (ii) proceeds from issue of convertible loans of RMB34.4 million, (iii) proceeds from bank and other borrowings of RMB26.1 million, which were partially offset by (i) payment of lease liabilities of RMB2.7 million.

WORKING CAPITAL

The Directors are of the opinion that, taking into account of the following financial resources available to us described below, we have sufficient working capital to cover at least 125% of our costs, R&D costs, selling and distribution expenses, general, administrative and operating expenses (including any production cost) for at least the next 12 months from the date of this Document:

- our future operating cash flows in respective periods;
- cash and cash equivalents;
- available equity financing and bank facilities; and
- the estimated net [REDACTED] from the [REDACTED].

Our cash burn rate refers to the average monthly (i) net cash used in operating activities, which includes research and development expenses, and (ii) capital expenditures. We had bank balance and cash of RMB381.5 million as of [August 31], 2021. We estimate that we will receive net [REDACTED] of approximately [REDACTED] million after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no [REDACTED] is exercised and assuming an [REDACTED] of [REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] of [REDACTED] to [REDACTED] per [REDACTED] in this Document. Assuming an average cash burn rate going forward of the same level in 2020, we estimate that our cash and cash equivalents as of [August 31], 2021 will be able to maintain our financial viability for [15] months. Assuming an average cash burn rate going forward of two times the level in 2020, we estimate that our cash and cash equivalents as of [August 31], 2021 will be able to maintain our financial viability for [36] months, if we take into account the estimated net [REDACTED] from the [REDACTED]. We will continue to monitor our working capital, cash flows, and our business development progress.

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CASH OPERATING COSTS

The following table sets forth key information relating to our cash operating costs for the periods indicated:

	For the year ended		For the six
	December 31,		months ended
	2019	2020	June 30,
	RMB'000	RMB'000	2021
			RMB'000
Research and Development Costs⁽¹⁾			
Research and Development Costs for Core			
Product Candidate⁽²⁾			
Employee costs	7,713	8,291	10,474
Clinical trial costs ⁽³⁾	10,603	–	7,593
CMC costs	2,114	729	7,262
License fees	552	–	–
Others	2,751	4,766	2,769
Research and Development Costs for Other			
Product Candidates			
Employee costs	7,119	7,653	9,668
Clinical trial costs ⁽⁴⁾	1,076	4,433	21,998
CMC costs	9,260	1,184	36,615
License fees	12,025	17,770	179,725
Others	6,276	6,762	4,369
Workforce Employment ⁽⁵⁾	31,686	46,865	35,427
Product Marketing	9,554	10,575	6,866
Direct Production/product purchase Cost	1,562	1,337	11,545
Non-income taxes, royalties and other			
governmental charges	–	1,427	5,130
Contingency allowances	–	–	–
Others	24,038	44,785	37,339
Total	126,329	156,577	376,780

Notes:

- (1) The difference between R&D expenses and cash operating costs for the R&D activities during the Track Record Period was mainly due to the R&D related trade payable accrual. The cash operating costs for the R&D of the Core Product and Other Product Candidates are recorded directly on a cash basis of payments actually made during our daily operations, while the R&D expenses are recorded pursuant to the accrual basis of accounting which depicts the effects of transactions and other events and circumstances on our economic resources and claims in the periods in which those effects occur, even if the resulting cash receipts and payments occur in a different period. For example, we recorded R&D expenses of RMB109.6 million for FY2020, as compared to cash operating costs for the R&D of the Core Product and Other Product Candidates of RMB51.6 million for the same period. This difference

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is primarily due to the R&D related trade payable accrual of approximately RMB40 million for FY2020, which was recorded as R&D expenses as the products and services are already received, but was not recorded as cash operating costs because the payment is not actually made yet due to the applicable credit term. For FY2019, however, as our scope of R&D activities was smaller than FY2020, the R&D expenses accrued and recorded in FY2019 was less than the payment of R&D expenses in this year because of the payment made in FY2019 to settle the R&D payables accrued in 2018. The difference between R&D expenses and cash operating costs for the R&D activities during the Track Record Period was also partly due to the non-cash expense of share-based payment.

- (2) The decreasing percentage of our R&D cash operating costs on Core Product to our total cash operating costs for the FY2020 as compared to FY2019 is primarily due to the clinical trial costs settled in 2019 for the completed trials, while we are in the design and preparation stage of our Phase II trial for CAN008 in 2020. The decreasing percentage of our R&D cash operating costs on Core Product to our total cash operating costs for the six months ended June 30, 2021 as compared to FY2019 is primarily due to the increased licensing fees paid for other product candidates in 2021.
- (3) Costs attributable to CROs were RMB9,726 thousand and nil for the year ended December 31, 2019 and 2020, respectively, and RMB7,502 thousand for the six months ended June 30, 2021. All the fees to CROs incurred during the Track Record Period were fees relating to clinical trials.
- (4) Costs attributable to CROs were RMB755 thousand and RMB911 thousand for the years ended December 31, 2019 and 2020, respectively, and RMB6,559 thousand for the six months ended June 30, 2021. All the fees to CROs incurred during the Track Record Period were fees relating to clinical trials.
- (5) Workforce employment costs represent total non-R&D staff costs mainly including salaries, bonus and benefits.

INDEBTEDNESS

The following table sets forth the breakdown of our financial indebtedness as of the dates indicated:

	As of December 31, 2019 RMB'000	As of December 31, 2020 RMB'000	As of June 30, 2021 RMB'000	As of [August 31], 2021 RMB'000
Interest-bearing bank and other borrowings	26,466	33,959	18,553	16,259
Lease liabilities	7,344	12,936	11,393	24,903
Convertible redeemable preferred shares	974,535	2,167,121	2,504,976	2,456,979
Convertible loans	36,465	-	-	-
Derivative financial instruments	1,569	36,472	-	-
	<u>1,046,379</u>	<u>2,250,488</u>	<u>2,534,922</u>	<u>2,498,141</u>
Total	<u>1,046,379</u>	<u>2,250,488</u>	<u>2,534,922</u>	<u>2,498,141</u>

As of the Latest Practicable Date, we had unutilized banking facilities of RMB27.0 million. See headed, “NET CURRENT ASSETS/LIABILITIES – Interest-bearing bank and other borrowings” and “NET CURRENT ASSETS/LIABILITIES – Lease Liabilities” of this document for further details in relation to our interest-bearing bank and other borrowings and lease liabilities in the Track Record Period.

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CAPITAL EXPENDITURES

We regularly make capital expenditures to expand our operations, upgrade our facilities and increase our operating efficiency. The table below sets forth our capital expenditures for the periods indicated:

	For the year		For the six months	
	ended December 31,		ended June 30,	
	2019	2020	2020	2021
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Purchases of property, plant and equipment	1,080	2,571	264	2,773
Additions to intangible assets	41,396	150,912	145,840	72
	<u>42,476</u>	<u>153,483</u>	<u>146,104</u>	<u>2,845</u>
Total	<u>42,476</u>	<u>153,483</u>	<u>146,104</u>	<u>2,845</u>

We expect to incur capital expenditures in 2021 primarily for develop our R&D and manufacturing facilities in both China and the U.S., and potential office and site expansion and upgrade in China and the U.S. For details, see “Future Plans and Use of [REDACTED].” We expect to finance such capital expenditures through a combination of operating cash flows, net [REDACTED] from the [REDACTED] and bank and other borrowings. We may adjust our capital expenditures for any given period according to our development plans or in light of market conditions and other factors we believe to be appropriate.

CONTRACTUAL OBLIGATIONS

Capital Commitments

As of December 31, 2019, 2020 and June 30, 2021, we did not have any material capital commitments.

CONTINGENT LIABILITIES

As of December 31, 2019, 2020 and June 30, 2021, we did not have any contingent liabilities. We confirm that as of the Latest Practicable Date, there had been no material changes or arrangements to our contingent liabilities.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet transactions.

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KEY FINANCIAL RATIOS

The table below sets forth the key financial ratios of our Group for the periods or as of the dates indicated:

	For the year ended		For the	
	December 31,		six months ended	
	2019	2020	June 30,	2021
			2020	2021
Gross margin ⁽¹⁾	65.7%	57.2%	56.9%	56.1%
				As of
		As of December 31,	As of December 31,	June 30,
		2019	2020	2021
Current ratio ⁽²⁾		86.6%	361.7%	476.0%

Notes:

- (1) Gross margin equals gross profit divided by revenue as of the end the year/period.
- (2) Current ratio equals current assets divided by current liabilities as of the end of the year/period.

Our gross margin decreased from 65.7% for 2019 to 57.2% for 2020, due to changes in the business models and decreases in the average selling prices of our commercialized products. Our gross margin remained stable at 56.9% for the six months ended June 30, 2020 and 56.1% for the six months ended June 30, 2021.

Our current ratio increased significantly from 86.6% as of December 31, 2019 to 361.7% as of December 31, 2020, mainly due to an increase in total current assets of RMB353.1 million as a result of an increases in cash and cash equivalents from new funding. Our current ratio margin increased from 361.7% as of December 31, 2020 to 476.0% as of June 30, 2021, mainly due to an increase in total current assets of RMB89.3 million as a result of an increase in cash and cash equivalents of RMB81.3 million.

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RELATED-PARTY TRANSACTIONS

The below table sets forth transactions between us and our related parties during the Track Record Period.

	For the year ended December 31,		For the six months ended June 30,	
	2019 <i>RMB'000</i>	2020 <i>RMB'000</i>	2020 <i>RMB'000</i>	2021 <i>RMB'000</i>
Purchase of services				
WuXi Biologics (Shanghai) Co., Ltd.	1,905	1,471	631	7,136
WuXi AppTec (Suzhou) Co., Ltd.	–	1,421	–	7,026
Wuxi Biologics (Hong Kong) limited	–	34,560	–	25,844
Hd Biosciences Co., Ltd	–	–	–	25
Rental of office from:				
Qiming U.S. Ventures Management, LLC	684	870	440	416
	<u>2,589</u>	<u>38,322</u>	<u>1,071</u>	<u>40,447</u>
 License granted from related parties				
Wuxi Biologics Ireland Limited	6,209	8,622	8,622	–

The below table sets forth outstanding balances with related parties as of the dates indicated.

	As of December 31,		As of
	2019 <i>RMB'000</i>	2020 <i>RMB'000</i>	June 30, 2021 <i>RMB'000</i>
Amounts due from related parties			
CANbridge Consulting LLC	582	582	–
Dr. Xue	8,965	9,198	–
	<u>9,547</u>	<u>9,780</u>	<u>–</u>
 Amounts due to related parties			
Dr. Xue	168	–	–
Wuxi Biologics (Hong Kong) limited	–	32,191	23,649
Wuxi Biologics Ireland Limited	–	4,894	3,236
	<u>168</u>	<u>37,085</u>	<u>26,885</u>

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Our Directors confirm that all material related party transactions during the Track Record Period were conducted on an arm’s length basis, and would not distort our results of operations over the Track Record Period or make our historical results over the Track Record Period not reflective of our expectations for our future performance. Except for the loan to Mr. James Qun Xue was non-trade in nature for his settlement of taxes arising from the Reorganisation, the amounts due from the related parties were trade in nature. All the balances of amounts due to related parties as at December 31, 2019 and 2020 and June 30, 2021 were trade in nature. Save as those outstanding balances with regard to trade basis transactions, which will be settled based on the agreed terms in the relevant agreements, we have settled the outstanding balances with related parties as of June 30, 2021. Details of our transactions with related parties during the Track Record Period are set out in note 31 to the Accountants’ Report included in Appendix I to this document.

MARKET RISK DISCLOSURE

We are exposed to a variety of financial risks, including currency risk, interest rate risk, credit risk and other price risk, as set out 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 we conduct business may affect our financial condition and results of operations. We seek to limit our exposure to foreign currency risk by minimizing our net foreign currency position. For further details, including relevant sensitivity analysis, please see Note 34 to the Accountants’ Report set out in Appendix I to this document.

Credit Risk

We trade with recognized and creditworthy third parties. It is our policy that counterparties who wish to trade on credit terms are subject to credit verification procedures. In addition, receivable balances are monitored on an ongoing basis and our exposure to bad debts is not significant. There are no significant concentrations of credit risk within our Group as the customer bases of our trade receivables are widely spread.

We are exposed to credit risk in relation to our cash and bank balances, financial assets measured at amortized cost, trade receivables, other receivables and other financial assets. The carrying amounts of each class of the above financial assets represent our maximum exposure to credit risk in relation to financial assets. Our cash and cash equivalents are deposited in high quality financial institutions without significant credit risk. For further details, see Note 34 to the Accountants’ Report set out in Appendix I to this document.

FINANCIAL INFORMATION

Liquidity Risk

In the management of the liquidity risk, we monitor and maintains a level of cash and cash equivalents deemed adequate by our management to finance the operations and mitigate the effects of fluctuations in cash flows. For further details, see Note 34 to the Accountants' Report set out in Appendix I to this document.

DIVIDEND

No dividend has been paid or declared by us during the Track Record Period. You should note that historical dividend distributions are not indicative of our future dividend distribution policy.

We are a holding company incorporated in the Cayman Islands. We may need dividends and other distributions on equity from our PRC subsidiary to satisfy our liquidity requirements. Current PRC regulations permit our PRC subsidiary to pay dividends to us only out of their accumulated after-tax profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiary is required to set aside at least 10% of their respective accumulated after-tax profits each year, if any, to fund certain reserve funds until the total amount set aside reaches 50% of their respective registered capital. Our PRC subsidiary may also allocate a portion of its after-tax profits based on PRC accounting standards to employee welfare and bonus funds at their discretion. These reserves are not distributable as cash dividends. Furthermore, if our PRC subsidiary incurs debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments to us.

We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash 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 Shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. As advised by our Cayman Islands legal advisor, under the Cayman Companies Act, a Cayman Islands company may pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in our Company being unable 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 unless the payment of such a dividend would result in our Company being unable to pay our debts as they fall due in the ordinary course of business. There is no assurance that dividends of any amount will be declared to be distributed in any year.

FINANCIAL INFORMATION

DISTRIBUTABLE RESERVES

As of June 30, 2021, we did not have any distributable reserves.

[REDACTED] EXPENSE

The total [REDACTED] expenses (including [REDACTED]) payable by our Company are estimated to be approximately [REDACTED] (or approximately [REDACTED] million) assuming the [REDACTED] is not exercised and based on an [REDACTED] of [REDACTED] (being the mid-point of our [REDACTED] of [REDACTED] to [REDACTED] per [REDACTED]). These [REDACTED] expenses mainly comprise legal and other professional fees paid and payable to the professional parties, commissions payable to the [REDACTED], and printing and other expenses for their services rendered in relation to the [REDACTED] and the [REDACTED].

In 2019, 2020 and for the six months ended June 30, 2021, [REDACTED] expenses charged to our consolidated statements of profit or loss were HK\$[REDACTED] million, HK\$[REDACTED] million, and HK\$[REDACTED] million, respectively. After June 30, 2021, approximately HK\$[REDACTED] million is expected to be charged to our consolidated statements of profit or loss, and approximately HK\$[REDACTED] million is expected to be charged against 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.

[REDACTED]

FINANCIAL INFORMATION

[REDACTED]

FINANCIAL INFORMATION

[REDACTED]

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that up to the date of this document, there has been no material adverse change in our financial, operational or trading positions or prospects since June 30, 2021, being the end of the period reported on as set out in the Accountants’ Report included in Appendix I to this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors have confirmed that, as of the Latest Practicable Date, there were no circumstances that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

FUTURE PLANS AND USE OF [REDACTED]

FUTURE PLANS

Please see “Business – Our Strategies” for a detailed description of our future plans.

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED] million, after deducting [REDACTED], fees and estimated expenses payable by us in connection with the [REDACTED], assuming no [REDACTED] is exercised and assuming an [REDACTED] of [REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] stated in this document.

We intend to use the net [REDACTED] for the following purposes, subject to changes in light of our evolving business needs and changing market conditions:

- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be allocated to fund the ongoing and future R&D (including planned clinical trials, preparation of registration filings and milestone fees), CMC development and manufacturing process development of our Core Product candidate CAN008, a glycosylation fusion protein being developed for the treatment of glioblastoma (GBM). For more details on the ongoing and further development plans of CAN008, please see “Business – Our Portfolio – Late Stage Drug Products and Candidates – CAN008 CD95-Fc fusion protein for GBM”;
 - i. Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the ongoing and future R&D, including planned clinical trials, preparation of registration filings and milestone fees of CAN008. We dosed the first patient in a first line Phase 2 clinical trial for CAN008 in China in October 2021;
 - ii. Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used to develop our CMC and manufacturing process for CAN008. The facilities under construction in Suzhou will cover the process development and clinical trial materials production in GMP environment for CAN008. The clinical trial materials production can also be transferred to Suzhou facility from current CMO;
- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be allocated to fund our major products and product candidates in our pipeline as follows. For more details on the ongoing and further development plans of our major products and product candidates, please see “Business – Our Portfolio”:
 - i. Approximately [REDACTED]%, or HK\$[REDACTED] million, is expected to fund the ongoing commercialization, post-approval study and milestone fees of Hunterase[®] (CAN101), an ERT for the treatment of mucopolysaccharidosis type 2 (“MPS II” or “Hunter Syndrome”). For more details on the post-approval study plan, “Business – Our Portfolio – Clinical Stage Candidates – Hunterase[®] (CAN101) targeting MPS II/Hunter syndrome”;

FUTURE PLANS AND USE OF [REDACTED]

- ii. Approximately [REDACTED]%, or HK\$[REDACTED] million, is expected to fund the ongoing and future R&D (including ongoing and planned clinical trials in Singapore and China, preparation of registration filings and milestone fees) of CAN106, a humanized monoclonal antibody against complement C5 being developed for the treatment of complement-mediated diseases.
 - o Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the ongoing clinical trials, and future R&D targeting paroxysmal nocturnal hemoglobinuria (PNH);
 - o Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for the future R&D targeting various other complement mediated diseases that are targeted by approved anti-C5 antibodies;
- iii. Approximately [REDACTED]%, or HK\$[REDACTED] million, is expected to fund the ongoing and future R&D (including ongoing and planned clinical trials, preparation of registration filings and milestone fees) of CAN103, a rare disease product candidate targeting GD by producing recombinant GCase with highly exposed mannose for efficient uptake by macrophage and Kupfer cells in Gaucher patients to break down glucocerebrosides (GL1), the lipids that accumulate in patients with GD. There are few effective treatments currently available for GD. We obtained the IND approval for CAN103 from the NMPA in October 2021. We are in preparation of a Phase 1 trial in adult and adolescent GD patients.
- iv. Approximately [REDACTED]%, or HK\$[REDACTED] million, is expected to fund the ongoing and future R&D (including ongoing and planned clinical trials, preparation of registration filings and milestone fees) and future commercial launches (including sales and marketing) of CAN108, an oral, minimally-absorbed agent designed to selectively inhibit apical sodium-dependent bile acid transporter (ASBT) and treat rare cholestatic liver diseases. There are no or very limited effective treatments currently available for such indications. We have started preparation of NDA for ALGS for CAN108 and expect to file a NDA by the end of 2021 in mainland China and Taiwan based on data obtained by Mirum, our collaboration partner, in global studies. For BA, we are supporting the patient recruitment and clinical site management in China for a Phase 2 clinical trial initiated in May 2021 by Mirum, our collaboration partner.

FUTURE PLANS AND USE OF [REDACTED]

- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be allocated to fund ongoing and future R&D (including ongoing and planned clinical trials, preparation of registration filings and milestone fees) of our other products and product candidates in our pipeline. For more details on the ongoing and further development plans of other non-gene therapy products and product candidates, please see “Business – Our Portfolio”:
- Approximately [REDACTED]%, or HK\$[REDACTED] million, is expected to fund the ongoing and future R&D (including ongoing and planned clinical trials, preparation of registration filings and milestone fees) of CAN201, CAN202 and our other gene therapy candidates;

We have a broad pipeline of more than ten product candidates focusing on rare disease and rare oncology diseases, each of which by nature has relatively small affected populations. The percentage of net [REDACTED] allocated for each individual product candidate will consequentially be lower.

The remaining [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be allocated to fund the R&D and other general business purposes as follows:

- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be allocated to develop our R&D and manufacturing facilities in both China and the U.S. for all our products and drug candidates, and potential office and site expansion and upgrade in China and the U.S. The [REDACTED] allocated to the R&D and manufacturing facilities in China under this item refers to the costs associated with the facilities under construction in Suzhou that will be used to develop and manufacture our products and drug candidates other than CAN008. There is no overlap of the use of [REDACTED] for R&D and manufacturing facilities under this item and CMC development and manufacturing of CAN008;
- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be allocated to our other R&D activities including employment costs in both China and the U.S.;
- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be allocated for potential strategic acquisitions, investments, in-licensing or collaborations. We do not have any concrete acquisition target but plan to explore drug candidates in the rare disease and gene therapy area which may be complimentary to our current drug portfolio;
- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for our commercialization activities, including expanding our sales and marketing team; and
- Approximately [REDACTED]%, or HK\$[REDACTED] million, will be used for our working capital and general corporate purposes.

FUTURE PLANS AND USE OF [REDACTED]

If the [REDACTED] is set at [REDACTED] per [REDACTED], being the high end of the indicative [REDACTED], the net [REDACTED] from the [REDACTED] will increase to approximately HK\$[REDACTED] million. If the [REDACTED] is set at HK\$[REDACTED] per [REDACTED], being the low end of the indicative [REDACTED], the net [REDACTED] from the [REDACTED] will decrease to approximately HK\$[REDACTED] million. The above allocation of the net [REDACTED] will be adjusted on a pro rata basis in the event that the [REDACTED] is fixed at a higher or lower level compared to the mid-point of the indicative [REDACTED] stated in this Document.

If the [REDACTED] is exercised in full, the net [REDACTED] that we will receive will be approximately HK\$[REDACTED] million, assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the mid-point of the indicative [REDACTED]). In the event that the [REDACTED] is exercised in full, we intend to apply the additional net [REDACTED] to the above purpose in the proportions stated above.

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 cash generated from operations, 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 financial institutions so long as it is deemed to be in the best interests of our Company. We will issue an appropriate announcement if there is any material change to the above proposed use of [REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

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HOW TO APPLY FOR [REDACTED]

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HOW TO APPLY FOR [REDACTED]

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

[To insert the firm’s letterhead]

ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF CANBRIDGE PHARMACEUTICALS INC., MORGAN STANLEY ASIA LIMITED AND JEFFERIES HONG KONG LIMITED

Introduction

We report on the historical financial information of CANBRIDGE PHARMACEUTICALS INC. (the “Company”) and its subsidiaries (together, the “Group”) set out on pages [I-4] to [I-72], which comprises the consolidated statements of profit or loss, statements of comprehensive income, statements of changes in equity and statements of cash flows of the Group for each of the years ended 31 December 2019 and 2020, and the six months ended 30 June 2021 (the “Relevant Periods”), and the consolidated statements of financial position of the Group and the statements of financial position of the Company as at 31 December 2019 and 2020 and 30 June 2021 and a summary of significant accounting policies and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages [I-4] to [I-72] 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 [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.

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

APPENDIX I**ACCOUNTANTS’ REPORT**

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 31 December 2019 and 2020 and 30 June 2021 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 financial information

We have reviewed the interim comparative financial information of the Group which comprises the consolidated statement of profit or loss, statement of comprehensive income, statement of changes in equity and statement of cash flows of the Group for the six months ended 30 June 2020 and other explanatory information (the “Interim Comparative Financial Information”). The directors of the Company are responsible for the preparation 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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ACCOUNTANTS' REPORT

Report on matters under the Rules Governing the Listing of Securities on the Main Board of the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page [I-4] have been made.

Dividends

We refer to note 11 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 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

[Date]

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION

Preparation of 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 Hong Kong Institute of Certified Public Accountants (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

	<i>Notes</i>	Year ended		Six months ended	
		2019	2020	2020	2021
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
				<i>(unaudited)</i>	
Revenue	5	1,469	12,032	1,944	12,192
Cost of sales		(504)	(5,154)	(838)	(5,353)
Gross profit		965	6,878	1,106	6,839
Other income and gains	5	580	1,359	747	11,052
Selling and distribution expenses		(28,881)	(51,008)	(16,401)	(44,768)
Administrative expenses		(53,719)	(77,716)	(29,337)	(52,928)
Research and development expenses		(55,383)	(109,642)	(35,884)	(274,837)
Fair value changes of convertible redeemable preferred shares	25	(73,694)	(591,385)	(79,043)	(21,848)
Fair value changes of convertible loans	24	(1,584)	1,689	1,689	–
Fair value changes of derivative financial instruments	26	(17)	(20,746)	3,175	34,454
Other expenses		(3,667)	(1,599)	(663)	(609)
Finance costs	7	(2,275)	(3,873)	(2,119)	(1,558)
LOSS BEFORE TAX	6	(217,675)	(846,043)	(156,730)	(344,203)
Income tax expense	10	–	–	–	–
LOSS FOR THE YEAR/PERIOD		<u>(217,675)</u>	<u>(846,043)</u>	<u>(156,730)</u>	<u>(344,203)</u>
Attributable to:					
Owners of the parent		<u>(217,675)</u>	<u>(846,043)</u>	<u>(156,730)</u>	<u>(344,203)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT (EXPRESSED IN RMB PER SHARE)					
Basic	12	<u>(31.77)</u>	<u>(123.34)</u>	<u>(22.88)</u>	<u>(46.79)</u>
Diluted	12	<u>(31.77)</u>	<u>(123.34)</u>	<u>(22.88)</u>	<u>(46.79)</u>

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	Year ended 31		Six months ended	
	December		30 June	
	2019	2020	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(unaudited)</i>	
LOSS FOR THE YEAR/PERIOD	<u>(217,675)</u>	<u>(846,043)</u>	<u>(156,730)</u>	<u>(344,203)</u>
OTHER COMPREHENSIVE INCOME				
Other comprehensive income that may not be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of the Company	<u>(5,309)</u>	<u>29,001</u>	<u>(7,099)</u>	<u>11,113</u>
Net other comprehensive income that may not be reclassified to profit or loss in subsequent periods	<u>(5,309)</u>	<u>29,001</u>	<u>(7,099)</u>	<u>11,113</u>
Other comprehensive income that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations	<u>(8,685)</u>	<u>45,307</u>	<u>(3,935)</u>	<u>7,476</u>
Net other comprehensive income that may be reclassified to profit or loss in subsequent periods	<u>(8,685)</u>	<u>45,307</u>	<u>(3,935)</u>	<u>7,476</u>
OTHER COMPREHENSIVE INCOME FOR THE YEAR/PERIOD, NET OF TAX	<u>(13,994)</u>	<u>74,308</u>	<u>(11,034)</u>	<u>18,589</u>
TOTAL COMPREHENSIVE INCOME FOR THE YEAR/PERIOD	<u>(231,669)</u>	<u>(771,735)</u>	<u>(167,764)</u>	<u>(325,614)</u>
Attributable to:				
Owners of the parent	<u>(231,669)</u>	<u>(771,735)</u>	<u>(167,764)</u>	<u>(325,614)</u>

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	<i>Notes</i>	As at 31 December 2019 <i>RMB’000</i>	2020 <i>RMB’000</i>	As at 30 June 2021 <i>RMB’000</i>
NON-CURRENT ASSETS				
Property, plant and equipment	<i>13</i>	2,881	4,026	5,846
Right-of-use assets	<i>14</i>	5,981	11,544	10,243
Intangible assets	<i>15</i>	41,783	179,743	54,850
		<u>50,645</u>	<u>195,313</u>	<u>70,939</u>
CURRENT ASSETS				
Inventories	<i>16</i>	1,447	553	1,269
Trade receivables	<i>17</i>	593	7,040	7,128
Prepayments, other receivables and other assets	<i>18</i>	21,992	22,648	29,935
Cash and cash equivalents	<i>20</i>	13,873	360,804	442,100
		<u>37,905</u>	<u>391,045</u>	<u>480,432</u>
CURRENT LIABILITIES				
Trade payables	<i>21</i>	6,576	46,713	42,108
Other payables and accruals	<i>22</i>	24,634	33,557	39,038
Interest-bearing bank and other borrowings	<i>23</i>	9,596	22,314	14,066
Lease liabilities	<i>14</i>	2,943	5,519	5,713
		<u>43,749</u>	<u>108,103</u>	<u>100,925</u>
NET CURRENT ASSETS/(LIABILITIES)				
		<u>(5,844)</u>	<u>282,942</u>	<u>379,507</u>
TOTAL ASSETS LESS CURRENT LIABILITIES				
		<u>44,801</u>	<u>478,255</u>	<u>450,446</u>
NON-CURRENT LIABILITIES				
Convertible redeemable preferred shares	<i>25</i>	974,535	2,167,121	2,504,976
Convertible loans	<i>24</i>	36,465	–	–
Interest-bearing bank and other borrowings	<i>23</i>	16,870	11,645	4,487
Lease liabilities	<i>14</i>	4,401	7,417	5,680
Other non-current liabilities		1,607	1,456	101
Derivative financial instruments	<i>26</i>	1,569	36,472	–
		<u>1,035,447</u>	<u>2,224,111</u>	<u>2,515,244</u>
Net liabilities				
		<u>(990,646)</u>	<u>(1,745,856)</u>	<u>(2,064,798)</u>
EQUITY				
Equity attributable to owners of the parent				
Share capital	<i>27</i>	5	5	5
Reserves	<i>28</i>	(990,651)	(1,745,861)	(2,064,803)
		<u>(990,646)</u>	<u>(1,745,856)</u>	<u>(2,064,798)</u>
Total equity				
		<u>(990,646)</u>	<u>(1,745,856)</u>	<u>(2,064,798)</u>

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

Year ended 31 December 2019

	Attributable to owners of the parent					Total equity RMB'000
	Share capital RMB'000 (note II 27)	Contributed surplus RMB'000 (note II 28(a))	Share-based payment reserve RMB'000 (note II 30)	Accumulated losses RMB'000	Exchange fluctuation reserve RMB'000 (note II 28(c))	
At 1 January 2019	5	9,581	16,804	(786,406)	(15,651)	(775,667)
Loss for the year	-	-	-	(217,675)	-	(217,675)
Exchange differences	-	-	-	-	(13,994)	(13,994)
Total comprehensive income for the year	-	-	-	(217,675)	(13,994)	(231,669)
Share-based payments (note II 30)	-	-	16,690	-	-	16,690
At 31 December 2019	<u>5</u>	<u>9,581*</u>	<u>33,494*</u>	<u>(1,004,081)*</u>	<u>(29,645)*</u>	<u>(990,646)</u>

Year ended 31 December 2020

	Attributable to owners of the parent					Total equity RMB'000	
	Share capital RMB'000 (note II 27)	Contributed surplus RMB'000 (note II 28(a))	Capital reserve RMB'000 (note II 28(b))	Share-based payment reserve RMB'000 (note II 30)	Accumulated losses RMB'000		Exchange fluctuation reserve RMB'000 (note II 28(c))
At 1 January 2020	5	9,581	-	33,494	(1,004,081)	(29,645)	(990,646)
Loss for the year	-	-	-	-	(846,043)	-	(846,043)
Exchange differences	-	-	-	-	-	74,308	74,308
Total comprehensive income for the year	-	-	-	-	(846,043)	74,308	(771,735)
Issue of shares	-	-	16,783	(14,913)	-	-	1,870
Share-based payments (note II 30)	-	-	-	14,655	-	-	14,655
At 31 December 2020	<u>5</u>	<u>9,581*</u>	<u>16,783*</u>	<u>33,236*</u>	<u>(1,850,124)*</u>	<u>44,663*</u>	<u>(1,745,856)</u>

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Six months ended 30 June 2021

	Attributable to owners of the parent						Total equity RMB’000
	Share capital RMB’000 (note II 27)	Contributed surplus RMB’000 (note II 28 (a))	Capital reserve RMB’000 (note II 28 (b))	Share-based	Accumulated losses RMB’000	Exchange fluctuation reserve RMB’000 (note II 28(c))	
				payment reserve RMB’000 (note II 30)			
At 1 January 2021	5	9,581	16,783	33,236	(1,850,124)	44,663	(1,745,856)
Loss for the period	-	-	-	-	(344,203)	-	(344,203)
Exchange differences	-	-	-	-	-	18,589	18,589
Total comprehensive income for the period	-	-	-	-	(344,203)	18,589	(325,614)
Share-based payments (note II 30)	-	-	-	6,672	-	-	6,672
At 30 June 2021	<u>5</u>	<u>9,581*</u>	<u>16,783*</u>	<u>39,908*</u>	<u>(2,194,327)*</u>	<u>63,252*</u>	<u>(2,064,798)</u>

Six months ended 30 June 2020

	Attributable to owners of the parent						Total equity RMB’000
	Share capital RMB’000 (note II 27)	Contributed surplus RMB’000 (note II 28(a))	Capital reserve RMB’000 (note II 30)	Share-based	Accumulated losses RMB’000	Exchange fluctuation reserve RMB’000 (note II 28)	
				payment reserve RMB’000 (note II 30)			
At 1 January 2020	5	9,581	33,494	(1,004,081)	(29,645)	(990,646)	
Loss for the period (unaudited)	-	-	-	(156,730)	-	(156,730)	
Exchange differences (unaudited)	-	-	-	-	(11,034)	(11,034)	
Total comprehensive income for the period (unaudited)	-	-	-	(156,730)	(11,034)	(167,764)	
Share-based payments (note II 30) (unaudited)	-	-	8,280	-	-	8,280	
At 30 June 2020 (unaudited)	<u>5</u>	<u>9,581*</u>	<u>41,774</u>	<u>(1,160,811)</u>	<u>(40,679)</u>	<u>(1,150,130)</u>	

* These reserve accounts comprise the consolidated reserves of RMB(990,651,000), RMB(1,745,861,000) and RMB(2,064,803,000) in the consolidated statements of financial position as at 31 December 2019 and 2020 and 30 June 2021, respectively.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

	Notes	Year ended		Six months	
		31 December 2019 RMB’000	2020 RMB’000	ended 30 June 2020 RMB’000 (unaudited)	2021 RMB’000
CASH FLOWS FROM OPERATING ACTIVITIES					
Loss before tax		(217,675)	(846,043)	(156,730)	(344,203)
Adjustments for:					
Finance costs	7	2,275	3,873	2,119	1,558
Foreign exchange differences, net	6	(247)	470	431	608
Interest income	5	(120)	(964)	(454)	(1,124)
Interests received from financial assets measured at amortised cost	5	(40)	–	–	–
Gain on disposal of an intangible asset	5	–	–	–	(9,727)
Depreciation of property, plant and equipment	6	1,277	1,426	674	953
Amortisation of intangible assets	6	13	12,951	2,368	3,775
Depreciation of right-of-use assets	6	2,305	3,462	1,393	2,573
Provision for impairment of other receivables	6	163	–	–	–
Fair value changes of convertible redeemable preferred shares	6	73,694	591,385	79,043	21,848
Fair value changes of convertible loans	6	1,584	(1,689)	(1,689)	–
Fair value changes of derivative financial instruments	6	17	20,746	(3,175)	(34,454)
Share-based payment expenses	30	16,690	14,655	8,280	6,672
Write-down of inventories to net realisable value	6	3,504	1,117	–	–
		<u>(116,560)</u>	<u>(198,611)</u>	<u>(67,740)</u>	<u>(351,521)</u>
(Increase)/decrease in inventories		(3,020)	66	(71)	(716)
Increase in trade receivables		(193)	(6,603)	(365)	(88)
(Increase)/decrease in prepayments, other receivables and other assets		112	1,806	576	(11,902)
(Decrease)/increase in trade payables		(16,370)	40,587	4,741	(4,605)
Increase/(decrease) in other payables and accruals		9,736	10,143	(7,783)	6,549
Interest received		<u>120</u>	<u>964</u>	<u>454</u>	<u>1,124</u>
Net cash flows used in operating activities		<u>(126,175)</u>	<u>(151,648)</u>	<u>(70,188)</u>	<u>(361,159)</u>
CASH FLOWS FROM INVESTING ACTIVITIES					
Proceeds from disposal of financial assets measured at amortised at cost		12,000	–	–	–
Interest received from financial assets measured at amortised cost	5	40	–	–	–
Proceeds from disposal of property, plant and equipment		16	–	–	–
Proceeds from disposal of an intangible asset		–	–	–	131,426

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	Notes	Year ended		Six months	
		31 December 2019 RMB'000	2020 RMB'000	ended 30 June 2020 RMB'000 (unaudited)	2021 RMB'000
Purchases of financial assets measured at amortised cost		(12,000)	–	–	–
Purchases of items of property, plant and equipment	13	(1,080)	(2,571)	(264)	(2,773)
Additions to intangible assets	15	(41,396)	(150,912)	(145,840)	(72)
Net cash flows from/(used in) investing activities		(42,420)	(153,483)	(146,104)	128,581
CASH FLOWS FROM FINANCING ACTIVITIES					
Proceeds from issue of convertible redeemable preferred shares	25	40,352	665,706	381,341	334,899
Proceeds from issue of convertible loans	24	34,369	–	–	–
Proceeds from issue of derivative financial instruments	26	1,563	15,356	15,356	–
Proceeds from issue of shares		–	985	–	885
Proceeds from bank and other borrowings		26,131	21,530	13,305	–
Repayment of bank and other borrowings		(1,000)	(14,246)	(6,781)	(15,833)
Transaction cost for issuance of convertible redeemable preferred shares	7	(926)	(79)	(39)	–
Payment of [REDACTED]		(148)	(1,172)	(32)	(716)
Interest paid on bank loans		(654)	(2,562)	(1,233)	(807)
Interest paid on convertible loans	24	–	(2,429)	(2,429)	–
Payment of lease liabilities	14	(2,720)	(3,826)	(1,950)	(3,045)
Net cash flows from financing activities		96,967	679,263	397,538	315,383
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS		(71,628)	374,132	181,246	82,805
Cash and cash equivalents at beginning of year/period		85,240	13,873	13,873	360,804
Effect of foreign exchange rate changes, net		261	(27,201)	(470)	(1,509)
CASH AND CASH EQUIVALENTS AT END OF YEAR/PERIOD		<u>13,873</u>	<u>360,804</u>	<u>194,649</u>	<u>442,100</u>
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS					
Cash and cash equivalents	20	<u>13,873</u>	<u>360,804</u>	<u>194,649</u>	<u>442,100</u>

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STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

	<i>Notes</i>	As at 31 December		As at
		2019	2020	30 June
		<i>RMB’000</i>	<i>RMB’000</i>	2021
				<i>RMB’000</i>
NON-CURRENT ASSETS				
Investments in subsidiaries		33,564	48,219	54,891
Total non-current assets		33,564	48,219	54,891
CURRENT ASSETS				
Due from subsidiaries	35(a)	1,050,668	1,402,382	1,592,236
Prepayments, other receivables and other assets		148	3,096	4,272
Cash and cash equivalents	20	–	228,918	360,221
Total current assets		1,050,816	1,634,396	1,956,729
CURRENT LIABILITIES				
Due to subsidiaries		163,150	152,676	152,494
Other payables and accruals		–	4,063	9,986
Total current liabilities		163,150	156,739	162,480
NET CURRENT ASSETS		887,666	1,477,657	1,794,249
TOTAL ASSETS LESS CURRENT LIABILITIES		921,230	1,525,876	1,849,140
NON-CURRENT LIABILITIES				
Convertible redeemable preferred shares	25	974,535	2,167,121	2,504,976
Convertible loans	24	36,465	–	–
Derivative financial instruments	26	1,569	36,472	–
Total non-current liabilities		1,012,569	2,203,593	2,504,976
Net liabilities		(91,339)	(677,717)	(655,836)
EQUITY				
Share capital	27	5	5	5
Reserves	35(b)	(91,344)	(677,722)	(655,841)
Total equity		(91,339)	(677,717)	(655,836)

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II NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE AND GROUP INFORMATION

The Company was incorporated as an exempted company with limited liability in the Cayman Islands on 30 January 2018. The registered office address of the Company is at the office of Ogier Global (Cayman) Limited, of 89 Nexus Way, Camana Bay, Grand Cayman, KY1-9009, Cayman Islands.

The Company is an investment holding company. During the Relevant Periods, the subsidiaries of the Company were principally engaged in the research and development and commercialisation of medical products.

The Company and its subsidiaries now comprising the Group underwent the Reorganisation as set out in the paragraph headed “Reorganisation” in the section headed “History, Reorganization and Corporate Structure” in the Document. Apart from the Reorganisation, the Company has not commenced any business or operation since its incorporation.

As at the date of this report, the Company had direct and indirect interests in its principal 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	
CANbridge Pharmaceuticals Limited (<i>note (a)</i>)	Hong Kong 12 March 2018	US\$10,000	100%	–	Investment holding
CANbridge Biomed Limited (<i>note (a)</i>) (“CANbridge BIOMED”)	Hong Kong 31 March 2014	US\$10,000	–	100%	Research and development and commercialisation of medical products
CANbridge Care Pharma Hong Kong Limited (<i>note (b)</i>) (“CANbridge CARE Pharma”)	Hong Kong 19 June 2018	US\$10,000	–	100%	Research and development and commercialisation of medical products
CANbridge Life Sciences Ltd. (北海康成(北京)医药科技有限公司) (“CANbridge Beijing”)* (<i>note (d)</i>)	People’s Republic of China (the “PRC”)/Mainland China 12 June 2012	RMB306,122,400	–	100%	Research and development and commercialisation of medical products
CANbridge (Shanghai) Life Sciences Ltd. (北海康成(上海)生物科技有限公司)* (<i>note (d)</i>)	PRC/Mainland China 22 June 2016	RMB120,000,000	–	100%	Research and development and commercialisation of medical products
CANbridge Pharmaceuticals, Inc. (“CANbridge US”) (<i>note (a)</i>)	United States of America (“USA”) 1 September 2017	US\$1	–	100%	Research and development and business 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	
CARE Pharma Shanghai Ltd. (诺爱药业(上海)有限公司)* (note (d))	PRC/Mainland China 17 January 2018	US\$10,204,100	–	100%	Research and development
CANbridge Pharma Co., Ltd. (北海康成股份有限公司)* (note (c))	Taiwan 5 October 2019	TW\$ 615,420	–	100%	Research and development and commercialisation of medical products
CANbridge (Suzhou) Bio-Pharma Co., Ltd.	Suzhou 15 April 2021	US\$1,000,000	–	100%	Research and development

* The English names of the companies registered in China represent the best efforts made by management of the Company to translate the Chinese names of the companies as they do not have official English names.

Notes:

- (a) No audited financial statements have been prepared for these entities for the years ended 31 December 2019 and 2020 as these entities were not subject to any statutory audit requirements under the relevant rules and regulations in the jurisdictions of their incorporation.
- (b) The statutory financial statements of the entity for the years ended 31 December 2019 and 2020 were audited by WOS CPA LIMITED (和氏會計師事務所有限公司), certified public accountants registered in Hong Kong.
- (c) The statutory financial statements of the entity for the year ended 31 December 2020 were audited by An-Tek & Co., CPAs, (安德聯合會計師事務所), certified public accountants registered in Taiwan.
- (d) The statutory financial statements of these entities for the years ended 31 December 2019 and 2020 were audited by Grant Thornton International Ltd. (致同會計師事務所(特殊普通合伙)), certified public accountants registered in the PRC.

2.1 BASIS OF PRESENTATION

Pursuant to the Reorganisation, as more fully explained in the paragraph headed “Reorganisation” in the section headed “History, Reorganisation and Corporate Structure” in the Document, the Company became the holding company of the companies now comprising the Group. As the Reorganisation only involved inserting a new holding company at the top of an existing company, the Historical Financial Information for the Relevant Periods has been presented as a continuation of the existing company by applying the principles of merger accounting as if the Reorganisation had been completed at the beginning of the Relevant Periods.

The consolidated statements of profit or loss, statements of comprehensive income, statements of changes in equity and statements of cash flows of the Group for the Relevant Periods include the results and cash flows of all companies now comprising the Group from the earliest date presented or the date of establishment of the companies. The consolidated statements of financial position of the Group as at 31 December 2019 and 2020 and 30 June 2021 have been prepared to present the assets and liabilities of the subsidiaries and/or businesses 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 Reorganisation.

All intra-group transactions and balances have been eliminated on consolidation.

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2.2 BASIS OF PREPARATION

The Historical Financial Information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”) (which include all International Financial Reporting Standards, International Accounting Standards (“IASs”) and Interpretations) issued by the International Accounting Standards Board (“IASB”). All IFRSs effective for the accounting period commencing from 1 January 2021, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the Historical Financial Information consistently throughout the Relevant Periods and the six months ended 30 June 2020.

The Historical Financial Information has been prepared under the historical cost convention, except for certain financial liabilities which have been measured at fair value through profit or loss.

The Historical Financial Information has been prepared on the assumption that the Group will continue as a going concern, which assumes that the Group will be able to meet its obligations and continue its operations for the coming twelve months notwithstanding that as at 30 June 2021, the Group had net liabilities of RMB2,064,798,000 and accumulated losses of RMB2,194,327,000. In the opinion of the directors of the Company, the Group will have the necessary liquid funds to finance its working capital and capital expenditure requirements for the next twelve months after 30 June 2021. This is due to the following considerations:

- (a) The primary causes for the net liabilities and accumulated losses as at 30 June 2021 were the significant fair value changes of the convertible redeemable preferred shares, details of which are included in note 25 to the Historical Financial Information. These fair value changes will not affect the future cash flows of the Group. In addition, in view of the redemption terms of the convertible redeemable preferred shares, the Group is not required to incur any cash outflows to redeem the preferred shares in the next twelve months after 30 June 2021;
- (b) The Group had net current assets of RMB379,507,000 as at 30 June 2021; and
- (c) The Group has performed a working capital forecast for the next twelve months and will have sufficient liquid funds to finance its operations and can operate as a going concern in the foreseeable future.

Basis of consolidation

The Historical Financial Information includes the financial information of the Company and its subsidiaries (collectively referred to as the “Group”) for the Relevant Periods. 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 information of the subsidiaries are prepared for the same Relevant Periods 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.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

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.

If the Group loses control over a subsidiary, it derecognises (i) the assets (including goodwill) and liabilities of the subsidiary, (ii) the carrying amount of any non-controlling interest and (iii) the cumulative translation differences recorded in equity; and recognises (i) the fair value of the consideration received, (ii) the fair value of

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any investment retained and (iii) any resulting surplus or deficit in profit or loss. The Group’s share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits or accumulated losses, as appropriate, on the same basis as would be required if the Group had directly disposed of therelated assets or liabilities.

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 this Historical Financial Information. The Group intends to adopt them, if applicable, when they become effective.

IFRS 17	<i>Insurance Contracts</i> ²
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current</i> ²
Amendments to IFRS 3	<i>Reference to the Conceptual Framework</i> ¹
Amendments to IAS 16	<i>Property, Plant and Equipment: Proceeds before Intended Use</i> ¹
Amendments to IAS 37	<i>Onerous Contracts – Costs of Fulfilling a Contract</i> ¹
<i>Annual Improvements to IFRS Standards 2018–2020</i>	<i>Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16 and IAS 41</i> ¹
Amendments to IFRS 17	<i>Insurance Contracts</i> ^{2, 4}
Amendments to IAS 12	<i>Deferred Tax related to Assets and Liabilities arising from a Single Transaction</i> ²
Amendments to IAS 28 and IFRS 10	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ³
Amendments to IAS 1	<i>Disclosure of Accounting Policies</i> ²
Amendments to IAS 8	<i>Definition of Accounting Estimates</i> ²
Amendment to IFRS 16	<i>Covid-19-Related Rent Concessions</i> ⁵

¹ Effective for annual periods beginning on or after 1 January 2022

² Effective for annual periods beginning on or after 1 January 2023

³ No mandatory effective date yet determined but available for adoption

⁴ As a consequence of the amendments to IFRS 17 issued in June 2020, 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 1 January 2023

⁵ Effective for annual periods beginning on or after 4 April 2021

The Group is in the process of making an assessment of the impact of these new and revised IFRSs upon initial application and has concluded that the adoption of them will not have a material impact on the Group’s financial position and financial performance.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Fair value measurement

The Group measures its financial derivatives 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, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

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All assets and liabilities for which fair value is measured or disclosed in the Historical Financial Information 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 inventories, deferred tax assets and 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 the statement of 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 the statement of 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 the statement of 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:

Electronic equipment	32%
Furniture and fixtures	19%
Motor vehicles	24%
Leasehold improvements	Over the shorter of the lease terms and 20%

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 each financial year end.

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 the statement of 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 property, plant and equipment under construction, which are stated at cost less any impairment losses, and are not depreciated. Cost comprises the direct costs of construction and capitalised borrowing costs on related borrowed funds during the period of construction. Construction in progress is reclassified to the appropriate category of property, 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 amortised 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 each financial year end.

Intangible assets not yet available for use are tested for impairment annually either individually or at the cash-generating unit level. Such intangible assets are not amortised.

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Patents and licences

Purchased patents and licences are stated at cost less any impairment losses and are amortised on the straight-line basis over their estimated useful lives of 10 years. When estimating the useful lives of the purchased patents and licences, the Company takes into account factors including the duration of the patents or licences, the anticipated duration of sales of product after patent expiration, as well as the useful lives of similar assets in the marketplace.

Research and development costs

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.

Deferred development costs are stated at cost less any impairment losses and are amortised using the straight-line basis over the commercial lives of the underlying products not exceeding ten years, commencing from the date when the products are put into commercial production.

Software

Software is stated at cost less any impairment losses and is amortised on the straight-line basis over the estimated useful life of 10 years. The estimated useful life of software is determined by considering the period of the economic benefits to the Group as well as by referring to the industry practice.

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.

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases. 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 (that is 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. 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:

Categories	Estimated useful lives
Leasehold office	1.2 to 8 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.

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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.

(c) Short-term leases

The Group applies the short-term lease recognition exemption to its short-term leases of equipment (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).

Lease payments on short-term leases 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, fair value through other comprehensive income, and fair value through profit or loss.

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 accordance with the policies set out for “Revenue recognition” below.

In order for a financial asset to be classified and measured at amortised 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 the statement of profit or loss when the asset is derecognised, modified or impaired.

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Financial assets at fair value through other comprehensive income (debt instruments)

For debt investments at fair value through other comprehensive income, interest income, foreign exchange revaluation and impairment losses or reversals are recognised in the statement of profit or loss and computed in the same manner as for financial assets measured at amortised cost. The remaining fair value changes are recognised in other comprehensive income. Upon derecognition, the cumulative fair value change recognised in other comprehensive income is recycled to the statement of profit or loss.

Financial assets designated at fair value through other comprehensive income (equity investments)

Upon initial recognition, the Group can elect to classify irrevocably its equity investments as equity investments designated at fair value through other comprehensive income when they meet the definition of equity under IAS 32 *Financial Instruments: Presentation* and are not held for trading. The classification is determined on an instrument-by-instrument basis.

Gains and losses on these financial assets are never recycled to the statement of profit or loss. Dividends are recognised as other income in the statement of profit or loss when the right of payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably, except when the Group benefits from such proceeds as a recovery of part of the cost of the financial asset, in which case such gains are recorded in other comprehensive income. Equity investments designated at fair value through other comprehensive income are not subject to impairment assessment.

Financial assets at fair value through profit or loss

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 the statement of profit or loss.

This category includes derivative instruments and equity investments which the Group had not irrevocably elected to classify at fair value through other comprehensive income. Dividends on equity investments classified as financial assets at fair value through profit or loss are also recognised as other income in the statement of profit or loss when the right of payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably.

A derivative embedded in a hybrid contract, with a financial liability or non-financial host, is separated from the host and accounted for as a separate derivative if the economic characteristics and risks are not closely related to the host; a separate instrument with the same terms as the embedded derivative would meet the definition of a derivative; and the hybrid contract is not measured at fair value through profit or loss. Embedded derivatives are measured at fair value with changes in fair value recognised in the statement of profit or loss. Reassessment only occurs if there is either a change in the terms of the contract that significantly modifies the cash flows that would otherwise be required or a reclassification of a financial asset out of the fair value through profit or loss category.

A derivative embedded within a hybrid contract containing a financial asset host is not accounted for separately. The financial asset host together with the embedded derivative is required to be classified in its entirety as a financial asset at fair value through profit or loss.

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.

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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 the Group’s 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 30 to 90 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.

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 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.

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Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, 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 and other payables, amounts due to related parties, lease liabilities, convertible redeemable preferred shares, a convertible loan, and loans and borrowings.

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at fair value through profit or loss

Financial liabilities at fair value through profit or loss include financial liabilities held for trading and financial liabilities designated upon initial recognition as at fair value through profit or loss.

Financial liabilities are classified as held for trading if they are incurred for the purpose of repurchasing in the near term. This category also includes derivative financial instruments entered into by the Group that are not designated as hedging instruments in hedge relationships as defined by IFRS 9. Separated embedded derivatives are also classified as held for trading unless they are designated as effective hedging instruments. Gains or losses on liabilities held for trading are recognised in the statement of profit or loss. The net fair value gain or loss recognised in the statement of profit or loss does not include any interest charged on these financial liabilities.

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 the statement of 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. The net fair value gain or loss recognised in the statement of profit or loss does not include any interest charged on these financial liabilities.

Financial liabilities at amortised cost (loans and borrowings)

After initial recognition, interest-bearing loans and borrowings 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 the 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.

Convertible loans

If the conversion option of convertible loans exhibits characteristics of an embedded derivative, it is separated from its liability component. On initial recognition, the derivative component of the convertible loans is measured at fair value and presented as part of derivative financial instruments. Any excess of proceeds over the amount initially recognised as the derivative component is recognised as the liability component. Transaction costs are apportioned between the liability and derivative components of the convertible loans based on the allocation of proceeds to the liability and derivative components when the instruments are initially recognised. The portion of the transaction costs relating to the liability component is recognised initially as part of the liability. The portion relating to the derivative component is recognised immediately in the statement of profit or loss.

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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 the statement of profit or loss.

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.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the weighted average basis and comprises all cost of purchase and other costs incurred in bringing the inventories to their present location and condition. 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 on hand and demand deposits, and short-term highly liquid investments that are readily convertible into known amounts of cash, are subject to an insignificant risk of changes in value, and have a short maturity of generally within three months when acquired, 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 the reporting period 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 the statement of profit or loss.

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.

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 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.

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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 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, 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 reporting period 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 reporting period 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.

Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to the statement of 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 the statement of 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.

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When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognised 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 the Group and the customer at contract inception. When the contract contains a financing component which provides the Group with a significant financial benefit for more than one year, revenue recognised 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.

During the Relevant Periods, revenue of the Group was primarily arising from the sale of medical products to the customers. Revenue is recognised at the point in time when control of the asset is transferred to the customer, generally on delivery of the goods and invoice.

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.

Share-based payments

The Company operates a share option scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. 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 for grants is measured by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is determined by an external valuer using a binomial model, further details of which are given 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 the statement of 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.

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.

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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.

The dilutive effect of outstanding options is reflected as additional share dilution in the computation of earnings per share.

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. These subsidiaries are required to contribute a certain percentage of their payroll costs to the central pension scheme. The contributions are charged to statement of profit or loss as they become payable in accordance with the rules of the central pension scheme.

Borrowing costs

Borrowing costs directly attributable to the acquisition, construction or production of qualifying assets, i.e., assets that necessarily take a substantial period of time to get ready for their intended use or sale, are capitalised as part of the cost of those assets. The capitalisation of such borrowing costs ceases when the assets are substantially ready for their intended use or sale. Investment income earned on the temporary investment of specific borrowings pending their expenditure on qualifying assets is deducted from the borrowing costs capitalised. All other 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.

Dividends

Dividends are recognised as a liability when they are approved by the shareholders in a general meeting. There were no dividends proposed by the Company in respect of the Relevant Periods.

Foreign currencies

The Historical Financial Information is presented in RMB. 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 the statement of 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).

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.

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The functional currencies of the Company and certain overseas subsidiaries are currencies other than RMB. The functional currency of the Company is the United States Dollar (“US\$”). As at the end of each of the Relevant Periods, the assets and liabilities of these entities are translated into RMB at the exchange rates prevailing at the end of each of the Relevant Periods and their statements of profit or loss are translated into RMB at the weighted average exchange rates for the year or period.

The resulting exchange differences are recognised in other comprehensive income and accumulated in the exchange fluctuation reserve. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognised in the statement of profit or loss.

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising on acquisition are treated as assets and liabilities of the foreign operation and translated at the closing rate.

For the purpose of the consolidated statement of cash flows, the cash flows of overseas subsidiaries are translated into RMB at the exchange rates ruling at the dates of the cash flows. Frequently recurring cash flows of overseas subsidiaries which arise throughout the year are translated into RMB at the weighted average exchange rates for the period.

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.

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.

Estimation of the fair value of financial liabilities

Certain financial liabilities are measured at fair value at the end of each of the Relevant Periods as disclosed in note 33 to the Historical Financial Information.

The convertible redeemable preferred shares and warrants issued by the Company are not traded in an active market and the respective fair value is determined by using valuation techniques. The Group applied the Backsolve Approach to determine the underlying equity value of the Company and adopted the option-pricing method and equity allocation model to determine the fair value of the convertible redeemable preferred shares and warrants. Key assumptions such as the timing of the liquidation, redemption or the event as well as the probability of the various scenarios were based on the Group’s best estimates. Further details are included in notes 25, 26 and 33 to the Historical Financial Information.

The convertible loans borrowed by the Company exhibits the characteristics of an embedded derivative and the Group has designated the entire instrument as a financial liability at fair value through profit or loss. As it is not traded in an active market, the Group applied the Backsolve Approach to determine its fair value. Key assumptions such as conversion possibility were based on the Group’s best estimates. Further details are included in notes 24 and 33 to the Historical Financial Information.

Research and development costs

Research and development costs are capitalised in accordance with the accounting policy for research and development costs in note 2.4 to the Historical Financial Information. Determining the amounts to be capitalised requires management to make assumptions regarding the expected future cash generation of the assets, discount rates to be applied and the expected period of benefits.

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Fair value measurement of share-based payments

The Group has set up a share-based payment scheme and granted options to the Company’s directors, the Group’s employees and consultants. The fair value of the options is determined by the binomial option-pricing model at the grant dates for options granted to directors and employees, and at the service provision dates for the consultants. Significant estimates on assumptions, including the underlying equity value, discount rate, expected volatility, and dividend yield, are made by management. Further details are included in note 30 to the Historical Financial Information.

Impairment of non-financial assets (other than goodwill)

The Group assesses whether there are any indicators of impairment for all non-financial assets at the end of each of the Relevant Periods. Intangible assets not yet available for intended use are tested for impairment annually and at other times when such an indicator exists. Other 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.

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).

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. Deferred tax assets are recognised in respect of deductible temporary differences and unused tax losses. As those deferred tax assets can only be recognised to the extent that it is probable that future taxable profits will be available against which the deductible temporary differences and the losses can be utilised, management’s judgement is required to assess the probability of future taxable profits. Management’s assessment is revised as necessary and additional deferred tax assets are recognised if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered. Further details are included in note 10 to the Historical Financial Information.

Provision for inventories

The Group reviews the carrying amounts of the inventories at the end of each of the Relevant Periods to determine whether the inventories are carried at lower of cost and net realisable value. The net realisable value is estimated based on the current market situation and historical experience. Any change in the assumptions would increase or decrease the amount of inventories written down or the related reversals of write-down and affect the Group’s financial position.

Useful lives of intangible assets

The intangible assets are amortised on the straight-line basis by taking into account the residual value. The Group reviews the estimated useful lives on an annual basis to determine the related amortisation charges for its intangible assets. The estimation is based on the legal protection period, with consideration of market condition. Management will increase the amortisation charges when useful lives become shorter than previously estimated.

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4. OPERATING SEGMENT INFORMATION

The Group has only one operating segment, which is the development, production, marketing and sale of medical products.

Geographical information

(a) Revenue from external customers

	Year ended 31 December		Six months ended 30 June	
	2019 RMB’000	2020 RMB’000	2020 RMB’000 (unaudited)	2021 RMB’000
Mainland China	1,061	5,448	117	3,837
Taiwan	–	319	–	5,418
Hong Kong	408	6,265	1,827	2,937
	<u>1,469</u>	<u>12,032</u>	<u>1,944</u>	<u>12,192</u>

The revenue information above is based on the locations of the customers.

(b) Non-current assets

	As at 31 December		As at 30 June
	2019 RMB’000	2020 RMB’000	2021 RMB’000
Hong Kong	42,010	179,681	53,454
Mainland China	8,629	15,613	17,215
Other countries/regions	6	19	270
	<u>50,645</u>	<u>195,313</u>	<u>70,939</u>

The non-current asset information above is based on the locations of the assets and excludes financial instruments and deferred tax assets.

Information about major customers

Revenue from each of the major customers which amounted to 10% or more of the Group’s revenue during the Relevant Periods is set out below:

	Year ended 31 December		Six months ended 30 June	
	2019 RMB’000	2020 RMB’000	2020 RMB’000 (unaudited)	2021 RMB’000
Customer A	1,061	60	52	–
Customer B	408	491	–	420
Customer C	–	2,173	–	253
Customer D	–	854	483	576
Customer E	–	5,324	–	2,162
Customer F	–	84	–	2,138

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5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue, other income and gains is as follows:

	Year ended 31 December		Six months ended 30 June	
	2019 <i>RMB'000</i>	2020 <i>RMB'000</i>	2020 <i>RMB'000</i> <i>(unaudited)</i>	2021 <i>RMB'000</i>
<u>Revenue from contracts with customers</u>				
Sale of medical products	1,469	12,032	1,944	12,192
<i>Timing of revenue recognition</i>				
Goods transferred at a point in time	1,469	12,032	1,944	12,192

The performance obligation is satisfied upon delivery of the goods and invoice and payment is generally due within 30 to 90 days from invoice.

	Year ended 31 December		Six months ended 30 June	
	2019 <i>RMB'000</i>	2020 <i>RMB'000</i>	2020 <i>RMB'000</i> <i>(unaudited)</i>	2021 <i>RMB'000</i>
<u>Other income and gains</u>				
Bank interest income	120	964	454	1,124
Government grants*	173	395	293	201
Interest income from financial assets measured at amortised cost	40	–	–	–
Net gain on disposal of an intangible asset	–	–	–	9,727
Foreign exchange gains, net	247	–	–	–
	580	1,359	747	11,052

* Government grants have been received from the PRC local government authorities to support the subsidiaries’ research and development activities. There are no unfulfilled conditions related to these government grants.

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6. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging/(crediting):

	Notes	Year ended 31 December		Six months ended 30 June	
		2019 RMB’000	2020 RMB’000	2020 RMB’000 (unaudited)	2021 RMB’000
Cost of inventories sold		504	5,154	838	5,353
Research and development costs		34,842	78,507	25,552	273,416
Depreciation of property, plant and equipment	13	1,277	1,426	674	953
Depreciation of right-of-use assets	14	2,305	3,462	1,393	2,573
Amortisation of intangible assets	15	13	12,951	2,368	3,775
Lease payments not included in the measurement of lease liabilities	14	714	940	437	451
Auditor’s remuneration [REDACTED] (excluding auditor’s remuneration)		1,367	3,396	1,763	2,280
Fair value changes of convertible redeemable preferred shares	25	–	7,132	118	6,994
Fair value changes of convertible loans	24	73,694	591,385	79,043	21,848
Fair value changes of derivative financial instruments	26	1,584	(1,689)	(1,689)	–
Employee benefit expense (excluding directors’ and chief executive’s remuneration (note 8)):					
Wages, salaries and welfare		38,702	67,956	26,431	40,223
Pension scheme contributions		1,646	768	162	1,624
Staff welfare expenses		1,507	3,229	327	2,526
Share-based payment expenses		7,653	6,119	4,009	5,246
Foreign exchange difference, net		(247)	470	431	608
Write-down of inventories to net realisable value		3,504	1,117	–	–
Impairment of other receivables		163	–	–	–

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7. FINANCE COSTS

An analysis of finance costs is as follows:

	Year ended 31 December		Six months ended 30 June	
	2019 <i>RMB'000</i>	2020 <i>RMB'000</i>	2020 <i>RMB'000</i> <i>(unaudited)</i>	2021 <i>RMB'000</i>
Transaction cost for issuance of the Company’s convertible redeemable preferred shares	926	79	39	–
Interest on bank loans	983	3,401	1,920	1,328
Interest on lease liabilities (note 14)	366	393	160	230
	<u>2,275</u>	<u>3,873</u>	<u>2,119</u>	<u>1,558</u>

8. DIRECTORS’ AND CHIEF EXECUTIVE’S REMUNERATION

Certain directors received remuneration from the subsidiaries now comprising the Group for their appointment as directors of these subsidiaries. The aggregate amounts of remuneration of the directors and chief executives for the Relevant Periods are set out below:

	Year ended 31 December		Six months ended 30 June	
	2019 <i>RMB'000</i>	2020 <i>RMB'000</i>	2020 <i>RMB'000</i> <i>(unaudited)</i>	2021 <i>RMB'000</i>
Fees	83	545	6	172
Other emoluments:				
Salaries, bonuses, allowances and benefits in kind	3,128	3,624	1,029	1,758
Pension scheme contributions	49	4	4	62
Share-based payment expenses	7,702	5,036	2,551	1,426
	<u>10,879</u>	<u>8,664</u>	<u>3,584</u>	<u>3,246</u>
	<u>10,962</u>	<u>9,209</u>	<u>3,590</u>	<u>3,418</u>

(a) Independent non-executive directors

There were no emoluments payable to the independent non-executive directors during the Relevant Periods.

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(b) Non-executive directors and the chief executive

	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 remuneration <i>RMB'000</i>
Year ended 31 December 2019					
Chief executive:					
James Qun Xue	—	3,128	49	6,634	9,811
Non-executive directors:					
Wei Cao	—	—	—	—	—
Bing Liu	—	—	—	—	—
Xubo Hu	—	—	—	—	—
Ming Li	—	—	—	—	—
Zhijia Yu	—	—	—	—	—
Jin Zhao	—	—	—	—	—
Xun Wang	—	—	—	—	—
James Arthur Geraghty	83	—	—	1,068	1,151
	<u>83</u>	<u>3,128</u>	<u>49</u>	<u>7,702</u>	<u>10,962</u>
Year ended 31 December 2020					
Chief executive:					
James Qun Xue	—	3,624	4	2,722	6,350
Non-executive directors:					
Richard James Gregory	462	—	—	490	952
Bing Liu	—	—	—	—	—
Xubo Hu	—	—	—	—	—
Ming Li	—	—	—	—	—
Zhijia Yu	—	—	—	—	—
Jin Zhao	—	—	—	—	—
Xun Wang	—	—	—	—	—
Lefei Sun	—	—	—	—	—
Derek Paul Di Rocco	—	—	—	—	—
James Arthur Geraghty	83	—	—	1,824	1,907
	<u>545</u>	<u>3,624</u>	<u>4</u>	<u>5,036</u>	<u>9,209</u>

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	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 remuneration <i>RMB'000</i>
Six months ended 30 June 2021					
Chief executive:					
James Qun Xue	–	1,758	62	684	2,504
Non-executive directors:					
Derek Paul Di Rocco	–	–	–	–	–
Kan Chen	–	–	–	–	–
Xiao Le	–	–	–	–	–
Richard James Gregory	133	–	–	130	263
James Arthur Geraghty	39	–	–	612	651
	<u>172</u>	<u>1,758</u>	<u>62</u>	<u>1,426</u>	<u>3,418</u>
Six months ended 30 June 2020 (unaudited)					
Chief executive:					
James Qun Xue	–	1,029	4	1,501	2,534
Non-executive directors:					
Wei Cao	–	–	–	–	–
Bing Liu	–	–	–	–	–
Xubo Hu	–	–	–	–	–
Ming Li	–	–	–	–	–
Zhihua Yu	–	–	–	–	–
Jin Zhao	–	–	–	–	–
Xun Wang	–	–	–	–	–
James Arthur Geraghty	6	–	–	1,050	1,056
	<u>6</u>	<u>1,029</u>	<u>4</u>	<u>2,551</u>	<u>3,590</u>

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9. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees during the Relevant Periods included one director, details of whose remuneration are set out in note 8 to the Historical Financial Information. Details of the remuneration of the remaining four highest paid employees who are neither a director nor chief executive of the Company are as follows:

	Year ended 31 December		Six months ended 30 June	
	2019	2020	2020	2021
	RMB'000	RMB'000	RMB'000	RMB'000
			<i>(unaudited)</i>	
Salaries, bonuses, allowances and benefits in kind	9,260	10,670	3,931	7,195
Pension scheme contributions	103	4	8	166
Share-based payment expenses	1,847	4,361	600	1,120
	11,210	15,035	4,539	8,481
	11,210	15,035	4,539	8,481

The number of non-director and non-chief executive highest paid employees whose remuneration fell within the following bands is as follows:

	Year ended 31 December		Six months ended 30 June	
	2019	2020	2020	2021
			<i>(unaudited)</i>	
HK\$500,001 to HK\$1,000,000	–	–	1	–
HK\$1,000,001 to HK\$1,500,000	–	–	3	–
HK\$1,500,001 to HK\$2,000,000	–	–	–	–
HK\$2,000,001 to HK\$2,500,000	–	–	–	3
HK\$2,500,001 to HK\$3,000,000	1	–	–	–
HK\$3,000,001 to HK\$3,500,000	2	1	–	1
HK\$3,500,001 to HK\$4,000,000	1	2	–	–
HK\$6,000,001 to HK\$6,500,000	–	1	–	–
	4	4	4	4
	4	4	4	4

10. 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

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains. In addition, upon payments of dividends by the Company to its shareholders, no Cayman Islands withholding tax is imposed.

Hong Kong

The subsidiaries incorporated in Hong Kong are subject to income tax at the rate of 16.5% on the estimated assessable profits arising in Hong Kong during the Relevant Periods.

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Taiwan

The subsidiary incorporated in Taiwan is subject to income tax at a rate of 20% on the estimated assessable profits arising in Taiwan during the Relevant Periods.

Mainland China

Pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”), the subsidiaries which operate in Mainland China are subject to CIT at a rate of 25% on the taxable income.

United States of America

The subsidiary incorporated in Delaware, the United States was subject to statutory United States federal corporate income tax at a rate of 21% during the Relevant Periods.

A reconciliation of the tax expense applicable to loss before tax at the statutory rate for the jurisdictions in which the majority of the Group’s subsidiaries are domiciled to the tax expense at the effective tax rate is as follows:

	Year ended 31 December		Six months ended 30 June	
	2019 RMB’000	2020 RMB’000	2020 RMB’000 (unaudited)	2021 RMB’000
Loss before tax	(217,675)	(846,043)	(156,730)	(344,203)
Tax at the statutory tax rate of 25%	(54,419)	(211,511)	(39,183)	(86,051)
Effect of tax rate differences in other jurisdictions	18,919	147,565	4,451	22,359
Expenses not deductible for tax	14,643	28,879	18,707	24,791
Additional deductible allowance for qualified research and development costs	(1,020)	(152)	(92)	(1,401)
Tax losses not recognised	21,877	48,213	16,117	40,302
Utilisation of previously unrecognised tax losses	–	(12,994)	–	–
Tax charge at the Group’s effective tax rate	–	–	–	–

The Group had tax losses of RMB101,781,000, RMB205,245,000, RMB103,999,000 and RMB196,785,000 for the years ended 31 December 2019 and 2020 and the six months ended 30 June 2020 and 2021, respectively, out of which the tax losses in Mainland China are available for a maximum of ten years for offsetting against future taxable profits of the companies in which the losses arose, while the tax losses incurred by overseas entities other than the one in Taiwan can be carried forward permanently to offset against the future taxable profits of these companies in which the losses arose. The tax losses incurred by the entity in Taiwan can be carried forward for a maximum of ten years. The Group’s entities in Mainland China had tax losses of RMB50,091,000, RMB55,151,000, RMB49,770,000 and RMB72,276,000 for the years ended 31 December 2019 and 2020 and the six months ended 30 June 2020 and 2021, respectively. The Group’s overseas entities had tax losses of RMB51,690,000, RMB150,094,000, RMB54,229,000 and RMB124,509,000 for the years ended 31 December 2019 and 2020 and the six months ended 30 June 2020 and 2021, respectively.

Deferred tax assets have not been recognised in respect of these losses as they have arisen in subsidiaries that have been loss-making for some time and it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

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11. DIVIDENDS

No dividends have been declared and paid by the Company in respect of the Relevant Periods.

12. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amounts is based on the loss for the year/period attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares. The calculation of the basic loss per share amounts is based on the loss for the year/period attributable to ordinary equity holders of the parent and the weighted average number of ordinary shares of 6,851,266, 6,859,567, 6,851,266 and 7,356,238 in issue during the years ended 31 December 2019 and 2020 and the six months ended 30 June 2020 and 2021, respectively.

The calculation of the diluted loss per share amounts is based on the loss for the year/period attributable to ordinary equity holders of the parent. The weighted average number of ordinary shares used in the calculation is the number of ordinary shares in issue during the year/period, as used in the basic loss per share calculation, and the weighted average number of ordinary shares assumed to have been issued at no consideration on the deemed exercise or conversion of all dilutive potential ordinary shares into ordinary shares.

No adjustment has been made to the basic loss per share amounts presented for the years ended 31 December 2019 and 2020 and the six months ended 30 June 2020 and 2021 as the impact of the convertible redeemable preferred shares, warrants, convertible loans, share options and restricted share units outstanding had an antidilutive effect on the basic loss per share amounts presented.

13. PROPERTY, PLANT AND EQUIPMENT

31 December 2019	Electronic equipment <i>RMB'000</i>	Furniture and fixtures <i>RMB'000</i>	Motor vehicles <i>RMB'000</i>	Leasehold improvements <i>RMB'000</i>	Total <i>RMB'000</i>
At 1 January 2019					
Cost	899	1,198	469	2,654	5,220
Accumulated depreciation	(292)	(339)	(185)	(1,310)	(2,126)
Net carrying amount	<u>607</u>	<u>859</u>	<u>284</u>	<u>1,344</u>	<u>3,094</u>
At 1 January 2019, net of accumulated depreciation	607	859	284	1,344	3,094
Additions	452	30	–	598	1,080
Disposals	(16)	–	–	–	(16)
Depreciation provided during the year	(316)	(234)	(111)	(616)	(1,277)
At 31 December 2019, net of accumulated depreciation	<u>727</u>	<u>655</u>	<u>173</u>	<u>1,326</u>	<u>2,881</u>
At 31 December 2019:					
Cost	1,335	1,228	469	3,252	6,284
Accumulated depreciation	(608)	(573)	(296)	(1,926)	(3,403)
Net carrying amount	<u>727</u>	<u>655</u>	<u>173</u>	<u>1,326</u>	<u>2,881</u>

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	Electronic equipment RMB’000	Furniture and fixtures RMB’000	Motor vehicles RMB’000	Leasehold improvements RMB’000	Total RMB’000
31 December 2020					
At 1 January 2020					
Cost	1,335	1,228	469	3,252	6,284
Accumulated depreciation	(608)	(573)	(296)	(1,926)	(3,403)
Net carrying amount	<u>727</u>	<u>655</u>	<u>173</u>	<u>1,326</u>	<u>2,881</u>
At 1 January 2020, net of accumulated depreciation	727	655	173	1,326	2,881
Additions	558	155	–	1,858	2,571
Depreciation provided during the year	(386)	(231)	(111)	(698)	(1,426)
At 31 December 2020, net of accumulated depreciation	<u>899</u>	<u>579</u>	<u>62</u>	<u>2,486</u>	<u>4,026</u>
At 31 December 2020:					
Cost	1,893	1,383	469	5,110	8,855
Accumulated depreciation	(994)	(804)	(407)	(2,624)	(4,829)
Net carrying amount	<u>899</u>	<u>579</u>	<u>62</u>	<u>2,486</u>	<u>4,026</u>
30 June 2021					
At 1 January 2021					
Cost	1,893	1,383	469	5,110	8,855
Accumulated depreciation	(994)	(804)	(407)	(2,624)	(4,829)
Net carrying amount	<u>899</u>	<u>579</u>	<u>62</u>	<u>2,486</u>	<u>4,026</u>
At 1 January 2021, net of accumulated depreciation	899	579	62	2,486	4,026
Additions	354	666	–	1,753	2,773
Depreciation provided during the period	(209)	(153)	(38)	(553)	(953)
At 30 June 2021, net of accumulated depreciation	<u>1,044</u>	<u>1,092</u>	<u>24</u>	<u>3,686</u>	<u>5,846</u>
At 30 June 2021:					
Cost	2,247	2,049	469	6,863	11,628
Accumulated depreciation	(1,203)	(957)	(445)	(3,177)	(5,782)
Net carrying amount	<u>1,044</u>	<u>1,092</u>	<u>24</u>	<u>3,686</u>	<u>5,846</u>

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14. LEASES

The Group as a lessee

	As at 31 December		As at 30 June
	2019	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Right-of-use assets			
Non-current portion	<u>5,981</u>	<u>11,544</u>	<u>10,243</u>
Lease liabilities			
Current portion	<u>2,943</u>	<u>5,519</u>	<u>5,713</u>
Non-current portion	<u>4,401</u>	<u>7,417</u>	<u>5,680</u>

The carrying amounts of the Group’s right-of-use assets and lease liabilities, and the movements during the Relevant Periods are as follows:

	Right-of-use assets	Lease liabilities
	Office	
	<i>RMB’000</i>	<i>RMB’000</i>
As at 1 January 2019	7,911	9,323
Additions	375	375
Accretion of interest	–	366
Payments	–	(2,720)
Depreciation charge	<u>(2,305)</u>	<u>–</u>
At 31 December 2019	<u>5,981</u>	<u>7,344</u>
Analysed into:		
Current portion		<u>2,943</u>
Non-current portion		<u>4,401</u>
As at 1 January 2020	5,981	7,344
Additions	9,025	9,025
Accretion of interest	–	393
Payments	–	(3,826)
Depreciation charge	<u>(3,462)</u>	<u>–</u>
As at 31 December 2020	<u>11,544</u>	<u>12,936</u>
Analysed into:		
Current portion		<u>5,519</u>
Non-current portion		<u>7,417</u>

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	Right-of-use assets	Lease liabilities
	Office	
	<i>RMB’000</i>	<i>RMB’000</i>
As at 1 January 2021	11,544	12,936
Additions	1,272	1,272
Accretion of interest	–	230
Payments	–	(3,045)
Depreciation charge	(2,573)	–
	<u>10,243</u>	<u>11,393</u>
As at 30 June 2021	<u>10,243</u>	<u>11,393</u>
Analysed into:		
Current portion		<u>5,713</u>
Non-current portion		<u>5,680</u>

The amounts recognised in profit or loss in relation to leases are as follows:

	Year ended 31 December		Six months ended 30 June	
	2019	2020	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(unaudited)</i>	
Interest on lease liabilities (note II 7)	366	393	160	230
Depreciation charge of right-of-use assets	2,305	3,462	1,393	2,573
Expense relating to short-term leases	714	940	437	451
	<u>3,385</u>	<u>4,795</u>	<u>1,990</u>	<u>3,254</u>

15. INTANGIBLE ASSETS

	Patents and licences	Software	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
As at 31 December 2019			
Cost at 1 January 2019, net of accumulated amortisation	–	12	12
Additions	41,245	151	41,396
Amortisation provided during the year	–	(13)	(13)
Currency translation differences	388	–	388
	<u>41,633</u>	<u>150</u>	<u>41,783</u>
At 31 December 2019	<u>41,633</u>	<u>150</u>	<u>41,783</u>
At 31 December 2019			
Cost	41,633	171	41,804
Accumulated amortisation	–	(21)	(21)
	<u>41,633</u>	<u>150</u>	<u>41,783</u>
Net carrying amount	<u>41,633</u>	<u>150</u>	<u>41,783</u>

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	Patents and licences RMB’000	Software RMB’000	Total RMB’000
As at 31 December 2020			
Cost at 1 January 2020, net of accumulated amortisation	41,633	150	41,783
Additions	150,871	41	150,912
Amortisation provided during the year	(12,934)	(17)	(12,951)
Currency translation differences	(1)	–	(1)
	<u>179,569</u>	<u>174</u>	<u>179,743</u>
At 31 December 2020			
At 31 December 2020			
Cost	190,248	212	190,460
Accumulated amortisation	(10,679)	(38)	(10,717)
	<u>179,569</u>	<u>174</u>	<u>179,743</u>
Net carrying amount			
	<u>179,569</u>	<u>174</u>	<u>179,743</u>
	Patents and licences RMB’000	Software RMB’000	Total RMB’000
As at 30 June 2021			
Cost at 1 January 2021, net of accumulated amortisation	179,569	174	179,743
Additions	–	72	72
Amortisation provided during the period	(3,763)	(12)	(3,775)
Disposal during the period	(121,569)	–	(121,569)
Currency translation differences	379	–	379
	<u>54,616</u>	<u>234</u>	<u>54,850</u>
At 30 June 2021			
At 30 June 2021			
Cost	59,264	284	59,548
Accumulated amortisation	(4,648)	(50)	(4,698)
	<u>54,616</u>	<u>234</u>	<u>54,850</u>
Net carrying amount			
	<u>54,616</u>	<u>234</u>	<u>54,850</u>

Impairment testing of the patents and licences

Management of the Group performed annual impairment testing during the Relevant Periods for the patents and technology know-how which were not yet available for use. For impairment testing, the development cost is allocated to the cash-generating unit (the “CGU”) at the product pipeline level, which is supposed to be able to generate cash flows independently from those of the other products.

As at 31 December 2019, the intangible asset was related to the capitalisation of the licence expense and clinical trial expenses of a rare disease product named Hunterase (CAN101), which has been available for use from 2020.

The recoverable amount of the CGU is determined based on a value-in-use calculation using cash flow projections from financial budgets approved by senior management of the Group covering a 5-year period based on the remaining valid term of the patent related to CAN101.

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Key assumptions used in the calculation are as follows:

CAN101	As at 31 December 2019
Gross margin (% of revenue)	57.4%
The pre-tax discount rate	19.6%

Assumptions were used in the value-in-use calculation of the CGU as at 31 December 2019. The following describes each key assumption on which management has based its cash flow projections to undertake impairment testing of the development cost:

Gross margin – The basis used to determine the value assigned to the budgeted gross margin is the average gross margin expected to achieve since the year when the CAN101 product has been launched.

The pre-tax discount rate used is before tax and reflects specific risks relating to the unit.

The following tables set forth the impact of reasonably possible changes in each of the key assumptions, with all other variables held constant, on impairment testing of the development cost as of the dates indicated.

CAN101	Recoverable amount of the development cost exceeds its carrying amount decrease by As at 31 December 2019 RMB’000
Possible changes of key assumptions	
The gross margin rate decreased by 5.0%	(7,045)
Pre-tax discount rate increased by 1.0%	(3,002)

Considering that there was sufficient headroom based on the assessment, the directors of the Company believe that any reasonably possible change in any of the key assumptions would not cause the carrying amount of the CGU to exceed its recoverable amount.

Details of the headroom measured by excess of the recoverable amounts over the carrying amounts of the CGU as at 31 December 2019 is set out as follows:

CAN101	As at 31 December 2019 RMB’000
Recoverable amounts	51,356
Less: carrying amounts	(41,633)
	<u>9,723</u>

The directors of the Company determined that there was no impairment of its CGU at the end of each of the Relevant Periods.

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16. INVENTORIES

	As at 31 December		As at
	2019	2020	30 June
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Finished goods	1,447	553	1,269
	<u>1,447</u>	<u>553</u>	<u>1,269</u>

17. TRADE RECEIVABLES

	As at 31 December		As at
	2019	2020	30 June
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Trade receivables	593	7,040	7,128
Impairment	—	—	—
	<u>593</u>	<u>7,040</u>	<u>7,128</u>

The Group’s trading terms with its customers are mainly on credit. The credit period is generally 30 to 90 days. The Group seeks to maintain strict control over its outstanding. Overdue balances are reviewed regularly by senior management. In view of the aforementioned and the fact that the Group’s trade receivables relate to certain customers, there is a significant concentration of credit risk. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. Trade receivables are non-interest-bearing.

An ageing analysis of the trade receivables as at the end of each of the Relevant Periods, based on the invoice date and net of loss allowance, is as follows:

	As at 31 December		As at
	2019	2020	30 June
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Within 3 months	593	7,040	4,966
Over 3 months	—	—	2,162
	<u>593</u>	<u>7,040</u>	<u>7,128</u>

The Group has applied the simplified approach to provide for ECLs prescribed by IFRS 9, which permits the use of the lifetime expected loss provision for all trade receivables. To measure the expected credit losses, trade receivables have been grouped based on shared credit risk characteristics and the ageing. Because there was no history of default of trade receivables, the Company assessed that the expected loss rate of trade receivables of the Group was very low. The Company also assessed that there was no significant change in the ECL rates during the Relevant Periods, mainly because there was no change of historical default rates of trade receivables and there were no significant changes in the economic conditions and performance and behaviour of the customers, based on which the ECL rates were determined. The directors of the Company are of the opinion that the ECL in respect of the balances of trade receivables is minimal.

No loss allowance for impairment of trade receivables is provided as at the end of each of the Relevant Periods.

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18. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	<i>Note</i>	As at 31 December		As at
		2019	2020	30 June
		<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Prepayments		278	4,683	19,769
Value-added tax recoverable		11,129	6,777	8,797
Loans to a director	<i>19</i>	8,965	9,198	–
Other receivables		1,620	1,990	1,369
		<u>21,992</u>	<u>22,648</u>	<u>29,935</u>
Current portion		<u>21,992</u>	<u>22,648</u>	<u>29,935</u>

Value-added tax recoverable represented the value-added tax that can be used for future deduction.

The financial assets included in the above balances are non-interest-bearing, unsecured and repayable on demand and relate to receivables for which there was no recent history of default.

The financial assets included in the above balances relate to receivables for which there were no recent history of default. In addition, there is no significant change in the economic factors based on the assessment of the forward looking information. The directors of the Company are of the opinion that the ECL in respect of these balances is minimal.

19. LOANS TO A DIRECTOR

Loans to a director, disclosed pursuant to section 383(1)(d) of the Hong Kong Companies Ordinance and Part 3 of the Companies (Disclosure of information about Benefits of Directors) Regulation, are as follows:

Name	At	Maximum	As at	Maximum	As at	Maximum	As at
	1 January	outstanding	31 December	outstanding	31 December	outstanding	
	2019	during	2019 and	during	2020 and	during	30 June
	<i>RMB'000</i>	the year	2020	the year	2021	the period	2021
		<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
James Qun Xue	8,745	8,965	8,965	9,198	9,198	9,264	–

According to the agreements, such lendings were interest-free and repayable on demand.

The loans to Mr. James Qun Xue were non-trade in nature which were interest-free and repayable on demand according to the agreements. The loans have been fully repaid by Mr. James Qun Xue in February 2021.

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20. CASH AND CASH EQUIVALENTS

Group

	As at 31 December		As at
	2019	2020	30 June
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Cash and bank balances	13,873	99,808	248,297
Time deposits	–	260,996	193,803
	<u>13,873</u>	<u>360,804</u>	<u>442,100</u>
Cash and cash equivalents	<u>13,873</u>	<u>360,804</u>	<u>442,100</u>
Denominated in:			
RMB	351	9,341	19,226
HK\$	56	1,392	1,942
US\$	13,325	349,494	417,426
TW\$	141	577	3,506
	<u>13,873</u>	<u>360,804</u>	<u>442,100</u>
Cash and cash equivalents	<u>13,873</u>	<u>360,804</u>	<u>442,100</u>

Company

	As at 31 December		As at
	2019	2020	30 June
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Cash and bank balances	–	33,171	166,418
Time deposits	–	195,747	193,803
	<u>–</u>	<u>228,918</u>	<u>360,221</u>
Cash and cash equivalents	<u>–</u>	<u>228,918</u>	<u>360,221</u>
Denominated in:			
US\$	–	228,918	360,221
	<u>–</u>	<u>228,918</u>	<u>360,221</u>

The RMB is not freely convertible into other currencies. However, under Mainland China’s Foreign Exchange Control Regulations and Administration of Settlement, Sales and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business. The remittance of funds out of Mainland China is subject to exchange restrictions imposed by the PRC government.

Cash at banks earns interest at floating rates based on daily bank deposit rates. Time deposits are made for varying periods of between seven days and twelve months depending on the immediate cash requirements of the Group and earn interest at the respective short-term time deposit rates. The bank balances and time deposits are deposited with creditworthy banks with no recent history of default.

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21. TRADE PAYABLES

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:

	As at 31 December		As at
	2019	2020	30 June
	RMB’000	RMB’000	2021
			RMB’000
Within 6 months	6,576	46,713	42,108

The trade payables are non-interest-bearing and settled on 30-day terms.

22. OTHER PAYABLES AND ACCRUALS

	As at 31 December		As at
	2019	2020	30 June
	RMB’000	RMB’000	2021
			RMB’000
Taxes other than income tax	710	995	1,115
Payroll payable	12,762	16,562	15,865
Other payables	7,692	13,692	21,192
Due to related parties	168	–	–
Accruals	3,302	2,308	866
	<u>24,634</u>	<u>33,557</u>	<u>39,038</u>

Other payables and accruals are non-interest-bearing and have no fixed terms of settlement.

23. INTEREST-BEARING BANK AND OTHER BORROWINGS

	As at 31 December 2019		
	Effective interest rate	Maturity	RMB’000
Current			
Bank loans-secured (iv)	11.70%~12.82%	2020	<u>9,596</u>
Non-current			
Bank loans-secured (iv)	11.70%~12.82%	2021-2023	<u>16,870</u>
			<u>26,466</u>

	As at 31 December 2020		
	Effective interest rate	Maturity	RMB’000
Current			
Bank loans-unsecured	5.30%	2021	8,500
Bank loans-secured (iv)	10.99%~12.18%	2021	<u>13,814</u>
			<u>22,314</u>

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	As at 31 December 2020		
	Effective interest rate	Maturity	RMB’000
Non-current			
Bank loans-secured (iv)	10.99%~12.18%	2022-2023	11,645
			33,959

	As at 30 June 2021		
	Effective interest rate	Maturity	RMB’000
Current			
Bank loans-secured (iv)	10.99%~12.18%	2021-2022	14,066
Non-current			
Bank loans-secured (iv)	10.99%~12.18%	2022-2023	4,487
			18,553

	As at 31 December		As at 30 June
	2019	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Analysed into:			
Bank loans:			
Within one year or on demand	9,596	22,314	14,066
In the second year	9,895	11,261	4,487
In the third to fifth years, inclusive	6,975	384	–
Beyond five years	–	–	–
	26,466	33,959	18,553

Notes:

- (i) The bank borrowings bear fixed nominal interest rates ranging from 5.30% to 6.50% per annum.
- (ii) As at 31 December 2019 and 2020 and 30 June 2021, except for secured bank borrowings of RMB9,763,000 (US\$1,399,000), RMB10,103,000 (US\$1,548,000) and RMB7,301,000 (US\$1,130,000) respectively, which were denominated in US\$, all the bank borrowings were denominated in RMB.
- (iii) The carrying amounts of the current bank borrowings approximate to their fair value.
- (iv) Pursuant to the agreements entered into by CANbridge BIOMED and CANbridge CARE Pharma, two subsidiaries of the Company, with SPD Silicon Valley Bank (“SSVB”), respectively, CANbridge BIOMED and CANbridge CARE Pharma have charged all of their assets in favour of SSVB by way of first fixed charge and floating charge as security for the payment of the bank borrowings from SSVB. Upon the occurrence of any event of default as defined in the agreements, SSVB may enforce to take possession and control of all the charged assets under the agreements and appoint a receiver over the charged assets, in which event CANbridge BIOMED and CANbridge CARE Pharma may be required to give up possession, ownership and control of their assets. As at 31 December 2019 and 2020 and 30 June 2021, there was no occurrence of any default by CANbridge BIOMED and CANbridge CARE Pharma. The Company also provided guarantee to these two subsidiaries for the bank borrowings from SSVB.

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24. CONVERTIBLE LOANS

Group and Company

	Convertible loans <i>RMB’000</i>
At 1 January 2019	–
Proceeds	34,369
Change in fair value	1,584
Currency translation differences	512
	<hr/>
At 31 December 2019 and 1 January 2020	36,465
	<hr/> <hr/>
Change in fair value	(1,689)
Payments of interests	(2,429)
Currency translation differences	(195)
Converted into convertible redeemable preferred shares (<i>note 25</i>)	(32,152)
	<hr/>
At 31 December 2020 and 1 January 2021	–
	<hr/> <hr/>
At 30 June 2021	–
	<hr/> <hr/>

In July 2019, the Company entered into a convertible loan agreement (the “Convertible Loan Agreement”) with Yuanming Healthcare Holdings Limited (“Yuanming Healthcare”). Yuanming Healthcare provided the Company with a convertible loan amounting to US\$5 million. Whether the loan would bear interest and the interest amount depended on factors including the timing of the Company’s completion of future round financing, the investment amount for such financing, the issue price of future round financing and the subscription price for Yuanming Healthcare to convert such loan to the Company’s convertible redeemable preferred shares. Under the Convertible Loan Agreement, Yuanming Healthcare shall convert its loan to the Company’s convertible redeemable preferred shares and shall enjoy the same rights and obligations as a non-leading investor in the future round financing with respect to the shares acquired through the conversion. The Company made payment of interest of RMB2,429,000 (US\$350,000) in March 2020 when the convertible loan was converted to the convertible redeemable preferred shares in accordance with the terms of the “Convertible Loan Agreement”. The Company has designated the convertible loan from Yuanming Healthcare as a financial liability at fair value through profit or loss.

25. CONVERTIBLE REDEEMABLE PREFERRED SHARES

Group and Company

Convertible redeemable preferred shares (the “Preferred Shares”) issued by the Company are redeemable upon occurrence of certain future events. These instruments can also be converted into ordinary shares of the Company at any time at the option of the holders, or automatically upon occurrence of an [REDACTED] of the Company’s shares, or when agreed by the holders of ordinary shares and the holders of each class of the Preferred Shares.

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Since the date of incorporation, the Company has completed several rounds of financing arrangements by issuing Preferred Shares, details of which are included below:

	Date of issuance	Purchase price US\$/Share	Number of Preferred Shares	Denominated in US\$’000	Total consideration approximately equivalent to RMB’000 (note b)
Series A-1 Preferred Shares	26 November 2014	2.84	1,761,145	5,000	30,611
Series A-2 Preferred Shares	3 December 2015	3.26	2,748,067	8,222	52,385
Series B-1 Preferred Shares	7 February 2017	5.55	3,783,144	21,000	144,255
Series B-1 Preferred Shares	7 May 2017	5.55	522,703	2,901	20,000
Series B-2 Preferred Shares	21 February 2018	8.28	3,624,926	30,000	190,590
Series C-1 Preferred Shares	30 September 2018	10.39	3,283,518	34,100	233,227
Series C-2 Preferred Shares	30 September 2018	9.35	641,940	6,000	41,033
Series C-3 Preferred Shares	31 March 2019	10.39	577,745	6,000	40,352
Series C-4 Preferred Shares (note a)	10 March 2020	10.39	481,232	5,000	34,369
Series D-1 Preferred Shares	11 March 2020	11.82	4,754,717	56,201	395,917
Series E Preferred Shares	11 November 2020	14.77	2,914,015	43,040	284,365
Series E (Tranche 2) Preferred Shares	7 May 2021	14.77	1,028,436	15,190	98,246
Series D-3 Preferred Shares (note b)	21 May 2021	11.82	21,824	–	–
Series D-1 (Second Completion) Preferred Shares	24 May 2021	11.82	3,113,409	36,800	236,650

Note a: Pursuant to shareholders’ agreements and the shareholders’ resolution passed on 25 February 2020, Yuanming Healthcare converted the convertible loan into 481,232 shares of the Company’s Series C-4 convertible redeemable preferred shares as disclosed in note 24.

b: In May 2021, China Equities HK Limited exercised its warrants for the issue of 21,824 preferred shares of the Company at nil consideration as disclosed in note 26.

c: Amounts in US\$ were translated into RMB at the exchange rate on the date of issuance.

The key terms of all series of the Preferred Shares are summarised as follows:

Dividend rights

Subject to the Company’s articles of association (the “Articles”), the directors may from time to time declare dividends (including interim dividends) and other distributions on shares (including the ordinary shares and the preferred shares) of the Company in issue and authorise payment of the same out of the funds of the Company lawfully available therefor. The declaration or payment of dividends and other distributions on shares shall obtain the affirmative written consent of the Series A directors, Series B directors, Series C directors, Series D directors and Series E directors. The holders of the Preferred Shares shall be entitled to receive their Pro Rata Share (see definition below) of the dividends as declared by the board of directors of the Company (the “Board”).

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No dividend or other distributions, whether in cash, in property or in shares of the capital of the Company, shall be paid or declared on any other class or series of shares of the Company unless and until the dividend which should be paid to each holder of Series E Preferred Shares is first paid in full to each holder of Series E Preferred Shares.

Each holder of Series D Preferred Shares shall be entitled to receive its Pro Rata Share of the dividends prior and in preference to the holders of ordinary shares, the holders of Series A preferred shares, Series B preferred shares, and Series C preferred shares. After the Series D preferred dividends are paid to each holder of Series D preferred shares in full, the Company shall pay each of the ordinary shareholders, each holder of Series A preferred shares, Series B preferred shares and Series C preferred shares its Pro Rata Share of the dividends.

In the event that the Company shall declare a distribution other than in cash, each of the holders of Preferred Shares shall be entitled to a proportionate share of any such distribution as though such holders of Preferred Shares were holders of the number of ordinary shares into which their Preferred Shares are convertible as of the record date fixed upon the determination of the holders of ordinary shares entitled to receive such distribution. No dividends have been declared by the Company up to the date of this report.

“Pro Rata Share” of a specified quantity of shares for any shareholder means such number of shares which equals the specified quantity of shares multiplied by a fraction equal to (i) the number of ordinary shares then held by the relevant shareholder on an as-converted but otherwise non-diluted basis, divided by (ii) the total number of shares then held by all shareholders (calculated on an as-converted but otherwise non-diluted basis) then outstanding.

Conversion option

Each Preferred Share shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable ordinary shares as is determined by dividing the Preferred Share original issue price by the Preferred Share conversion price in effect at the time of conversion.

Upon either (a) the occurrence of a qualified [REDACTED] by the Company (the “[REDACTED]”); or (b) the date and time, or the occurrence of an event, specified by mutual written consent of the holders of the ordinary shares and Preferred Shares, all outstanding Preferred Shares shall automatically be converted into ordinary shares, at the then effective Preferred Share conversion price; and such shares may not be reissued by the Company.

Liquidation preferences

In the event of any liquidation, dissolution or winding up of the Company, or upon the occurrence of a Deemed Liquidation Event (see definition below) of the Company, whether voluntary or involuntary, all assets and funds of the Company legally available for distribution to the shareholders (after satisfaction of all creditors’ claims and claims that may be preferred by law) shall be distributed to the shareholders of the Company as follows:

Firstly, each holder of the Series E Preferred Shares shall be entitled to receive for each Series E Preferred Share held by such holder, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of ordinary shares, the holders of Series A Preferred Shares, Series B Preferred Shares, Series C Preferred Shares, Series D Preferred Shares and any other class or series of shares by reason of their ownership of such shares, the amount equal to (i) the original issue price plus (ii) such amount as necessary to provide an annual compound interest rate of 5% of the original issue price calculated from the date of payment of the original issue price by such holder to the Group through the date of the holder’s receipt of the Series E Preference Amount (as defined below), plus (iii) all declared but unpaid dividends and distributions on such Series E Preferred Shares (collectively, the “Series E Preference Amount”).

Secondly, after the payment of the aggregate Series E Preference Amount has been made in full, each holder of the Series D Preferred Shares shall be entitled to receive for each Series D Preferred Share held by such holder, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of ordinary shares, the holders of Series A-1 Preferred Shares, Series A-2 Preferred Shares, Series B-1 Preferred Shares, Series B-2 Preferred Shares, Series C Preferred Shares and any other class or series of shares by reason of their ownership of such shares, the amount equal to (i) the original issue price plus (ii) annual compound internal rate of return of 5% of the original issue price calculated from the date of payment of the original issue price by such holder to the Group Companies through the date of the holder’s receipt of the Series D Preference Amount (as defined below), plus (iii) all declared but unpaid dividends and distributions on such Series D Preferred Shares (collectively, the “Series D Preference Amount”).

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Thirdly, after the payment of the aggregate Series E Preference Amount and aggregate Series D Preference Amount has been made in full, the holders of the Series C Preferred Shares shall be entitled to receive for each Series C Preferred Share held by such holder, prior and in preference to the remaining assets and funds of the Company available for distribution to the holders of ordinary shares, the holders of Series A-1 Preferred Shares, Series A-2 Preferred Shares, Series B-1 Preferred Shares, Series B-2 Preferred Shares and any other class or series of shares by reason of their ownership of such shares, the amount equal to (i) such holder’s original issue price plus (ii) annual compound internal rate of return of 5% of the original issue price calculated from the date of payment of original issue price by such holder into the Group through the date of the holder’s receipt of the Series C Preference Amount (as defined below), plus (iii) all declared but unpaid dividends and distributions on such Series C Preferred Shares (collectively, the “Series C Preference Amount”).

Fourthly, after the payment of the aggregate Series E Preference Amount, aggregate Series D Preference Amount and aggregate Series C Preference Amount has been made in full, the holders of the Series B-2 Preferred Shares shall be entitled to receive for each Series B-2 Preferred Share held by such holder, prior and in preference to the remaining assets and funds of the Company available for distribution to the holders of ordinary shares, the holders of Series A-1 Preferred Shares, Series A-2 Preferred Shares, Series B-1 Preferred Shares and any other class or series of shares by reason of their ownership of such shares, the amount equal to (i) such holder’s original issue price plus (ii) annual compound internal rate of return of 5% of the original issue price calculated from the date of payment of original issue price by such holder into the Group through the date of the holder’s receipt of the Series B-2 Preference Amount (as defined below), plus (iii) all declared but unpaid dividends and distributions on such Series B-2 Preferred Shares (collectively, the “Series B-2 Preference Amount”).

Fifthly, after the payment of the aggregate Series E Preference Amount, aggregate Series D Preference Amount, aggregate Series C Preference Amount and aggregate Series B-2 Preference Amount has been made in full, the holders of the Series B-1 Preferred Shares shall be entitled to receive for each Series B-1 Preferred Share held by such holder, prior and in preference to the remaining assets and funds of the Company available for distribution to the holders of ordinary shares, the holders of Series A-1 Preferred Shares, Series A-2 Preferred Shares and any other class or series of shares by reason of their ownership of such shares, the amount equal to (i) such holder’s original issue price plus (ii) annual compound internal rate of return of 5% of the Original Issue Price calculated from the date of payment of the original issue price by such holder to the Group through the date of the holder’s receipt of the Series B-1 Preference Amount (as defined below), plus (iii) all declared but unpaid dividends and distributions on such Series B-1 Preferred Shares (collectively, the “Series B-1 Preference Amount”).

Sixthly, after the payment of the aggregate Series E Preference Amount, aggregate Series D Preference Amount, aggregate Series C Preference Amount, aggregate Series B-2 Preference Amount and aggregate Series B-1 Preference Amount has been made in full, the holders of the Series A-1 Preferred Shares and the Series A-2 Preferred Shares shall be entitled to receive for each Series A-1 Preferred Share or Series A-2 Preferred Share held by such holder, prior and in preference to the remaining assets and funds of the Company available for distribution to the holders of ordinary shares by reason of their ownership of such shares, the amount equal to (i) such holder’s original issue price plus (ii) annual compound internal rate of return of 5% of the original issue price calculated from the date of payment of original issue price by such holder to the Group through the date of the holder’s receipt of the Series A Preference Amount (as defined below), plus (iii) all declared but unpaid dividends and distributions on such Series A-1 Preferred Shares and Series A-2 Preferred Shares (collectively, the “Series A Preference Amount”, together with the Series E Preference Amount Series D Preference Amount, Series C Preference Amount, the Series B-2 Preference Amount and the Series B-1 Preference Amount, the “Investor Preference Amount”).

If the remaining assets and funds thus distributed among the holders of the same series of preferred shares shall be insufficient to permit the payment to such holders of the full Investor Preference Amount, then the entire remaining assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of such class or series of Preferred Shares in proportion to the amount that each such holder is otherwise entitled to receive.

After the payment of the Investor Preference Amount has been made in full, the remaining assets and funds of the Company legally available for distribution shall be distributed among all holders of ordinary shares and preferred shares on a pro rata and as-converted but otherwise non-diluted basis.

“Deemed Liquidation Event” is defined as: (a) any consolidation, amalgamation, scheme of arrangement or merger of any group companies with or into any other person or other reorganisation in which the shareholders or shareholders of such group companies immediately prior to such consolidation, amalgamation, merger, scheme of arrangement or reorganisation own less than fifty percent of such group company’s voting power in the aggregate immediately after such consolidation, merger, amalgamation, scheme of arrangement or reorganisation, or any

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transaction or series of related transactions to which such group company is a party and in which in excess of fifty percent of such group company’s voting power is transferred; (b) a transaction or series of related transactions in which a person, or a group of related persons, acquires from shareholders of the company, shares of the Company representing more than fifty percent of the outstanding voting power of the company; (c) a sale, transfer, lease or other disposition of all or substantially all of the assets of any group company (or any series of related transactions resulting in such sale, transfer, lease or other disposition of all or substantially all of the assets of such Group Company); and (d) the exclusive licensing of all or substantially all of any group company’s intellectual property to a third party.

Redemption feature

At any time upon the occurrence of any of the Redeeming Events (see definition below), upon written request of any holders of any Preferred Shares, the Company is obliged to, either by itself or through its designee, repurchase, at the election of each redeeming shareholder, all or part of the outstanding Preferred Shares held by such redeeming holders.

The redemption price is equal to the higher of: (i) the Preferred Shares’ applicable original issue price plus the annual rate of return on the original issue price at 10% per annum per share (calculated on the basis of 365 days per year, and if less than one year, on the actual number of days) from the original issue date of the Preferred Shares through the date when such redemption price is fully paid; and (ii) the amount of liquidation proceeds that the redeeming shareholder is entitled to receive pursuant to the terms of liquidation preference as if a liquidation event has occurred.

“Redeeming Events” is defined as any of the following events for the respective series of Preferred Shares.

For Series E Preferred Shares and Series D Preferred Shares, the “Redeeming Events” refers to any of the events: (i) if the [REDACTED] is not completed before the third (3rd) year anniversary of the first Series D completion date; or (ii) any other investor requires the Company to redeem any of its shares in accordance with the shareholders agreement; or (iii) a material violation of criminal or other applicable laws by any group companies, the founder or the founder entity, and (A) such group company, founder or founder entity is convicted, or adjudicated or determined to have been in violation, by a governmental entity, or (B) such violation triggers an official investigation by a governmental entity and the investigation is not voluntarily cancelled or terminated by such governmental entity within six (6) months after commencement, and such violation has caused a material adverse effect on the Group as a whole or the founder and is not cured or remedied, if curable or remediable, by such group company, the founder or the founder entity within sixty (60) days of such violation.

For Series C Preferred Shares, the “Redeeming Events” refers to any of the events: (i) if the [REDACTED] is not completed before the third (3rd) year anniversary of the first Series D completion date; or (ii) if the group companies or its their sublicensee have not obtained approval of NMPA for commercial sales of its neratinib product upon the fifth (5th) year anniversary of the first Series C completion date; or (iii) departure of the founder from the Group; or (iv) a material violation of applicable laws by the Group in conducting the restructuring which has caused or will cause a Material Adverse Effect or has materially and adversely affected or will materially and adversely affect the [REDACTED].

For Series A-1 Preferred Shares, Series A-2 Preferred Shares, Series B-1 Preferred Shares or Series B-2 Preferred Shares, the “Redeeming Events” refers to the event when if the [REDACTED] is not completed before 31 December 2023.

The Group does not bifurcate any embedded derivatives from the host instruments and has designated the entire instruments as financial liabilities at fair value through profit or loss. Any directly attributable transaction costs are recognised as finance costs in profit or loss. Subsequent to initial recognition, the fair value change of the Preferred Shares is recognised in profit or loss except for the portion attributable to credit risk change which shall be recognised in other comprehensive income, if any. The directors of the Company considered that there was no material credit risk change during the Relevant Periods.

The convertible redeemable preferred shares were classified as non-current liabilities unless the preferred shareholders demand the Company to redeem the preferred shares within 12 months after the end of each of the Relevant Periods.

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The movements of the convertible redeemable preferred shares are set out below:

	Series A Preferred Shares RMB’000	Series B Preferred Shares RMB’000	Series C Preferred Shares RMB’000	Series D Preferred Shares RMB’000	Series E Preferred Shares RMB’000	Total RMB’000
At 1 January 2019	177,920	385,457	283,207	–	–	846,584
Issue	–	–	40,352	–	–	40,352
Changes in fair value	12,543	42,475	18,676	–	–	73,694
Currency translation differences	2,606	5,644	5,655	–	–	13,905
At 31 December 2019	193,069	433,576	347,890	–	–	974,535
Issue	–	–	–	381,341	284,365	665,706
Converted from convertible loans (note 24)	–	–	32,152	–	–	32,152
Changes in fair value	176,568	250,505	83,042	80,609	661	591,385
Currency translation differences	(12,489)	(28,048)	(24,426)	(28,162)	(3,532)	(96,657)
At 31 December 2020	357,148	656,033	438,658	433,788	281,494	2,167,121
Issue	–	–	–	236,653	98,246	334,899
Converted from exercise of warrants (note 26)	–	–	–	1,659	–	1,659
Changes in fair value	(1,943)	(4,979)	(5,170)	35,622	(1,682)	21,848
Currency translation differences	(3,548)	(6,515)	(4,356)	(3,218)	(2,914)	(20,551)
At 30 June 2021	<u>351,657</u>	<u>644,539</u>	<u>429,132</u>	<u>704,504</u>	<u>375,144</u>	<u>2,504,976</u>

The Group applied the Backsolve Approach method to determine the underlying equity value of the Company and adopted the option-pricing method and equity allocation model to determine the fair value of the convertible redeemable preferred shares. Key assumptions are set out below:

	As at 31 December 2019	2020	As at 30 June 2021
Risk-free interest rate	1.74%	0.16%	0.20%
Lack of marketability discount	9.10%~28.10%	6.67%~29.54%	5.93%~29.06%
Volatility	48.60%	45.02%	45.52%

The Group estimated the risk-free interest rate based on the yield of the United States Government Bond or Hong Kong Bond as of each valuation date with a maturity life equal to the period from the respective appraisal dates to the expected liquidation date. The lack of marketability discount was estimated based on the option-pricing method. Under the option-pricing method, the cost of a put option, which can theoretically hedge the price change before the privately held share can be sold, was considered as a basis to determine the discount for lack of marketability. The volatility was estimated based on historical volatility of comparable companies as of the valuation date. Probability weight under each of the redemption feature and liquidation preferences were based on the Group’s best estimates.

Management considered that fair value changes of the Preferred Shares that are attributable to changes of credit risk of these instruments are not material.

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26. DERIVATIVE FINANCIAL INSTRUMENTS

Group and Company

	Warrants <i>RMB’000</i>
At 1 January 2019	–
Issue	1,563
Changes in fair value	17
Currency translation differences	(11)
	<hr/>
At 31 December 2019	1,569
Issue	15,356
Changes in fair value	20,746
Currency translation differences	(1,199)
	<hr/>
At 31 December 2020	36,472
Converted into convertible redeemable preferred shares	(1,659)
Changes in fair value	(15,132)
Derecognised	(19,322)
Currency translation differences	(359)
	<hr/>
At 30 June 2021	–
	<hr/> <hr/>

The derivative financial instruments represented warrants issued by the Company to the holders who will be entitled to exercise the warrants in exchange for the Company’s Preferred Shares. The warrants are measured at fair value through profit or loss.

On 30 September 2019, the Company entered into agreements with China Equities HK Limited., a wholly-owned subsidiary of SSVB for the issuance of warrants. In accordance with the agreements, China Equities HK Limited would be entitled to subscribe the warrants after the banking facility granted by SSVB were utilised by the Company. As at 31 December 2019 and 2020, the numbers of warrants issued were 45,616 shares, 68,596 shares, respectively. The warrants may be exercised either at US\$10.39 per warrant share for cash or, if the fair market value of the warrant shares exceeds the exercise price and effect a cashless exchange of the warrants for a certain number of warrant shares to be issued according to the formula stipulated in the agreement, in whole or in part, at the discretion of the relevant warrant holder at any time during the 7 years commencing from the date of issuance of the respective warrants. In May 2021, China Equities HK Limited exercised the warrants for the issue of 21,824 preferred shares of the Company at nil consideration.

On 10 March 2020, the Company entered into agreements with Series D-1 Preferred Shares investors for the issuance of warrants. In accordance with the agreements, investors of Series D-1 Preferred Shares would be entitled to subscribe the warrants after the next series preferred shares financing. As at 31 December 2020, the issuance number of warrants was 1,538,482. The warrants may be exercised at an adjusted price per warrant share, in whole or in part, at the discretion of the relevant warrant holder at any time after the 3 months commencing from the next series preferred share financing or twenty-one months commencing from the completion of Series D-1 Preferred Share financing. In May 2021, investors of Series D-1 Preferred Shares agreed to terminate their rights to exercise warrants in writing and the corresponding warrants were derecognised.

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27. SHARE CAPITAL

The Company was incorporated in the Cayman Islands on 30 January 2018 with an initial authorised share capital of US\$1 divided into 10,000 shares with a par value of US\$0.0001 each. On 31 December 2018, as part of the Reorganisation, the authorised share capital was subsequently divided into 6,851,266 Ordinary Shares with a par value of US\$0.0001 each.

	As at 31 December		As at
	2019	2020	30 June
	RMB’000	RMB’000	2021
			RMB’000
Issued and fully paid:			
Ordinary shares of US\$0.0001 each	5	5	5

A summary of movements in the Company’s share capital is as follows:

	Number of shares in issue	Share capital RMB’000
Ordinary shares of US\$0.0001 each at 1 January 2019 and 31 December 2019	6,851,266	5
Share options exercised (Note (a))	504,972	–
	<u>7,356,238</u>	<u>5</u>
Ordinary shares of US\$0.0001 each at 31 December 2020 and 1 January 2021	7,356,238	5
	<u>7,356,238</u>	<u>5</u>

Note:

- (a) The subscription rights attaching to 504,972 share options were exercised at the subscription price (note 30), resulting in the issue of 504,972 shares with a par value of US\$0.0001 each for a total cash consideration of RMB1,870,000. An amount of RMB14,913,000 was transferred from the share-based payments reserve to share premium upon the exercise of the share options.

28. RESERVES

The amounts of the Group’s reserves and the movements therein for the Relevant Periods are presented in the consolidated statements of changes in equity.

(a) Contributed surplus

Contributed surplus represents the excess of the nominal value of the shares of the subsidiaries acquired pursuant to the Reorganisation set out in note 2.1 over the nominal value of the Company’s shares issued in exchange therefor.

(b) Capital reserve

Capital reserve represents the excess of the nominal value of the shares pursuant to the exercise of the share options set out in note 30 over the nominal value of the Company’s shares issued in exchange therefor.

(c) Exchange fluctuation reserve

The exchange fluctuation reserve comprises all foreign exchange differences arising from the translation of the financial statements of companies of which the functional currency is not RMB. The reserve is dealt with in accordance with the accounting policy set out in note 2.4.

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29. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

During the Relevant Periods, the Group had non-cash additions to right-of-use assets and lease liabilities of RMB375,000, RMB9,025,000, RMB1,393,000 and RMB1,272,000 for the years ended 31 December 2019 and 2020 and the six months ended 30 June 2020 and 2021, respectively, in respect of lease arrangements for offices.

The convertible loans amounting to RMB32,152,000 were converted to the convertible redeemable preferred shares in accordance with the term of the “Convertible Loan Agreement” in March 2020.

(b) Changes in liabilities arising from financing activities

	Interest-bearing bank and other borrowings RMB'000	Derivative financial instruments RMB'000	Lease liabilities RMB'000	Convertible loans RMB'000	Convertible redeemable preferred shares RMB'000
At 1 January 2019	1,000	–	9,323	–	846,584
Changes from financing activities	24,477	1,563	(2,720)	34,369	40,352
Change in fair value	–	17	–	1,584	73,694
New lease	–	–	375	–	–
Interest expense	983	–	366	–	–
Currency translation differences	6	(11)	–	512	13,905
At 31 December 2019	26,466	1,569	7,344	36,465	974,535
At 31 December 2019 and 1 January 2020	26,466	1,569	7,344	36,465	974,535
Changes from financing activities	4,722	15,356	(3,826)	(2,429)	665,706
Converted to convertible redeemable preferred shares	–	–	–	(32,152)	32,152
Change in fair value	–	20,746	–	(1,689)	591,385
New lease	–	–	9,025	–	–
Interest expense	3,401	–	393	–	–
Currency translation differences	(630)	(1,199)	–	(195)	(96,657)
At 31 December 2020	33,959	36,472	12,936	–	2,167,121
At 31 December 2020 and 1 January 2021	33,959	36,472	12,936	–	2,167,121
Changes from financing activities	(16,640)	–	(3,045)	–	334,899
Converted to convertible redeemable preferred shares	–	(1,659)	–	–	1,659
Change in fair value	–	(34,454)	–	–	21,848
New lease	–	–	1,272	–	–
Interest expense	1,328	–	230	–	–
Currency translation differences	(94)	(359)	–	–	(20,551)
At 30 June 2021	18,553	–	11,393	–	2,504,976

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(b) Changes in liabilities arising from financing activities

	Interest-bearing bank and other borrowings <i>RMB’000</i>	Derivative financial instruments <i>RMB’000</i>	Lease liabilities <i>RMB’000</i>	Convertible loans <i>RMB’000</i>	Preferred Shares <i>RMB’000</i>
At 31 December 2019 and 1 January 2020	26,466	1,569	7,344	36,465	974,535
Changes from financing activities (Unaudited)	5,291	15,356	(1,950)	(2,429)	380,621
Converted to convertible redeemable preferred shares (Unaudited)	–	–	–	(32,152)	32,152
Change in fair value (Unaudited)	–	(3,175)	–	(1,689)	79,043
Interest expense (Unaudited)	1,920	–	160	–	–
Currency translation differences (Unaudited)	(1,788)	116	–	(195)	18,196
At 30 June 2020 (Unaudited)	31,889	13,866	5,554	–	1,484,547

(c) Total cash outflow for leases

The total cash outflow for leases included in the statements of cash flows is as follows:

	Year ended 31 December		Six months ended 30 June	
	2019	2020	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(unaudited)</i>	
Within operating activities	(714)	(940)	(437)	(451)
Within financing activities	(2,720)	(3,826)	(1,950)	(3,045)
	(3,434)	(4,766)	(2,387)	(3,496)

30. SHARE-BASED PAYMENTS

The Company operates a share-based payment scheme (the “Scheme”) for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. Eligible participants of the Scheme include the Company’s directors, the Group’s employees and consultants.

The 2016 Plan

A share incentive plan (the “2016 Plan”) became effective in April 2016 when the board of directors of CANbridge Beijing approved the 2016 Plan. The maximum aggregate number of shares that may be issued under this plan is 1,250,000 ordinary shares of CANbridge Beijing. The 2016 Plan permits the awards of share options through a limited liability partnership (the “LLP”). The participants will indirectly hold share options of CANbridge Beijing through direct holding of the LLP’s interest. As part of the red-chip restructuring of the Company and its subsidiaries, the New Plan (see definition below) was adopted to replace the 2016 Plan and the shares will be granted to replace the shares of CANbridge Beijing previously granted.

The New Plan

A new share incentive plan (the “New Plan”) became effective on 25 July 2019 when the Board and the shareholders approved the New Plan. The New Plan will continue in effect for a term of ten years unless sooner terminated. The maximum number of shares that may be subject to the awards granted and sold under this New Plan is 2,855,650 shares, which comprises 1,250,000 shares reserved under the New Plan to substitute the shares of CANbridge Beijing previously granted under the 2016 Plan and 1,605,650 additional shares.

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Share options

The share options have vesting terms in schedule from the grant date over 5 years years on the condition that the directors and employees remain in service and fulfil certain performance conditions of individuals.

For those awards, evaluations are made as of each reporting period to assess the likelihood of performance criteria being met. Share-based payment expenses are then adjusted to reflect the revision of original estimates.

The exercise prices and exercise periods of the share options outstanding as at the end of each of the Relevant Periods are as follows:

	Number of share options	Average exercise price per share option RMB
At 1 January 2019	1,356,115	15.30
Granted during the year	1,217,625	37.00
Forfeited during the year	(29,200)	12.79
	<u>2,544,540</u>	
At 31 December 2019	<u>2,544,540</u>	25.49
	Number of share options	Average exercise price per share option RMB
At 1 January 2020	2,544,540	25.49
Granted during the year	464,000	48.34
Forfeited during the year	(406,891)	36.72
Exercised during the year	(504,972)	3.81
	<u>2,096,677</u>	
At 31 December 2020	<u>2,096,677</u>	33.20
	Number of share options	Average exercise price per share option RMB
At 1 January 2021	2,096,677	33.20
Forfeited during the period	(9,050)	33.07
	<u>2,087,627</u>	
At 30 June 2021	<u>2,087,627</u>	33.20

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The exercise prices and exercise periods of the share options outstanding as at the end of each of the Relevant Periods are as follows:

Year ended 31 December 2019

Number of options	Exercise price	Exercise period
5,000	–	2022
245,000	RMB1.00	2016-2025
221,667	RMB1.50	2017-2026
124,000	RMB5.38	2017-2029
51,000	RMB6.22	2017-2027
92,000	RMB12.70	2019-2030
185,334	US\$1.85	2019-2032
1,270,539	US\$5.20	2019-2030
350,000	US\$5.89	2020-2033
<u>2,544,540</u>		

Year ended 31 December 2020

Number of options	Exercise price	Exercise period
5,000	–	2022
85,000	RMB1.00	2016-2025
30,000	RMB1.50	2017-2026
99,725	RMB5.38	2017-2029
50,000	RMB5.44	2020-2033
6,000	RMB6.22	2017-2027
50,250	RMB12.70	2019-2030
102,029	US\$1.85	2019-2032
1,089,673	US\$5.20	2019-2030
350,000	US\$5.89	2020-2033
30,000	US\$7.06	2020-2034
199,000	US\$7.53	2021-2034
<u>2,096,677</u>		

Six months ended 30 June 2021

Number of options	Exercise price	Exercise period
5,000	–	2022
85,000	RMB1.00	2016-2025
30,000	RMB1.50	2017-2026
99,725	RMB5.38	2017-2029
50,000	RMB5.44	2020-2033
6,000	RMB6.22	2017-2027
50,000	RMB12.70	2019-2030
102,029	US\$1.85	2019-2032
1,080,873	US\$5.20	2019-2030
350,000	US\$5.89	2020-2033
30,000	US\$7.06	2020-2034
199,000	US\$7.53	2021-2034
<u>2,087,627</u>		

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Fair value of share options

The fair value of equity-settled share options granted was estimated as at the date of grant using a binomial model, taking into account the terms and conditions upon which the options were granted. The following table lists the key assumptions that the model used.

	As at 31 December 2019	2020	As at 30 June 2021
Expected volatility (%)	53.22-57.24	48.49-56.53	49.09-50.84
Risk-free interest rate (%)	1.76-1.84	0.15-0.89	0.11-1.35
Expected life of options (year)	1.00-13.57	1.0-12.56	0.50-12.94
Weighted average share price (US\$ per share)	5.43	11.85	11.79

The risk-free interest rate was based on the yield of the Hong Kong Bond as of each valuation date. The volatility was estimated based on historical volatility of comparable companies as of the valuation date. The expected life of the options is based on the historical data over the past years and is not necessarily indicative of the exercise patterns that may occur.

The Group recognised share-based payment expenses of RMB16,690,000, RMB14,655,000, RMB8,280, 000 and RMB6,672,000 for the years ended 31 December 2019 and 2020 and the six months ended 30 June 2020 and 2021, respectively.

31. RELATED PARTY TRANSACTIONS

(a) Name and relationship

The directors of the Group are of the view that the following companies are related parties that had transactions or balances with the Group during the Relevant Periods:

Name of related parties	Relationship with the Group
CANbridge Consulting LLC	An entity controlled by a member of key management personnel
Mr. James Xue Qun	Key management personnel of the entity or its parent
Wuxi Biologics (Hong Kong) limited	An entity controlled by one of the Company’s shareholders
Hd Biosciences Co., Ltd.	An entity controlled by one of the Company’s shareholders
Qiming U.S. Ventures Management, LLC	An entity affiliated with one of the Company’s shareholders
WuXi AppTec(Suzhou) Co., Ltd.	An entity controlled by one of the Company’s shareholders
Wuxi Biologics Ireland Limited	An entity controlled by one of the Company’s shareholders
WuXi Biologics (Shanghai) Co., Ltd.	An entity controlled by one of the Company’s shareholders

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(b) Transactions with related parties

The Company had following transactions with related parties during the Relevant Periods:

	Notes	Year ended 31 December		Six months ended 30 June	
		2019 RMB'000	2020 RMB'000	2020 RMB'000 (Unaudited)	2021 RMB'000
Purchase of services					
Wuxi Biologics (Shanghai) Co., Ltd.	(i)	1,905	1,471	631	7,136
Wuxi AppTec (Suzhou) Co., Ltd.	(ii)	–	1,421	–	7,026
Wuxi Biologics (Hong Kong) Limited	(iii)	–	34,560	–	25,844
Hd Biosciences Co., Ltd.		–	–	–	25
Rental of office from:					
Qiming U.S. Ventures Management, LLC		684	870	440	416
Licence granted from related parties:					
Wuxi Biologics Ireland Limited	(iv)	<u>6,209</u>	<u>8,622</u>	<u>8,622</u>	<u>–</u>

Notes:

- (i) Wuxi Biologics (Shanghai) Co., Ltd. provided Contract Development Manufacture Organization (“CDMO”) services to the Group.
- (ii) Wuxi AppTec (Suzhou) Co., Ltd. provided Contract Research Organization (“CRO”) services to the Group.
- (iii) Wuxi Biologics (Hong Kong) Limited provided CDMO services to the Group.
- (iv) CANbridge CARE Pharma entered into licence agreements with Wuxi Biologics Ireland Limited, pursuant to which CANbridge CARE Pharma was granted with certain licence rights and shall bear all costs and expenses to develop the licensed products. The payment arrangement comprised an upfront payment, a milestone payment and royalty payments.

The pricing was determined according to the published prices and conditions similar to those offered to the major customers of the suppliers.

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(c) Outstanding balances with related parties

	<i>Notes</i>	As at 31 December		As at
		2019	2020	30 June
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Amounts due from related parties:				
CANbridge Consulting LLC		582	582	–
Mr. James Qun Xue	(v)	8,965	9,198	–
		<u>9,547</u>	<u>9,780</u>	<u>–</u>
Amounts due to related parties:				
Mr. James Qun Xue		168	–	–
Wuxi Biologics (Hong Kong) limited		–	32,191	23,649
Wuxi Biologics Ireland Limited		–	4,894	3,236
		<u>168</u>	<u>37,085</u>	<u>26,885</u>

Notes:

(v) In 2018, the Company entered into a loan agreement with Mr. James Qun Xue, to lend fund to him for his settlement of taxes arising from the Reorganisation. According to the agreements, such lendings were not secured, interest-free and repayable on demand.

Except for the loan to Mr. James Qun Xue amounting to RMB8,965,000, RMB9,198,000 and nil as at 31 December 2019 and 2020 and 30 June 2021, respectively, which was non-trade in nature as explained in (v) above, the amounts due from the related parties were trade in nature.

All the balances of amounts due to related parties as at 31 December 2019 and 2020 and 30 June 2021 were trade in nature.

(d) Compensation of key management personnel of the Group:

	Year ended 31 December		Six months ended 30 June	
	2019	2020	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(unaudited)</i>	
Short term employee benefits	4,249	6,713	1,609	6,321
Post-employment benefits	49	4	4	205
Share-based payments	6,634	5,145	1,501	1,255
	<u>10,932</u>	<u>11,862</u>	<u>3,114</u>	<u>7,781</u>
Total compensation paid to key management personnel				

Further details of directors’ and the chief executive’s emoluments are included in note 8 to the Historical Financial Information.

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32. 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 are as follows:

31 December 2019

Financial assets

	Financial assets at amortised cost RMB’000
Trade receivables	593
Financial assets included in prepayments, other receivables and other assets	10,585
Cash and cash equivalents	13,873
	<hr/>
	25,051
	<hr/> <hr/>

Financial liabilities

	Financial liabilities at fair value through profit or loss RMB’000	Financial liabilities at amortised cost RMB’000	Total RMB’000
Convertible redeemable preferred shares	974,535	–	974,535
Convertible loans	36,465	–	36,465
Derivative financial instruments	1,569	–	1,569
Trade payables	–	6,576	6,576
Lease liabilities	–	7,344	7,344
Financial liabilities included in other payables and accruals	–	7,860	7,860
Interest-bearing bank and other borrowings	–	26,466	26,466
	<hr/>	<hr/>	<hr/>
	1,012,569	48,246	1,060,815
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

31 December 2020

Financial assets

	Financial assets at amortised cost RMB’000
Trade receivables	7,040
Financial assets included in prepayments, other receivables and other assets	11,188
Cash and cash equivalents	360,804
	<hr/>
	379,032
	<hr/> <hr/>

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Financial liabilities

	Financial liabilities at fair value through profit or loss	Financial liabilities at amortised cost	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Convertible redeemable preferred shares	2,167,121	–	2,167,121
Derivative financial instruments	36,472	–	36,472
Trade payables	–	46,713	46,713
Lease liabilities	–	12,936	12,936
Financial liabilities included in other payables and accruals	–	13,692	13,692
Interest-bearing bank and other borrowings	–	33,959	33,959
	<u>2,203,593</u>	<u>107,300</u>	<u>2,310,893</u>

30 June 2021

Financial assets

	Financial assets at amortised cost
	<i>RMB’000</i>
Trade receivables	7,128
Financial assets included in prepayments, other receivables and other assets	1,369
Cash and cash equivalents	442,100
	<u>450,597</u>

Financial liabilities

	Financial liabilities at fair value through profit or loss	Financial liabilities at amortised cost	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Convertible redeemable preferred shares	2,504,976	–	2,504,976
Trade payables	–	42,108	42,108
Lease liabilities	–	11,393	11,393
Financial liabilities included in other payables and accruals	–	21,192	21,192
Interest-bearing bank and other borrowings	–	18,553	18,553
	<u>2,504,976</u>	<u>93,246</u>	<u>2,598,222</u>

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33. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

Management has assessed that the fair values of cash and cash equivalents, the current portion of interest-bearing bank and other borrowings, trade payables, financial assets included in prepayments, other receivables and other assets and 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 headed by the finance manager is responsible for determining the policies and procedures for the fair value measurement of financial instruments. The finance manager reports directly to the chief financial officer. At the end of each of the Relevant Periods, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The valuation is reviewed and approved by the chief financial officer.

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 following methods and assumptions were used to estimate the fair values:

The fair values of the non-current portion of interest-bearing bank and other borrowings have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities. The changes in fair value as a result of the Group’s own non-performance risk for interest-bearing bank and other borrowings as at the end of each of the Relevant Periods were assessed to be insignificant.

The Group invests in financial products which represent wealth management products issued by banks in Mainland China. The Group has estimated the fair value of these financial products by using a discounted cash flow valuation model based on the market interest rates of instruments with similar terms and risks.

Financial instruments in Level 3

Set out below is a summary of significant unobservable inputs to the valuation of financial instruments together with a quantitative sensitivity analysis as at the end of each of the Relevant Periods:

31 December 2019	Valuation technique	Significant unobservable inputs	Range of inputs	Sensitivity of fair value to the input
Convertible redeemable preferred shares	Backsolve method	Volatility	48.6%	Increase of 1% would result in decrease in fair value by RMB5,239,000; Decrease of 1% would result in increase in fair value by RMB5,059,000.
Convertible loans	Backsolve method	Volatility	48.6%	Increase of 1% would result in decrease in fair value by RMB165,000; Decrease of 1% would result in increase in fair value by RMB158,000.
Derivative financial instruments	Backsolve method	Volatility	48.6%	Increase of 1% would result in increase in fair value by RMB8,000; Decrease of 1% would result in decrease in fair value by RMB9,000.
Convertible redeemable preferred shares	Backsolve method	Probability for [REDACTED]	45%	Increase of 1% would result in increase in fair value by RMB51,000; Decrease of 1% would result in decrease in fair value by RMB51,000.
Convertible loans	Backsolve method	Probability for [REDACTED]	45%	Increase of 1% would result in decrease in fair value by RMB200,000; Decrease of 1% would result in increase in fair value by RMB200,000.
Derivative financial instruments	Backsolve method	Probability for [REDACTED]	45%	Increase of 1% would result in decrease in fair value by nil; Decrease of 1% would result in increase in fair value by nil.

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31 December 2020	Valuation technique	Significant unobservable inputs	Range of inputs	Sensitivity of fair value to the input
Convertible redeemable preferred shares	Backsolve method	Volatility	45.02%	Increase of 1% would result in decrease in fair value by RMB11,546,000; Decrease of 1% would result in increase in fair value by RMB11,691,000.
Derivative financial instruments	Backsolve method	Volatility	45.02%	Increase of 1% would result in decrease in fair value by RMB124,000; Decrease of 1% would result in increase in fair value by RMB142,000.
Convertible redeemable preferred shares	Backsolve method	Probability for [REDACTED]	80%	Increase of 1% would result in decrease in fair value by RMB989,000; Decrease of 1% would result in increase in fair value by RMB989,000.
Derivative financial instruments	Backsolve method	Probability for [REDACTED]	80%	Increase of 1% would result in decrease in fair value by nil; Decrease of 1% would result in increase in fair value by nil.
30 June 2021	Valuation technique	Significant unobservable inputs	Range of inputs	Sensitivity of fair value to the input
Convertible redeemable preferred shares	Backsolve method	Volatility	45.8%	Increase of 1% would result in decrease in fair value by RMB9,745,000; Decrease of 1% would result in increase in fair value by RMB9,821,000.
Convertible redeemable preferred shares	Backsolve method	Probability for [REDACTED]	80%	Increase of 1% would result in decrease in fair value by RMB2,620,000; Decrease of 1% would result in increase in fair value by RMB2,620,000.

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.

Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group’s financial instruments:

Assets measured at fair value

The Group did not have any financial assets measured at fair value as at the end of each of the Relevant Periods.

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Liabilities measured at fair value

As at 31 December 2019

	Fair value measurement using			Total RMB’000
	Quoted prices in active markets (Level 1) RMB’000	Significant observable inputs (Level 2) RMB’000	Significant unobservable inputs (Level 3) RMB’000	
Financial liabilities at fair value through profit or loss:				
Convertible redeemable preferred shares	–	–	974,535	974,535
Convertible loans	–	–	36,465	36,465
Derivative financial instruments	–	–	1,569	1,569
	–	–	1,012,569	1,012,569

As at 31 December 2020

	Fair value measurement using			Total RMB’000
	Quoted prices in active markets (Level 1) RMB’000	Significant observable inputs (Level 2) RMB’000	Significant unobservable inputs (Level 3) RMB’000	
Financial liabilities at fair value through profit or loss:				
Convertible redeemable preferred shares	–	–	2,167,121	2,167,121
Derivative financial instruments	–	–	36,472	36,472
	–	–	2,203,593	2,203,593

As at 30 June 2021

	Fair value measurement using			Total RMB’000
	Quoted prices in active markets (Level 1) RMB’000	Significant observable inputs (Level 2) RMB’000	Significant unobservable inputs (Level 3) RMB’000	
Financial liabilities at fair value through profit or loss:				
Convertible redeemable preferred shares	–	–	2,504,976	2,504,976

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The carrying amounts and fair values of the Group’s financial instruments, other than those with carrying amounts that reasonably approximate to the fair values, are as follows:

	Carrying amounts		
	As at 31 December		As at 30 June
	2019	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
<u>Financial liabilities</u>			
Non-current portion of interest-bearing bank and other borrowings	<u>16,870</u>	<u>11,645</u>	<u>4,487</u>

	Fair values		
	As at 31 December		As at 30 June
	2019	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
<u>Financial liabilities</u>			
Non-current portion of interest-bearing bank and other borrowings	<u>18,106</u>	<u>12,685</u>	<u>5,054</u>

Management has assessed that the fair values of cash and cash equivalents, trade receivables, trade payables, financial assets included in prepayments, other receivables and other assets, financial liabilities included in other payables and accruals, and the current portion of interest-bearing bank and other borrowings approximate to their carrying amounts largely due to the short term maturities of these instruments.

34. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group’s principal financial instruments comprise cash and cash equivalents, trade receivables, financial assets included in prepayments, other receivables and other assets, trade payables, financial liabilities included in other payables and accruals, interest-bearing bank and other borrowings, convertible loans, derivative financial instruments and convertible redeemable 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 and senior management meet periodically to analyse and formulate measures to manage the Group’s exposure to these risks.

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 Group seeks to limit its exposure to foreign currency risk by minimising its net foreign currency position.

The Company and its subsidiaries mainly transacted in foreign currencies. Management considers the Group’s exposure to foreign currency risk is not significant.

Credit risk

The carrying amounts of cash and bank balances, financial assets measured at amortised cost, trade receivables, other receivables and other financial assets represent the Group’s maximum exposure equal to credit risk in relation to the financial assets.

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The Group expects that there is no significant credit risk associated with cash and bank balances since they are substantially held in reputable state-owned banks and other medium or large-sized listed banks. Management does not expect that there will be any significant losses from non-performance by these counterparties.

The Group trades only with recognised and creditworthy third parties. It is the Group’s policy that all customers who wish to trade on credit terms are subject to credit verification procedures. In order to minimise the credit risk, the Group reviews the recoverable amount of each individual trade receivable periodically and management also has monitoring procedures to ensure the follow-up action is taken to recover overdue receivables. In this regard, the directors of the Company consider that the Group’s credit risk is significantly reduced.

The Group also expects that there is no significant credit risk associated with other receivables and other financial assets since the counterparties to these financial assets have no history of default.

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 31 December. The amounts presented are gross carrying amounts for financial assets and the exposure to credit risk for the financial guarantee contracts.

As at 31 December 2019

	12-month ECLs	Lifetime ECLs			Simplified approach	Total
	Stage 1 RMB’000	Stage 2 RMB’000	Stage 3 RMB’000	RMB’000		
Trade receivables*	–	–	–	593	593	
Financial assets included in prepayments, other receivables and other assets – Normal**	10,585	–	–	–	10,585	
Cash and cash equivalents – Not yet past due	13,873	–	–	–	13,873	
	<u>24,458</u>	<u>–</u>	<u>–</u>	<u>593</u>	<u>25,051</u>	

As at 31 December 2020

	12-month ECLs	Lifetime ECLs			Simplified approach	Total
	Stage 1 RMB’000	Stage 2 RMB’000	Stage 3 RMB’000	RMB’000		
Trade receivables*	–	–	–	7,040	7,040	
Financial assets included in prepayments, other receivables and other assets – Normal**	11,188	–	–	–	11,188	
Cash and cash equivalents – Not yet past due	360,804	–	–	–	360,804	
	<u>371,992</u>	<u>–</u>	<u>–</u>	<u>7,040</u>	<u>379,032</u>	

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As at 30 June 2021

	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*	–	–	–		7,128	7,128
Financial assets included in prepayments, other receivables and other assets – Normal**	1,369	–	–		–	1,369
Cash and cash equivalents – Not yet past due	442,100	–	–		–	442,100
	<u>443,469</u>	<u>–</u>	<u>–</u>		<u>7,128</u>	<u>450,597</u>

* For trade receivables to which the Group applies the simplified approach for impairment, information is disclosed in note 17 to the Historical Financial Information.

** The credit quality of amounts due from related parties and the financial assets included in prepayments, other receivables and other assets are 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. Otherwise, the credit quality of the financial assets are considered to be “doubtful”.

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 31 December 2019				Total RMB’000
	On demand RMB’000	Within 1 year RMB’000	1 to 5 years RMB’000	Above 5 years RMB’000	
Trade payables	6,576	–	–	–	6,576
Financial liabilities included in other payables and accruals	7,860	–	–	–	7,860
Interest-bearing bank and other borrowings	2,368	7,228	18,225	–	27,821
Convertible redeemable preferred shares (note a)	–	–	860,817	–	860,817
Convertible loans (note a)	–	2,284	35,039	–	37,323
Derivative financial instruments	–	13,508	–	–	13,508
Lease liabilities	–	2,943	6,018	–	8,961
	<u>16,804</u>	<u>25,963</u>	<u>920,099</u>	<u>–</u>	<u>962,866</u>

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	As at 31 December 2020				
	On demand RMB’000	Within 1 year RMB’000	1 to 5 years RMB’000	Above 5 years RMB’000	Total RMB’000
Trade payables	46,713	–	–	–	46,713
Financial liabilities included in other payables and accruals	13,692	–	–	–	13,692
Interest-bearing bank and other borrowings	11,900	10,414	12,553	–	34,867
Convertible redeemable preferred shares (note a)	–	–	1,662,006	–	1,662,006
Derivative financial instruments	–	171,620	–	–	171,620
Lease liabilities	–	5,519	8,641	–	14,160
	<u>72,305</u>	<u>187,553</u>	<u>1,683,200</u>	<u>–</u>	<u>1,943,058</u>

	As at 30 June 2021				
	On demand RMB’000	Within 1 year RMB’000	1 to 5 years RMB’000	Above 5 years RMB’000	Total RMB’000
Trade payables	42,108	–	–	–	42,108
Financial liabilities included in other payables and accruals	21,192	–	–	–	21,192
Interest-bearing bank and other borrowings	–	14,066	5,989	–	20,055
Convertible redeemable preferred shares (note a)	–	–	1,841,207	–	1,841,207
Lease liabilities	–	5,713	8,205	–	13,918
	<u>63,300</u>	<u>19,779</u>	<u>1,855,401</u>	<u>–</u>	<u>1,938,480</u>

Note:

- (a) The liquidity risk of convertible redeemable preferred shares and convertible loans is the original issue price of the Preferred Shares plus the respective predetermined interest (the “redemption amount”), assuming that there is no consummation of [REDACTED] of the Company’s shares before certain dates as agreed by the holders of ordinary shares and the holders of each class of the Preferred Shares and the holders of the Preferred Shares request the Company to redeem all of the Preferred Shares.

Capital management

The primary objectives of the Group’s capital management are to safeguard the Group’s ability 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 adjust the dividend payment to shareholders, 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 during the Relevant Periods.

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35. FINANCIAL POSITION AND RESERVE MOVEMENTS OF THE COMPANY

(a) The amounts due from subsidiaries

The amounts due from subsidiaries are non-interest bearing, denominated in US\$, repayable on demand and their carrying amount approximate to their fair value.

(b) Reserves

	At 31 December 2019				
	Share capital <i>RMB'000</i>	Share option reserve <i>RMB'000</i>	Accumulated losses <i>RMB'000</i>	Exchange fluctuation reserve <i>RMB'000</i>	Total <i>RMB'000</i>
At 1 January 2019	5	16,804	(41,174)	(3,207)	(27,572)
Loss for the year	–	–	(75,148)	–	(75,148)
Exchange differences	–	–	–	(5,309)	(5,309)
Total comprehensive loss for the year	–	–	(75,148)	(5,309)	(80,457)
Share-based payments	–	16,690	–	–	16,690
At 31 December 2019	<u>5</u>	<u>33,494*</u>	<u>(116,322)*</u>	<u>(8,516)*</u>	<u>(91,339)</u>

	At 31 December 2020					
	Share capital <i>RMB'000</i>	Capital reserve <i>RMB'000</i> <i>(note 28(b))</i>	Share option reserve <i>RMB'000</i>	Accumulated losses <i>RMB'000</i>	Exchange fluctuation reserve <i>RMB'000</i>	Total <i>RMB'000</i>
At 1 January 2020	5	–	33,494	(116,322)	(8,516)	(91,339)
Loss for the year	–	–	–	(631,904)	–	(631,904)
Exchange differences	–	–	–	–	29,001	29,001
Total comprehensive loss for the year	–	–	–	(631,904)	29,001	(602,903)
Issue of shares	–	16,783	(14,913)	–	–	1,870
Share-based payments	–	–	14,655	–	–	14,655
At 31 December 2020	<u>5</u>	<u>16,783*</u>	<u>33,236*</u>	<u>(748,226)*</u>	<u>20,485*</u>	<u>(677,717)</u>

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	At 30 June 2021					Total RMB'000
	Share capital RMB'000	Capital reserve RMB'000 (note 28(b))	Share option reserve RMB'000	Accumulated losses RMB'000	Exchange fluctuation reserve RMB'000	
At 1 January 2021	5	16,783	33,236	(748,226)	20,485	(677,717)
Loss for the period	–	–	–	4,096	–	4,096
Exchange differences	–	–	–	–	11,113	11,113
Total comprehensive loss for the period	–	–	–	4,096	11,113	15,209
Share-based payments	–	–	6,672	–	–	6,672
At 30 June 2021	<u>5</u>	<u>16,783*</u>	<u>39,908*</u>	<u>(744,130)*</u>	<u>31,598*</u>	<u>(655,836)</u>

	At 30 June 2020					Total RMB'000
	Share capital RMB'000	Share option reserve RMB'000	Accumulated losses RMB'000	Exchange fluctuation reserve RMB'000		
At 1 January 2020	5	33,494	(116,322)	(8,516)	(91,339)	
Loss for the period (Unaudited)	–	–	(82,271)	–	(82,271)	
Exchange differences (Unaudited)	–	–	–	(7,099)	(7,099)	
Total comprehensive loss for the period (Unaudited)	–	–	(82,271)	(7,099)	(89,370)	
Share-based payments (Unaudited)	–	8,280	–	–	8,280	
At 30 June 2020 (Unaudited)	<u>5</u>	<u>41,774</u>	<u>(198,593)</u>	<u>(15,615)</u>	<u>(172,429)</u>	

* These reserve accounts comprise the reserves of RMB(91,344,000), RMB(677,722,000) and RMB(655,841,000) as at 31 December 2019 and 2020 and 30 June 2021, respectively, in the statements of financial position of the Company.

36. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company, the Group or any of its subsidiaries in respect of any period subsequent to 30 June 2021.

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

[REDACTED]

APPENDIX III SUMMARY OF THE CONSTITUTION OF OUR COMPANY AND CAYMAN COMPANIES ACT

Set out below is a summary of certain provisions of the Memorandum and Articles of Association of the Company and of certain aspects of the Cayman Companies Act.

The Company was incorporated in the Cayman Islands as an exempted company with limited liability on 30 January 2018 under the Cayman Companies Act. The Company's constitutional documents consist of its Memorandum and Articles of Association.

1. MEMORANDUM OF ASSOCIATION

1.1 The Memorandum provides, *inter alia*, that the liability of members of the Company is limited and that the objects for which the Company is established are unrestricted (and therefore include acting as an investment company), and that the Company shall have and be capable of exercising any and all of the powers at any time or from time to time exercisable by a natural person or body corporate whether as principal, agent, contractor or otherwise and, since the Company is an exempted company, that the Company will not trade in the Cayman Islands with any person, firm or corporation except in furtherance of the business of the Company carried on outside the Cayman Islands.

1.2 By special resolution the Company may alter the Memorandum with respect to any objects, powers or other matters specified in it.

2. ARTICLES OF ASSOCIATION

The Articles were conditionally adopted on [●]. A summary of certain provisions of the Articles is set out below.

2.1 Shares

(a) *Classes of shares*

The share capital of the Company consists of ordinary shares.

(b) *Variation of rights of existing shares or classes of shares*

Subject to the Cayman 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 any class of shares may (unless otherwise provided for by the terms of issue of the shares 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. The provisions of the Articles relating to general meetings shall *mutatis mutandis* apply to every such separate general meeting, provided that the necessary quorum (other than at an adjourned meeting) shall be not less

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than two persons together holding (or, in the case of a shareholder being a corporation, by its duly authorised representative) or representing by proxy not less than one-third in nominal value of the issued shares of that class. Every holder of shares of the class shall be entitled on a poll to one vote for every such share held by him, and any holder of shares of the class present in person or by proxy may demand a poll.

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.

(c) Alteration of capital

The Company may, by an ordinary resolution of its members: (a) increase its share capital by the creation of new shares of such amount as it thinks expedient; (b) consolidate or divide all or any of its share capital into shares of larger or smaller amount than its existing shares; (c) divide its unissued shares into several classes and attach to such shares any preferential, deferred, qualified or special rights, privileges or conditions; (d) subdivide its shares or any of them into shares of an amount smaller than that fixed by the Memorandum; (e) cancel any shares which, at the date of the resolution, have not been taken or agreed to be taken by any person and diminish the amount of its share capital by the amount of the shares so cancelled; (f) make provision for the allotment and issue of shares which do not carry any voting rights; (g) change the currency of denomination of its share capital; and (h) reduce its share premium account in any manner authorised and subject to any conditions prescribed by law.

(d) Transfer of shares

Subject to the Cayman Companies Act and the requirements of the Stock Exchange, all transfers of shares shall be effected by an instrument of transfer in the usual or common form or in such other form as the Board may approve and may be under hand or, if the transferor or transferee is a Clearing House (as defined in the Articles) or its nominee(s), under hand or by machine imprinted signature, or by such other manner of execution as the Board may approve from time to time.

Execution of the instrument of transfer shall be by or on behalf of the transferor and the transferee, provided that the Board may dispense with the execution of the instrument of transfer by the transferor or transferee or accept mechanically executed transfers. The transferor shall be deemed to remain the holder of a share until the name of the transferee is entered in the register of members of the Company in respect of that share.

The Board may, in its absolute discretion, at any time and from time to time remove any share on the principal register to any branch register or any share on any branch register to the principal register or any other branch register.

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Unless the Board otherwise agrees, no shares on the principal register shall be removed to any branch register nor shall shares on any branch register be removed to the principal register or any other branch register. All removals and other documents of title shall be lodged for registration and registered, in the case of shares on any branch register, at the relevant registration office and, in the case of shares on the principal register, at the place at which the principal register is located.

The Board may, in its absolute discretion, decline to register a transfer of any share (not being a fully paid up share) to a person of whom it does not approve or on which the Company has a lien. It may also decline to register a transfer of any share issued under any share option scheme upon which a restriction on transfer subsists or a transfer of any share to more than four joint holders.

The Board may decline to recognise any instrument of transfer unless a certain fee, up to such maximum sum as the Stock Exchange may determine to be payable, is paid to the Company, the instrument of transfer is properly stamped (if applicable), is in respect of only one class of share and is lodged at the relevant registration office or the place at which the principal register is located accompanied by the relevant share certificate(s) and such other evidence as the Board may reasonably require is provided to show the right of the transferor to make the transfer (and if the instrument of transfer is executed by some other person on his behalf, the authority of that person so to do).

The register of members may, subject to the Listing Rules, be closed at such time or for such period not exceeding in the whole 30 days in each year as the Board may determine (or such longer period as the members of the Company may by ordinary resolution determine, provided that such period shall not be extended beyond 60 days in any year).

Fully paid shares shall be free from any restriction on transfer (except when permitted by the Stock Exchange) and shall also be free from all liens.

(e) Power of the Company to purchase its own shares

The Company may 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 requirement imposed from time to time by the Articles or any code, rules or regulations issued from time to time by the Stock Exchange and/or the Securities and Futures Commission of Hong Kong.

Where the Company purchases for redemption a redeemable share, purchases not made through the market or by tender shall be limited to a maximum price and, if purchases are by tender, tenders shall be available to all members alike.

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(f) Power of any subsidiary of the Company to own shares in the Company

There are no provisions in the Articles relating to the ownership of shares in the Company by a subsidiary.

(g) Calls on shares and forfeiture of shares

The Board may, from time to time, make such calls as it thinks fit upon the members in respect of any monies unpaid on the shares held by them respectively (whether on account of the nominal value of the shares or by way of premium) and not by the conditions of allotment of such shares made payable at fixed times. A call may be made payable either in one sum or by instalments. 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 20 per cent per annum as the Board shall fix from the day appointed for payment 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 money uncalled and unpaid or instalments payable upon any shares held by him, and in respect of all or any of the monies so advanced the Company may pay interest at such rate (if any) not exceeding 20 per cent per annum as the Board may decide.

If a member fails to pay any call or instalment of a call on the day appointed for payment, the Board may, for so long as any part of the call or instalment remains unpaid, serve not less than 14 days' notice on the member requiring payment of so much of the call or instalment as is unpaid, together with any interest which may have accrued and which may still accrue up to the date of actual payment. The notice shall name a further day (not earlier than the expiration of 14 days from the date of the notice) on or before which the payment required by the notice is to be made, and shall also name the place where payment is to be made. The notice shall also state that, in the event of non-payment at or before the appointed time, the shares in respect of which the call was made will be liable to be forfeited.

If 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, nevertheless, remain liable to pay to the Company all monies which, as at the date of forfeiture, were payable by him to the Company in respect of the shares together with (if the Board shall in its discretion so require) interest thereon from the date of forfeiture until payment at such rate not exceeding 20 per cent per annum as the Board may prescribe.

2.2 Directors

(a) Appointment, retirement and removal

At any time or from time to time, the Board shall have the power to appoint any person as a Director either to fill a casual vacancy on the Board or as an additional Director to the existing Board subject to any maximum number of Directors, if any, as may be determined by the members in general meeting. Any Director so appointed to fill a casual vacancy shall hold office only until the first general meeting of the Company after his appointment and be subject to re-election at such meeting. Any Director so appointed as an addition to the existing Board shall hold office only until the first annual general meeting of the Company after his appointment and be eligible for re-election at such meeting. Any Director so appointed by the Board shall not be taken into account in determining the Directors or the number of Directors who are to retire by rotation at an annual general meeting.

At each annual general meeting, one-third of the Directors for the time being shall retire from office by rotation. However, if the number of Directors is not a multiple of three, then the number nearest to but not less than one-third shall be the number of retiring Directors. The Directors to retire in each year shall be those who have been in office longest 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 shall (unless they otherwise agree among themselves) be determined by lot.

No person, other than a retiring Director, shall, unless recommended by the Board for election, be eligible for election to the office of Director at any general meeting, unless notice in writing of the intention to propose that person for election as a Director and notice in writing by that person of his willingness to be elected has been lodged at the head office or at the registration office of the Company. The period for lodgment of such notices shall commence no earlier than the day after despatch of the notice of the relevant meeting and end no later than seven days before the date of such meeting and the minimum length of the period during which such notices may be lodged must be at least seven days.

A Director is not required to hold any shares in the Company by way of qualification nor is there any specified upper or lower age limit for Directors either for accession to or retirement from the Board.

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(b) Power to allot and issue shares and warrants

Subject to the provisions of the Cayman Companies Act, the Memorandum and Articles and without prejudice to any special rights conferred on the holders of any shares or class of shares, any share may be issued with or have attached to it such rights, or such restrictions, whether with regard to dividend, voting, return of capital or otherwise, as the Company may by ordinary resolution determine (or, in the absence of any such determination or so far as the same may not make specific provision, as the Board may determine). Any share may be issued on terms that, upon the happening of a specified event or upon a given date and either at the option of the Company or the holder of the share, it is liable to be redeemed.

The Board may issue warrants to subscribe for any class of shares or other securities of the Company on such terms as it may from time to time determine.

Where warrants are issued to bearer, no certificate in respect of such warrants shall be issued to replace one that has been lost unless the Board is satisfied beyond reasonable doubt that the original certificate has been destroyed and the Company has received an indemnity in such form as the Board thinks fit with regard to the issue of any such replacement certificate.

Subject to the provisions of the Cayman Companies Act, the Articles and, where applicable, the rules of any stock exchange of the Relevant Territory 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 shall be 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, provided that no shares shall be issued at a discount.

Neither the Company nor the Board shall be obliged, when making or granting any allotment of, offer of, option over or disposal of shares, to make, or make available, any such allotment, offer, option or shares to members or others whose registered addresses are in any particular territory or territories where, in the absence of a registration statement or other special formalities, this is or may, in the opinion of the Board, be unlawful or impracticable. However, no member affected as a result of the foregoing shall be, or be deemed to be, a separate class of members for any purpose whatsoever.

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(c) Power to dispose of the assets of the Company or any of its subsidiaries

While there are no specific provisions in the Articles relating to the disposal of the assets of the Company or any of its subsidiaries, the Board may 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 Cayman Companies Act to be exercised or done by the Company in general meeting, but if such power or act is regulated by the Company in general meeting, such regulation shall not invalidate any prior act of the Board which would have been valid if such regulation had not been made.

(d) 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 uncalled capital of the Company and, subject to the Cayman Companies Act, to issue debentures, debenture stock, 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.

(e) Remuneration

The Directors shall be entitled to receive, as ordinary remuneration for their services, such sums as shall from time to time be determined by the Board or the Company in general meeting, as the case may be, such sum (unless otherwise directed by the resolution by which it is determined) to be divided among the Directors in such proportions and in such manner as they may agree or, failing agreement, either equally or, in the case of any Director holding office for only a portion of the period in respect of which the remuneration is payable, *pro rata*. The Directors shall also be entitled to be repaid all expenses reasonably incurred by them in attending any Board meetings, committee meetings or general meetings or otherwise in connection with the discharge of their duties as Directors. Such remuneration shall be in addition to any other remuneration to which a Director who holds any salaried employment or office in the Company may be entitled by reason of such employment or office.

Any Director who, at the request of the Company, performs services which in the opinion of the Board go beyond the ordinary duties of a Director may be paid such special or extra remuneration as the Board may determine, 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 shall be in addition to his ordinary remuneration as a Director.

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The Board may establish, either on its own or jointly in concurrence or agreement with subsidiaries of the Company or companies with which the Company is associated in business, or may make 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 former Director who may hold or have held any executive office or any office of profit with the Company or any of its subsidiaries) and former employees of the Company and their dependents or any class or classes of such persons.

The Board may also pay, enter into agreements to pay or make grants of revocable or irrevocable, whether or not subject to any terms or conditions, pensions or other benefits to employees and former employees and their dependents, or to any of such persons, including pensions or benefits additional to those, if any, to which such employees or former employees or their dependents are or may become entitled under any such scheme or fund as mentioned above. Such pension or benefit may, if deemed desirable by the Board, be granted to an employee either before and in anticipation of, or upon or at any time after, his actual retirement.

(f) Compensation or payments for loss of office

Payments to any present 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 or statutorily entitled) must be approved by the Company in general meeting.

(g) Loans and provision of security for loans to Directors

The Company shall not directly or indirectly make a loan to a Director or a director of any holding company of the Company or any of their respective close associates, enter into any guarantee or provide any security in connection with a loan made by any person to a Director or a director of any holding company of the Company or any of their respective close associates, or, if any one or more Directors hold(s) (jointly or severally or directly or indirectly) a controlling interest in another company, make a loan to that other company or enter into any guarantee or provide any security in connection with a loan made by any person to that other company.

(h) Disclosure of interest in contracts with the Company or any of its subsidiaries

With the exception of the office of auditor of the Company, a Director may hold any other office or place of profit with the Company in conjunction with his office of Director for such period and upon such terms as the Board may determine, and may be paid such extra remuneration for that other office or place of profit, in whatever form, in addition to any remuneration provided for by or pursuant to any other Articles. A Director may be

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or become a director, officer or member of any other company in which the Company may be interested, and shall not be liable to account to the Company or the members for any remuneration or other benefits received by him as a director, officer or member of such other company. 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 in favour of any resolution appointing the Directors or any of them to be directors or officers of such other company.

No Director or intended Director shall be disqualified by his office from contracting with the Company, 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 for any profit realised by any such contract or arrangement by reason only of such Director holding that office or the fiduciary relationship established by it. A Director who is, in any way, materially interested in a contract or arrangement or proposed contract or arrangement with the Company shall declare the nature of his interest at the earliest meeting of the Board at which he may practically do so.

There is no power to freeze or otherwise impair any of the rights attaching to any share by reason that the person or persons who are interested directly or indirectly in that share have failed to disclose their interests to the Company.

A Director shall not vote or be counted in the quorum on any resolution of the Board in respect of any contract or arrangement or proposal in which he or any of his close associate(s) has/have a material interest, and if he shall do so his vote shall not be counted nor shall he be counted in the quorum for that resolution, but this prohibition shall not apply to any of the following matters:

- (i) the giving of any security or indemnity to the Director or his close associate(s) in respect of money lent or obligations incurred or undertaken by him or any of them at the request of or for the benefit of the Company or any of its subsidiaries;
- (ii) the giving of any security or indemnity to a third party in respect of a debt or obligation of the Company or any of its subsidiaries for which the Director or his close associate(s) has/have himself/themselves assumed responsibility in whole or in part whether alone or jointly under a guarantee or indemnity or by the giving of security;
- (iii) any proposal concerning an offer of shares, debentures or other securities of or by the Company or any other company which the Company may promote or be interested in for subscription or purchase, where the Director or his close associate(s) is/are or is/are to be interested as a participant in the underwriting or sub- underwriting of the offer;

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An ordinary resolution, by contrast, is 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 members which are corporations, by their duly authorised representatives or by proxy at a general meeting of which notice has been duly given.

A resolution in writing signed by or on behalf of all members shall be treated as an ordinary resolution duly passed at a general meeting of the Company duly convened and held, and where relevant as a special resolution so passed.

(b) Voting rights and right to demand a poll

Subject to any special rights, restrictions or privileges as to voting for the time being attached to any class or classes of shares at any general meeting: (a) on a poll every member present in person or by proxy or, in the case of a member being a corporation, by its duly authorised representative shall have one vote for every share which is fully paid or credited as fully paid registered in his name in the register of members of the Company, provided that no amount paid up or credited as paid up on a share in advance of calls or instalments is treated for this purpose as paid up on the share; and (b) on a show of hands every member who is present in person (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy shall have one vote. 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. On a poll, a member entitled to more than one vote need not use all his votes or cast all the votes he does use in the same way.

At any general meeting a resolution put to the vote of the meeting is to be decided by poll save that the chairman of the meeting may, pursuant to the Listing Rules, allow a resolution to be voted on by a show of hands. Where a show of hands is allowed, before or on the declaration of the result of the show of hands, a poll may be demanded by (in each case by members present in person or by proxy or by a duly authorised corporate representative):

- (i) at least two members;
- (ii) any member or members representing not less than one-tenth of the total voting rights of all the members having the right to vote at the meeting; or
- (iii) a member or members holding shares in the Company conferring a right to vote at the meeting on which an aggregate sum has been paid equal to not less than one-tenth of the total sum paid up on all the shares conferring that right.

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Should a Clearing House or its nominee(s) be a member of the Company, such person or persons may be authorised 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 in accordance with this provision shall be deemed to have been duly authorised without further evidence of the facts and be entitled to exercise the same rights and powers on behalf of the Clearing House or its nominee(s) as if such person were an individual member including the right to vote individually on a show of hands.

Where the Company has knowledge that any member is, under the Listing Rules, required to abstain from voting on any particular resolution or restricted to voting only for or only against any particular resolution, any votes cast by or on behalf of such member in contravention of such requirement or restriction shall not be counted.

(c) *Annual general meetings*

The Company must hold an annual general meeting each year other than the year of the Company's adoption of the Articles. Such meeting must be held not more than 15 months after the holding of the last preceding annual general meeting, or such longer period as may be authorised by the Stock Exchange at such time and place as may be determined by the Board.

(d) *Notices of meetings and business to be conducted*

An annual general meeting of the Company shall be called by at least 21 days' (and not less than 20 clear business days') notice in writing, and any other general meeting of the Company shall be called by at least 14 days' (and not less than 10 clear business days') notice in writing. The notice shall be exclusive of the day on which it is served or deemed to be served and of the day for which it is given, and must specify the time, place and agenda of the meeting and particulars of the resolution(s) to be considered at that meeting and, in the case of special business, the general nature of that business.

Except where otherwise expressly stated, any notice or document (including a share certificate) to be given or issued under the Articles shall be in writing, and may be served by the Company on any member personally, by post to such member's registered address or (in the case of a notice) by advertisement in the newspapers. Any member whose registered address is outside Hong Kong may notify the Company in writing of an address in Hong Kong which shall be deemed to be his registered address for this purpose. Subject to the Cayman Companies Act and the Listing Rules, a notice or document may also be served or delivered by the Company to any member by electronic means.

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Although a meeting of the Company may be called by shorter notice than as specified above, such meeting may be deemed to have been duly called if it is so agreed:

- (i) in the case of an annual general meeting, by all members of the Company entitled to attend and vote thereat; and
- (ii) in the case of any other meeting, by a majority in number of the members having a right to attend and vote at the meeting holding not less than 95 per cent of the total voting rights in the Company.

All business transacted at an extraordinary general meeting shall be deemed special business. All business shall also be deemed special business where it is transacted at an annual general meeting, with the exception of certain routine matters which shall be deemed ordinary business.

(e) *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, and continues to be present until the conclusion of the meeting.

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 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.

(f) *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 shall be 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 shall be entitled to exercise the same powers on behalf of a member which is a corporation and for which he acts as proxy as such member could exercise if it were an individual member. On a poll or on a show of hands, votes may be given either personally (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy.

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The instrument appointing a proxy shall be in writing under the hand of the appointor or of his attorney duly authorised in writing, or if the appointor is a corporation, either under seal or under the hand of a duly authorised officer or attorney. Every instrument of proxy, whether for a specified meeting or otherwise, shall be in such form as the Board may from time to time approve, provided that it shall not preclude the use of the two-way form. Any form issued to a member for appointing a proxy to attend and vote at an extraordinary general meeting or at an annual general meeting at which any business is to be transacted shall be such as to enable the member, according to his intentions, to instruct the proxy to vote in favour of or against (or, in default of instructions, to exercise his discretion in respect of) each resolution dealing with any such business.

(g) *Members' requisition for meetings*

Extraordinary general meetings shall be convened on the requisition of one or more members holding, as 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. Such requisition shall be made in writing to the Board or the secretary of the Company for the purpose of requiring an extraordinary general meeting to be called by the Board for the transaction of any business specified in such requisition. Such meeting shall be held within two 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 (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.

2.6 Accounts and audit

The Board shall cause proper books of account to be kept of the sums of money received and expended by the Company, and of the assets and liabilities of the Company and of all other matters required by the Cayman Companies Act (which include all sales and purchases of goods by the Company) necessary to give a true and fair view of the state of the Company's affairs and to show and explain its transactions.

The books of accounts of the Company shall be kept at the head office of the Company 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 account, book or document of the Company except as conferred by the Cayman Companies Act or ordered by a court of competent jurisdiction or authorised by the Board or the Company in general meeting.

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The Board shall from time to time cause to be prepared and laid before the Company at its annual general meeting balance sheets and profit and loss accounts (including every document required by law to be annexed thereto), together with a copy of the Directors' report and a copy of the auditors' report, not less than 21 days before the date of the annual general meeting. Copies of these documents shall be sent to every person entitled to receive notices of general meetings of the Company under the provisions of the Articles together with the notice of annual general meeting, not less than 21 days before the date of the meeting.

Subject to the rules of the stock exchange of the Relevant Territory, the Company may send summarised financial statements to shareholders who have, in accordance with the rules of the stock exchange of the Relevant Territory, consented and elected to receive summarised financial statements instead of the full financial statements. The summarised financial statements must be accompanied by any other documents as may be required under the rules of the stock exchange of the Relevant Territory, and must be sent to those shareholders that have consented and elected to receive the summarised financial statements not less than 21 days before the general meeting.

The Company shall appoint auditor(s) to hold office until the conclusion of the next annual general meeting on such terms and with such duties as may be agreed with the Board. The auditors' remuneration shall be fixed by the Company in general meeting or by the Board if authority is so delegated by the members. The members may, at any general meeting convened and held in accordance with the Articles, remove the auditors by special resolution at any time before the expiration of the term of office and shall, by ordinary resolution, at that meeting appoint new auditors in its place for the remainder of the term.

The auditors shall audit the financial statements of the Company in accordance with generally accepted accounting principles of Hong Kong, the International Accounting Standards or such other standards as may be permitted by the Stock Exchange.

2.7 Dividends and other methods of distribution

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.

Except in so far as the rights attaching to, or the terms of issue of, any share may otherwise provide:

- (a) all dividends shall be declared and paid according to the amounts paid up on the shares in respect of which the dividend is paid, although no amount paid up on a share in advance of calls shall for this purpose be treated as paid up on the share;

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3.1 Company operations

An exempted company such as the Company must conduct its operations mainly outside the Cayman Islands. An exempted company is also required to file an annual return each year with the Registrar of Companies of the Cayman Islands and pay a fee which is based on the amount of its authorised share capital.

3.2 Share capital

Under the Cayman Companies Act, a Cayman Islands company may issue ordinary, preference or redeemable shares or any combination thereof. Where a company issues shares at a premium, whether for cash or otherwise, a sum equal to the aggregate amount or value of the 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 arrangements in consideration of the acquisition or cancellation of shares in any other company and issued at a premium. The share premium account may be applied by the company subject to the provisions, if any, of its memorandum and articles of association, in such manner as the company may from time to time determine including, but without limitation, the following:

- (a) paying distributions or dividends to members;
- (b) paying up unissued shares of the company to be issued to members as fully paid bonus shares;
- (c) any manner provided in section 37 of the Cayman Companies Act;
- (d) writing-off the preliminary expenses of the company; and
- (e) writing-off the expenses of, or the commission paid or discount allowed on, any issue of shares or debentures of the company.

Notwithstanding the foregoing, no distribution or dividend may be paid to members out of the share premium account unless, immediately following the date on which the distribution or dividend is proposed to be paid, the company will be able to pay its debts as they fall due in the ordinary course of business.

Subject to confirmation by the court, a company limited by shares or a company limited by guarantee and having a share capital may, if authorised to do so by its articles of association, by special resolution reduce its share capital in any way.

APPENDIX III SUMMARY OF THE CONSTITUTION OF OUR COMPANY AND CAYMAN COMPANIES ACT

3.5 Dividends and distributions

Subject to a solvency test, as prescribed in the Cayman Companies Act, and the provisions, if any, of the company's memorandum and articles of association, a company may pay dividends and distributions out of its share premium account. In addition, based upon English case law which is likely to be persuasive in the Cayman Islands, dividends may be paid out of profits.

For so long as a company holds treasury shares, no dividend may be declared or paid, and no other distribution (whether in cash or otherwise) of the company's assets (including any distribution of assets to members on a winding up) may be made, in respect of a treasury share.

3.6 Protection of minorities and shareholders' suits

It can be expected that the Cayman Islands courts will ordinarily follow English case law precedents (particularly the rule in the case of *Foss vs. Harbottle* and the exceptions to that rule) which permit a minority member to commence a representative action against or derivative actions in the name of the company to challenge acts which are ultra vires, illegal, fraudulent (and performed by those in control of the Company) against the minority, or represent an irregularity in the passing of a resolution which requires a qualified (or special) majority which has not been obtained.

Where a company (not being a bank) is one which has a share capital divided into shares, the court may, on the application of members holding not less than one-fifth of the shares of the company in issue, appoint an inspector to examine the affairs of the company and, at the direction of the court, to report on such affairs. In addition, any member of a company may petition the court, which may make a winding up order if the court is of the opinion that it is just and equitable that the company should be wound up.

In general, claims against a company by its members must be based on the general laws of contract or tort applicable in the Cayman Islands or be based on potential violation of their individual rights as members as established by a company's memorandum and articles of association.

3.7 Disposal of assets

There are no specific restrictions on the power of directors to dispose of assets of a company, however, the directors are expected to exercise certain duties of care, diligence and skill to the standard that a reasonably prudent person would exercise in comparable circumstances, in addition to fiduciary duties to act in good faith, for proper purpose and in the best interests of the company under English common law (which the Cayman Islands courts will ordinarily follow).

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3.8 Accounting and auditing requirements

A company must cause proper records of accounts to be kept with respect to: (i) all sums of money received and expended by it; (ii) all sales and purchases of goods by it; and (iii) its assets and liabilities.

Proper books of account shall not be deemed to be kept if there are not kept such books as are necessary to give a true and fair view of the state of the company's affairs and to explain its transactions.

If a company keeps its books of account at any place other than at its registered office or any other place within the Cayman Islands, it shall, upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act (2017 Revision) of the Cayman Islands, make available, in electronic form or any other medium, at its registered office copies of its books of account, or any part or parts thereof, as are specified in such order or notice.

3.9 Exchange control

There are no exchange control regulations or currency restrictions in effect in the Cayman Islands.

3.10 Taxation

The Cayman Islands currently levy no taxes on individuals or corporations based upon profits, income, gains or appreciations and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to the Company levied by the Government of the Cayman Islands save for certain stamp duties which may be applicable, from time to time, on certain instruments.

3.11 Stamp duty on transfers

No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies save for those which hold interests in land in the Cayman Islands.

3.12 Loans to directors

There is no express provision prohibiting the making of loans by a company to any of its directors. However, the company's articles of association may provide for the prohibition of such loans under specific circumstances.

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In the case of a members' voluntary winding up of a company, one or more liquidators are appointed for the purpose of winding up the affairs of the company and distributing its assets.

As soon as the affairs of a company are fully wound up, the liquidator must make a report and an account of the winding up, showing how the winding up has been conducted and the property of the company disposed of, and call a general meeting of the company for the purposes of laying before it the account and giving an explanation of that account.

When a resolution has been passed by a company to wind up voluntarily, the liquidator or any contributory or creditor may apply to the court for an order for the continuation of the winding up under the supervision of the court, on the grounds that: (i) the company is or is likely to become insolvent; or (ii) the supervision of the court will facilitate a more effective, economic or expeditious liquidation of the company in the interests of the contributories and creditors. A supervision order takes effect for all purposes as if it was an order that the company be wound up by the court except that a commenced voluntary winding up and the prior actions of the voluntary liquidator shall be valid and binding upon the company and its official liquidator.

For the purpose of conducting the proceedings in winding up a company and assisting the court, one or more persons may be appointed to be called an official liquidator(s). The court may appoint to such office such person or persons, either provisionally or otherwise, as it thinks fit, and if more than one person is appointed to such office, the court shall declare whether any act required or authorised to be done by the official liquidator is to be done by all or any one or more of such persons. The court may also determine whether any and what security is to be given by an official liquidator on his appointment; if no official liquidator is appointed, or during any vacancy in such office, all the property of the company shall be in the custody of the court.

3.17 Reconstructions

Reconstructions and amalgamations may be approved by a majority in number representing 75 per cent in value of the members or creditors, depending on the circumstances, as are present at a meeting called for such purpose and thereafter sanctioned by the courts. Whilst a dissenting member has the right to express to the court his view that the transaction for which approval is being sought would not provide the members with a fair value for their shares, the courts are unlikely to disapprove the transaction on that ground alone in the absence of evidence of fraud or bad faith on behalf of management, and if the transaction were approved and consummated, the dissenting member would have no rights comparable to the appraisal rights (that is, the right to receive payment in cash for the judicially determined value of their shares) ordinarily available, for example, to dissenting members of a United States corporation.

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3.18 Take-overs

Where an offer is made by a company for the shares of another company and, within four months of the offer, the holders of not less than 90 per cent of the shares which are the subject of the offer accept, the offeror may, at any time within two months after the expiration of that four-month period, by notice require the dissenting members to transfer their shares on the terms of the offer. A dissenting member may apply to the Cayman Islands courts within one month of the notice objecting to the transfer. The burden is on the dissenting member to show that the court should exercise its discretion, which it will be unlikely to do unless there is evidence of fraud or bad faith or collusion as between the offeror and the holders of the shares who have accepted the offer as a means of unfairly forcing out minority members.

3.19 Indemnification

The Cayman Islands laws do not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, save to the extent any such provision may be held by the court to be contrary to public policy, for example, where a provision purports to provide indemnification against the consequences of committing a crime.

3.20 Economic Substance

The Cayman Islands enacted the International Tax Co-operation (Economic Substance) Act (2020 Revision), which became effective on 1 January 2019, together with the Guidance Notes published by the Cayman Islands Tax Information Authority from time to time. The Company is required to comply with the economic substance requirements from 1 July 2019 and make an annual report in the Cayman Islands as to whether or not it is carrying on any relevant activities and if it is, it must satisfy an economic substance test.

4. GENERAL

Harney Westwood & Riegels, the Company's legal adviser on Cayman Islands law, have sent to the Company a letter of advice summarising certain aspects of the Cayman Companies Act. This letter, together with a copy of the Cayman Companies Act, is available for inspection as referred to in the paragraph headed "Documents Delivered to the Registrar of Companies and Available on Display" in Appendix V. Any person wishing to have a detailed summary of the Cayman Companies Act or advice on the differences between it and the laws of any jurisdiction with which he is more familiar is recommended to seek independent legal advice.

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A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation of our Company

Our Company was incorporated in the Cayman Islands as an exempted company with limited liability under the Cayman Companies Act on January 30, 2018. Our registered office address is at the offices of Ogier Global (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman, KY1-9009, Cayman Islands. As our Company is incorporated in the Cayman Islands, our operation is subject to the relevant laws and regulations of the Cayman Islands, the Articles and the Memorandum. A summary of the relevant laws and regulations of the Cayman Islands and of our constitution is set out in the section headed “Appendix III – Summary of the Constitution of Our Company and Cayman Companies Act” in this document.

Our Company was registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on April 21, 2021. Our principal place of business in Hong Kong is at Unit A131, 16/F, Tower 5, The Gateway, Harbour City, 15 Canton Road, Tsim Sha Tsui, Hong Kong. Ms. Ying Zhao has been appointed as our authorized representative for the acceptance of service of process and notices in Hong Kong. The address of service of process is the same as our principal place of business in Hong Kong set out above.

As of the date of this document, our Company’s head offices are located at Suite 301, 3F, Timeloit, No. 17 Rong Chuang Road, Chaoyang District, Beijing, PRC.

2. Changes in the Share Capital of Our Company

On the date of incorporation of our Company, our authorized share capital was US\$50,000 divided into 500,000,000 ordinary shares with a par value of US\$0.0001 each. On the same day, 1 subscriber share was allotted and issued at par value to our initial subscriber, Sertus Nominees (Cayman) Limited, which was then transferred at par value to CTX Pharma, a company held as to 100% by Dr. Xue. On the same day, 9,999 ordinary shares were allotted and issued at nominal value to CTX Pharma.

The following sets out the changes in the share capital of our Company during the two years immediately preceding the date of this document:

- (a) On March 10, 2020 our Company allotted and issued 481,232 Series C-4 Preferred Shares to Yuanming Healthcare Holdings Limited.
- (b) On March 10, 2020, our Company allotted and issued shares in the following manner:
 - (1) 1,015,242 Series D-1 Preferred Shares to General Atlantic Singapore CP Pte. Ltd.;

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CANbridge Life Sciences

On December 11, 2020, the registered capital of CANbridge Life Sciences Limited increased from RMB80,000,000 to RMB150,000,000. On May 27, 2021, the registered capital of CANbridge Life Sciences increased from RMB150,000,000 to RMB306,122,400.

CANbridge Shanghai

On December 30, 2020, the registered capital of CANbridge Shanghai increased from RMB30 million to RMB120 million.

Care Pharma Shanghai

On January 20, 2021, the registered capital of Care Pharma Shanghai increased from US\$200,000 to US\$5,000,000. On May 26, 2021, the registered capital of Care Pharma Shanghai increased from US\$5,000,000 to US\$10,204,100.

Save as disclosed above, there has been no alteration in the share capital of any of the subsidiaries of our Company within the two years immediately preceding the date of this document.

[Save for the subsidiaries mentioned in the section headed “History, Reorganization and Corporate Structure – Our Structure Immediately Following the [REDACTED]” this document, our Company has no other subsidiaries.]

4. Resolutions of our Shareholders

Resolutions of our Shareholders were passed on [●], 2021 pursuant to which, among others:

- (a) conditional on (i) the [REDACTED] Committee granting the [REDACTED] of, and permission to deal in, the Shares in issue and to be issued as to be stated in this document and such [REDACTED] and permission not subsequently having been revoked prior to the commencement of [REDACTED] the [REDACTED] on the Stock Exchange; (ii) the [REDACTED] having been determined; (iii) the obligations of the [REDACTED] under the [REDACTED] Agreements becoming unconditional and not being terminated in accordance with the terms of the [REDACTED] Agreements or otherwise, in each case on or before such dates as may be specified in the [REDACTED] Agreements; (iv) the [REDACTED] Agreements having been duly executed by the [REDACTED] and our Company; and (v) the [REDACTED] constituting a Qualified [REDACTED] (as defined under the existing articles of the Company) or an [REDACTED] approved by the Board in accordance with existing articles of the Company and the shareholders agreement:
 - (1) the [REDACTED] (including the [REDACTED]) was approved, and the proposed allotment and issue of the [REDACTED] under the [REDACTED] were approved, and the Directors were authorized to determine the [REDACTED] for, and to allot and issue the [REDACTED];

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- (2) a general unconditional mandate was given to our Directors to exercise all powers of our Company to allot, issue and deal with Shares or securities convertible into Shares and to make or grant offers, agreements or options (including any warrants, bonds, notes and debentures conferring any rights to subscribe for or otherwise receive Shares) which might require Shares to be allotted and issued or dealt with subject to the requirement that the aggregate nominal value of the Shares so allotted and issued or agreed conditionally or unconditionally to be allotted and issued, otherwise than by way of the [REDACTED], rights issue or pursuant to the exercise of any subscription rights attaching to any warrants which may be allotted and issued by the Company from time to time or, pursuant to the exercise of any options which may be granted under the [REDACTED] Equity Incentive Plan or allotment and issue of Shares in lieu of the whole or part of a dividend on Shares in accordance with the Articles of Association on a specific authority granted by our Shareholders in general meeting, shall not exceed 20% of the aggregate nominal value of the Shares in issue immediately following completion of the [REDACTED], excluding any Shares which may fall to be issued pursuant to the exercise of the [REDACTED];
 - (3) a general unconditional mandate (the "**Repurchase Mandate**") was given to our Directors to exercise all powers of our Company to repurchase on the Stock Exchange or on any other stock exchange on which the securities of our Company may be [REDACTED] and which is recognized by the SFC and the Stock Exchange for this purpose, such number of Shares as will represent up to 10% of the aggregate nominal value of the Shares in issue immediately following completion of the [REDACTED], excluding any Shares which may fall to be issued pursuant to the exercise of the [REDACTED];
 - (4) the general unconditional mandate as mentioned in paragraph (2) above was 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 repurchased by our Company pursuant to the mandate to purchase Shares referred to in paragraph (3) 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 issued pursuant to the exercise of the [REDACTED];
 - (5) immediately prior to the completion of the [REDACTED], each of the Preferred Shares be converted into ordinary shares at the conversion of 1:1 by way of redesignation; and
- (b) our Company conditionally approved and adopted the Memorandum and the Articles with effect from the [REDACTED].

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Each of the general mandates referred to in paragraphs (a)(2), (a)(3) and (a)(4) above will remain in effect until whichever is the earliest of:

- the conclusion of the next annual general meeting of our Company;
- the expiration of the period within which the next annual general meeting of our Company is required to be held by any applicable law or the Articles of Association; or
- the time when such mandate is revoked or varied by an ordinary resolution of the Shareholders in a general meeting.

5. Repurchases of Our Own Securities

The following paragraphs include, among others, certain information required by the Stock Exchange to be included in this document concerning the repurchase of our own securities.

(a) Provision of the Listing Rules

The Listing Rules permit companies with a primary [REDACTED] on the Stock Exchange to repurchase their own securities on the Stock Exchange subject to certain restrictions, the most important of which are summarized below:

(i) Shareholders' Approval

All proposed repurchases of securities (which must be fully paid up in the case of shares) by a company with a primary [REDACTED] on the Stock Exchange must be approved in advance by an ordinary resolution of the shareholders in general meeting, either by way of general mandate or by specific approval of a particular transaction.

Pursuant to a resolution passed by our Shareholders on [●], 2021, the Repurchase Mandate was given to our Directors authorizing them to exercise all powers of our Company to repurchase Shares on the Stock Exchange, or on any other stock exchange on which the securities of our Company may be [REDACTED] and which is recognized by the SFC and the Stock Exchange for this purpose, with a total nominal value up to 10% of the aggregate nominal value of our Shares in issue immediately following completion of the [REDACTED] (excluding any Shares which may be issued under the [REDACTED]), with such mandate to expire at the earliest of (i) the conclusion of the next annual general meeting of our Company (unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions), (ii) the expiration of the period within which our Company's next annual general meeting is required by the Articles of Association or any other applicable laws to be held, and (iii) the date when it is varied or revoked by an ordinary resolution of our Shareholders in general meeting.

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(ii) Source of Funds

Purchases must be funded out of funds legally available for the purpose in accordance with the Memorandum and the Articles and the applicable laws and regulations of Hong Kong and the Cayman Islands. A listed company may not purchase 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.

(iii) Trading Restrictions

The total number of shares which a listed company may repurchase on the Stock Exchange is the number of shares representing up to 10% of the aggregate number of shares in issue. A company may not issue or announce a proposed issue of new securities for a period of 30 days immediately following a repurchase (other than an issue of securities pursuant to an exercise of warrants, options or similar instruments requiring the company to issue securities which were outstanding prior to such repurchase) without the prior approval of the Stock Exchange. In addition, a listed company is prohibited from repurchasing its shares on the Stock Exchange if the purchase price is 5% or more than the average closing market price for the five preceding trading days on which its shares were traded on the Stock Exchange. The Listing Rules also prohibit a listed company from repurchasing its securities if the repurchase would result in the number of listed securities which are in the hands of the public falling below the relevant prescribed minimum percentage as required by the Stock Exchange. A company is required to procure that the broker appointed by it to effect a repurchase of securities discloses to the Stock Exchange such information with respect to the repurchase as the Stock Exchange may require.

(iv) Status of Repurchased Shares

The listing of all purchased securities (whether on the Stock Exchange or otherwise) is automatically cancelled and the relevant certificates must be cancelled and destroyed. Under the laws of the Cayman Islands, unless the Directors resolve to hold the shares purchased by our Company as treasury shares prior to the purchase, shares purchased by our Company shall be treated as cancelled and the amount of our Company's issued share capital shall be diminished by the nominal value of those shares. However, the purchase of shares will not be taken as reducing the amount of the authorized share capital under Cayman Islands law.

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(v) Suspension of Repurchase

A listed company may not make any repurchase of securities after a price sensitive development has occurred or has been the subject of a decision until such time as the price sensitive information has been made publicly available. In particular, during the period of one month immediately preceding the earlier of (a) the date of the board meeting (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of a listed company’s results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules) and (b) the deadline for publication of an announcement of a listed company’s results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules), the listed company may not repurchase its shares on the Stock Exchange other than in exceptional circumstances. In addition, the Stock Exchange may prohibit a repurchase of securities on the Stock Exchange if a listed company has breached the Listing Rules.

(vi) Reporting Requirements

Certain information relating to repurchases of securities on the Stock Exchange or otherwise must be reported to the Stock Exchange not later than 30 minutes before the earlier of the commencement of the morning trading session or any pre-opening session on the following Business Day. In addition, a listed company’s annual report is required to disclose details regarding repurchases of securities made during the year, including a monthly analysis of the number of securities repurchased, the purchase price per share or the highest and lowest price paid for all such repurchases, where relevant, and the aggregate prices paid.

(vii) Core Connected Persons

The Listing Rules prohibit a company from knowingly purchasing securities on the Stock Exchange from a “core connected person”, that is, a director, chief executive or substantial shareholder of the company or any of its subsidiaries or a close associate of any of them (as defined in the Listing Rules) and a core connected person shall not knowingly sell its securities to the company.

(b) Reasons for Repurchases

Our Directors believe that it is in the best interests of our Company and Shareholders for our Directors to have a general authority from the Shareholders to enable our Company to repurchase Shares in the 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 our Company and Shareholders.

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(c) Funding of Repurchases

In repurchasing shares, the Company may only apply funds legally available for such purpose in accordance with the Memorandum and Articles of Association and the applicable laws of the Cayman Islands. Our Directors may not repurchase the Shares on the Stock Exchange for a consideration other than cash or for settlement otherwise than in accordance with the trading rules of the Stock Exchange. Any payment for the repurchases of Shares will be drawn from the profits of our Company or from a fresh issue of shares made for the purpose of the repurchase or, if authorized by the Memorandum and Articles of Association and subject to the Cayman Companies Act, out of capital and, in the case of any premium payable on the repurchase, out of profits of our Company or from sums standing to the credit of the share premium account of our Company or, if authorized by the Memorandum and Articles of Association and subject to Cayman Companies Act, out of capital.

However, our Directors do not propose to exercise the Repurchase Mandate to such an extent as would, in the circumstances, have a material adverse effect on the working capital requirements of our Company or its gearing levels which, in the opinion of the Directors, are from time to time appropriate for our Company.

(d) General

The exercise in full of the Repurchase Mandate, on the basis of [REDACTED] Shares in issue immediately following completion of the [REDACTED], but assuming the [REDACTED] outstanding as at the Latest Practicable Date and the [REDACTED] are not exercised, could accordingly result in up to [REDACTED] Shares being repurchased by our Company during the period prior to the earliest of:

- the conclusion of the next annual general meeting of our Company unless renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions;
- the expiration of the period within which our Company's next annual general meeting is required by the Articles of Association or any other applicable laws to be held; or
- the date when it is varied or revoked by an ordinary resolution of the Shareholders in general meeting.

None of our Directors nor, to the best of their knowledge having made all reasonable enquiries, any of their close associates currently intends to sell any Shares to our Company.

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Our Directors have undertaken to the Stock Exchange that, so far as the same may be applicable, they will exercise the Repurchase Mandate in accordance with the Listing Rules and the applicable laws in the Cayman Islands.

If, as a result of any repurchase of Shares, a Shareholder's proportionate interest in the voting rights of our Company increases, such increase will be treated as an acquisition for the purposes of the Takeovers Code. Accordingly, a Shareholder or a group of Shareholders acting in concert could obtain or consolidate control of our Company and become obliged to make a mandatory offer in accordance with Rule 26 of the Takeovers Code. Save as aforesaid, our Directors are not aware of any consequences which would arise under the Takeovers Code as a consequence of any repurchases pursuant to the Repurchase Mandate.

Any repurchase of Shares that results in the number of Shares held by the public being reduced to less than 25% of the Shares then in issue could only be implemented if the Stock Exchange agreed to waive the Listing Rules requirements regarding the public shareholding referred to above. It is believed that a waiver of this provision would not normally be given other than in exceptional circumstances.

No core connected person of our Company has notified our Company that he or she has a present intention to sell Shares to our Company, or has undertaken not to do so, if the Repurchase Mandate is exercised.

B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of Material Contracts

The following contracts (not being contracts entered into in the ordinary course of business) were entered into by members of our Group within the two years immediately preceding the date of this document which are or may be material:

- (a) the series D-1 preferred share subscription agreement dated February 15, 2020 entered into among our Company, CANbridge Biomed Limited, CANbridge Care Pharma HongKong Limited (formerly known as Care Pharma Hongkong Limited), CANbridge Life Sciences Ltd. (北海康成(北京)醫藥科技有限公司), CANbridge (Shanghai) Life Sciences Ltd. (北海康成(上海)生物科技有限公司), Care Pharma Shanghai Ltd. (諾愛藥業(上海)有限公司), CANbridge Pharmaceuticals Limited, Canbridgepharma Limited, Canbridge Pharmaceuticals, Inc., Care Pharma Inc., CANbridge Pharma Co., Ltd. (北海康成股份有限公司), Beijing Xinyao Pharmaceutical Technology Co., Ltd. (北京欣耀醫學科技有限公司), Xue James Qun (薛群), CTX Pharma Holdings Limited, General Atlantic Singapore CP Pte. Ltd., WuXi PharmaTech Healthcare Fund I L.P., RA Capital Healthcare Fund, L.P., RA CAPITAL NEXUS FUND, L.P., BLACKWELL PARTNERS LLC – SERIES A, HBC Asia Healthcare Opportunities I LLC, Hongkong Tigermed Co., Limited, THE MARK R. BAMFORTH IRREVOCABLE TRUST, U/I/T APRIL 2, 2015 and

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Yuanming Healthcare Holdings Limited, in relation to the sale and purchase of Series D-1 Preferred Shares for an aggregate consideration of US\$93,001,246 and the issuance of Series C-4 Preferred Shares to Yuanming Healthcare Holdings Limited for a convertible loan conversion price of US\$5,000,000;

- (b) the series E preferred share subscription agreement dated October 26, 2020 entered into among our Company, CANbridge Biomed Limited, CANbridge Care Pharma HongKong Limited (formerly known as Care Pharma Hongkong Limited), CANbridge Life Sciences Ltd. (北海康成(北京)醫藥科技有限公司), CANbridge (Shanghai) Life Sciences Ltd. (北海康成(上海)生物科技有限公司), Care Pharma Shanghai Ltd. (諾愛藥業(上海)有限公司), CANbridge Pharmaceuticals Limited, Canbridgepharma Limited, Canbridge Pharmaceuticals, Inc., CANbridge Pharma Co., Ltd. (北海康成股份有限公司), Xue James Qun (薛群), CTX Pharma Holdings Limited, 3W Global Fund, CASDIN PARTNERS MASTER FUND, L.P., Summer Bridge Holdings Limited, SPDBI Eagle L.P., Yaly Capital Healthcare Investment 1 Limited, Blue Ridge Mountains Limited, HBC Asia Healthcare Opportunities I LLC, Hongkong Tigermed Co., Limited, RA CAPITAL HEALTHCARE FUND, L.P., RA CAPITAL NEXUS FUND, L.P., BLACKWELL PARTNERS LLC – SERIES A and Michael Joseph Glynn, in relation to the sale and purchase of Series E Preferred Shares (Tranche 1), for an aggregate consideration of US\$43,039,999.63;
- (c) the series E preferred share subscription agreement (Tranche 2) dated April 26, 2021 entered into among our Company, CANbridge Biomed Limited, CANbridge Care Pharma HongKong Limited (formerly known as Care Pharma Hongkong Limited), CANbridge Life Sciences Ltd. (北海康成(北京)醫藥科技有限公司), CANbridge (Shanghai) Life Sciences Ltd. (北海康成(上海)生物科技有限公司), Care Pharma Shanghai Ltd. (諾愛藥業(上海)有限公司), CANbridge (Suzhou) Bio-pharma Co., Ltd. (北海康成(蘇州)生物製藥有限公司), CANbridge Pharmaceuticals Limited, Canbridge Pharmaceuticals, Inc., CANbridge Pharma Co., Ltd. (北海康成股份有限公司), Xue James Qun (薛群), CTX Pharma Holdings Limited, Janus Henderson Biotech Innovation Master Fund Limited, Janus Henderson Capital Funds plc on behalf of its Series Janus Henderson Global Life Sciences Fund, Janus Henderson Global Life Sciences Fund, Janus Henderson Emerging Markets Fund, Janus Henderson Investment Fund Series I – Janus Henderson Emerging Markets Opportunities Fund, Janus Henderson Fund – Janus Henderson Emerging Markets Fund, Yingke Innovation Fund LP, Casdin Partners Master Fund, L.P. and Michael Joseph Glynn, in relation to the sale and purchase of Series E Preferred Shares (Tranche 2), for an aggregate consideration of US\$15,190,000.74;
- (d) the eighth amended and restated shareholders agreement dated May 7, 2021 entered into among our Company, CANbridge Pharmaceuticals Limited, CANbridge Biomed Limited, CANbridge Care Pharma HongKong Limited (formerly known as Care Pharma Hongkong Limited), CANbridge Life Sciences Ltd (北海康成(北京)醫藥科技有限公司), Canbridge (Shanghai) Life Sciences Ltd. (北海康成(上海)生物科技有限公司), Canbridge Pharmaceuticals, Inc., CARE Pharma Shanghai Ltd. (諾愛

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藥業(上海)有限公司), CANbridge (Suzhou) Bio-pharma Co., Ltd. (北海康成(蘇州)生物製藥有限公司), CANbridge Pharma Co., Ltd. (北海康成股份有限公司), Xue James Qun, CTX Pharma Holdings Limited, Xiangyun Holdings Limited, Hongweikx Holdings Limited, Yike Holdings Limited, Apollo China Holdings Limited, Clear Stone Holdings Limited, Sea&Sky Holdings Limited, Merrifield Holdings Ltd., Flemingddf Holdings Limited, Michael Joseph Glynn, Belinda Ann Termeer, James Arthur Geraghty, Goldberg & Kaiser Family Foundation, Paul Arthur Wagner, Fusion Capital Management Limited, Win Yin (HK) Investment Company Limited, Spring Wind Holdings Limited, Grand Path Holdings Limited, QIMING VENTURE PARTNERS IV, L.P., QIMING MANAGING DIRECTORS FUND IV, L.P., Maxtec Group Limited, Yuhao Holdings Limited, Medkelvin Holdings Limited, Hangzhou Tigermed Consulting Co., Ltd. (杭州泰格醫藥科技股份有限公司), Chengzhang Holdings Limited, Dingkai Holdings Limited, Beijing Longpan Health Medical Investment Centre L.P. (北京龍磐健康醫療投資中心(有限合夥)), Beijing Longpan Life Pharmaceutical Startup Investment Centre L.P. (北京龍磐生物醫藥創業投資中心(有限合夥)), BEIJING CHONGDE YINGSHENG STARTUP INVESTMENT CO., LIMITED (北京崇德英盛創業投資有限公司), Beijing Zhongling Yanyuan Startup Investment Centre L.P. (北京中嶺燕園創業投資中心(有限合夥)), WuXi PharmaTech Healthcare Fund I L.P., Shenzhen Qianhai Yuanming Medical Industry Investment Fund L.P. (深圳前海元明醫療產業投資基金(有限合夥)), WuXi AppTec (Hong Kong) Limited, YUHAO HK LIMITED, Mayfair Holdings Limited, Yuanming Healthcare Holdings Limited, Nanjing BGI-Cowin No. 1 Venture Investment Partnership(南京華大共贏一號創業投資企業(有限合夥)), Shenzhen BGI-Usum Venture Investment Centre (深圳華大渝商創業投資中心(有限合夥)), Huangpu River Capital SPC, Blue Ridge Mountains Limited, WuXi Biologics Healthcare Venture, Fortune Creation Ventures Limited, BioTrack BH Limited, SVB Leerink Holdings LLC, Healthcare Innovation Investment Fund LLC, SACF GP I, L.P., JUMBO HERO LIMITED, General Atlantic Singapore CP Pte. Ltd., RA CAPITAL HEALTHCARE FUND, L.P., RA CAPITAL NEXUS FUND, L.P., BLACKWELL PARTNERS LLC – SERIES A, HBC Asia Healthcare Opportunities I LLC, Hongkong Tigermed Co., Limited, THE MARK R. BAMFORTH IRREVOCABLE TRUST, U/I/T APRIL 2, 2015, 3W Global Fund, CASDIN PARTNERS MASTER FUND, L.P., Summer Bridge Holdings Limited, SPDBI Eagle L.P., Yaly Capital Healthcare Investment 1 Limited, I-CHINA HOLDINGS LIMITED, Janus Henderson Biotech Innovation Master Fund Limited, Janus Henderson Capital Funds plc on behalf of its Series Janus Henderson Global Life Sciences Fund, Janus Henderson Global Life Sciences Fund, Janus Henderson Emerging Markets Fund, Janus Henderson Investment Fund Series I – Janus Henderson Emerging Markets Opportunities Fund, Janus Henderson Fund – Janus Henderson Emerging Markets Fund, Yingke Innovation Fund LP, CHEN Song (陳松), CAO Wei (曹威), LIU Bing (劉兵), XU Ping (徐萍), XU Ying (許瑩), SONG Chunsheng (宋春勝), Caroline Ann Merrifield, David Daniel Fleming, LAI Chunbao (賴春寶), Ying Liu, QIAN Hui (錢輝), XUE Yintong (薛殷彤), HUANG Wei (黃衛) and MA Jikai (馬繼凱), pursuant to which shareholder rights were agreed among the parties;

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- (e) [●];
- (f) [●]; and
- (g) the [REDACTED].






2. Intellectual Property Rights

(a) Trademarks

As of the Latest Practicable Date, the Company has registered the following material trademarks in the PRC:

No.	Trademark	Registered Owner
1.		CANbridge Life Sciences Limited
2.		CANbridge Life Sciences Limited
3.		CANbridge Life Sciences Limited
4.	北海康成	CANbridge Life Sciences Limited
5.	北海康成	CANbridge Life Sciences Limited

As of the Latest Practicable Date, the Company has registered the following material trademarks in Hong Kong:

No.	Trademark	Registered Owner
1.		CANBRIDGE BIOMED LIMITED
		
3.		CANBRIDGE BIOMED LIMITED
		
4.		CANBRIDGE BIOMED LIMITED

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(b) Domain Names

As of the Latest Practicable Date, the following was the key domain name registration of our Group:

www.canbridgepharma.com

(c) Patent Applications

For a discussion of the details of the material filed patent applications in connection with our product candidates, please refer to the section headed “Business – Intellectual Property” in this document.

Save as aforesaid, as of the Latest Practicable Date, there were no other trade or service marks, patents, intellectual or industrial property rights which were material in relation to our Group’s business.

C. FURTHER INFORMATION ABOUT OUR DIRECTORS

1. Particulars of Directors’ Service Contracts and Appointment Letters

(a) Executive and non-executive Directors

Each of our executive Director and non-executive Directors has entered into a service contract with us under which the initial term of their service contract shall be three years commencing from the date of their appointment until terminated in accordance with the terms and service contract or by either party giving to the other not less than [3] months’ prior notice.

Pursuant to the service contracts entered into with us, none of the executive and non-executive Directors will receive any remuneration as director’s fee.

(b) Independent non-executive Directors

Each of our independent non-executive Directors has entered into an appointment letter with us effective from [the date of this document]. The initial term of their appointment letters shall commence from the date of their appointment for a period of three years or until the third annual general meeting of our Company after the [REDACTED], whichever is earlier (subject always to re-election as and when required under the Articles of Association) until terminated in accordance with the terms and conditions of the appointment letter or by either party giving to the other not less than one month’s prior notice in writing. Under these appointment letters, each of our independent non-executive Directors will receive an annual director’s fee of US\$[30,000] commencing on the effective date of their appointment.

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Details of our Company’s remuneration policy is described in the section headed “Directors and Senior Management – Remuneration of Directors and Senior Management” in this document.

2. Remuneration of Directors

For the two years ended December 31, 2019 and 2020 and the six months ended June 30, 2021:

- (a) the total amount of salaries, bonuses, allowances, benefits in kind and pension scheme contributions paid or payable by us to the Directors were approximately RMB3.3 million, RMB4.2 million and RMB2.0 million, respectively;
- (b) the total amount of share-based payment expenses paid or payable by us to the Directors were approximately RMB7.7 million, RMB5.0 million and RMB1.4 million, respectively.

The aggregate amount of emoluments which were paid by the Company to the five highest paid individuals of the Group (including both employees and Directors) for the two years ended December 31, 2019 and 2020 and the six months ended June 30, 2021 were approximately RMB21.0 million, RMB21.4 million and RMB11.0 million, respectively.

It is estimated that emoluments of approximately RMB6.3 million in aggregate will be paid to our Directors and proposed Directors in respect of the financial year ending December 31, 2021 under arrangements in force as of the date of this document.

Under the arrangements currently in force, as of the Latest Practicable Date, none of our Directors had a service contract with the Company other than contracts expiring or determinable by the employer within one year without the payment of compensation (other than statutory compensation).

3. Disclosure of Interests

- (a) *Interests and short positions of our Directors in the share capital of our Company following completion of the [REDACTED]*

Immediately following completion of the [REDACTED] (assuming the [REDACTED] outstanding as at the Latest Practicable Date and the [REDACTED] are not exercised), the interests and/or short positions (as applicable) of our Directors and chief executive in the Shares, underlying shares and debentures of our Company and its associated corporations, within the meaning of Part XV of the SFO, which will have to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and/or short positions (as applicable) which they are taken or deemed to have taken under such provisions of the SFO), or which will be required, pursuant to section 352 of the SFO, to be recorded in the register referred to

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therein, or which will be required to be notified to our Company and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules (“**Model Code**”), will be as follows:

Long position in our Company

Name of Director or CEO	Nature of Interest	Number of Shares held immediately following completion of the [REDACTED] ⁽¹⁾	Approximate percentage of interest in our Company immediately following completion of the [REDACTED] ⁽²⁾ (%)
Dr. Xue	Interest in controlled corporation ⁽³⁾	2,604,238	[REDACTED]
	Founder of a discretionary trust ⁽⁴⁾	1,500,000	[REDACTED]
	Beneficial interest ⁽⁵⁾	73,305	[REDACTED]
James Arthur Geraghty	Beneficial interest	65,000	[REDACTED]

Notes:

- Assuming the conversion of the Preferred Shares into Shares on a one-to-one-basis has been completed prior to the [REDACTED]. The number of Shares held are subject to adjustments as a result of the Share Subdivision.
- Assuming the [REDACTED] and the Share Options outstanding as at the Latest Practicable Date are not exercised.
- CTX Pharma Holdings Limited directly held 2,604,238 Shares and is wholly-owned by Dr. Xue. Pursuant to a voting rights proxy agreement dated February 9, 2020, each of Xiangyun Holdings Limited, Apollo China Holdings Limited, Sea&Sky Holdings Limited, Clear Stone Holdings Limited, Hongweix Holdings Limited, Medkelvin Holdings Limited, Chengzhang Holdings Limited, Dingkai Holdings Limited, Merrifield Holdings Limited and Flemingddf Holdings Limited, which held an aggregate of 2,790,416 Shares, voluntarily entrusted all of the voting rights of the Shares held to CTX Pharma Holdings Limited. As such, Dr. Xue is deemed to be interested in an aggregate of 6,967,959 Shares. Such voting rights proxy agreement will terminate upon [REDACTED].
- 1,500,000 Shares of our Company are held by the Family Trust. Under the terms of the Family Trust, Dr. Xue has the power to exercise all the voting rights attached to the Shares of our Company. Accordingly, Dr. Xue is deemed interested in the Shares held by the Family Trust.
- Dr. Xue beneficially holds 73,305 Shares of our Company under his own name.

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(b) Interests and short positions discloseable under Divisions 2 and 3 of Part XV of the SFO

For information on the persons who will, immediately following completion of the [REDACTED], having or be deemed or taken to have beneficial interests or short position in our Shares or underlying shares which would fall to be disclosed to our Company under the provisions of Divisions 2 and 3 of Part XV of the SFO, or directly or indirectly be interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other member of our Group, please see the section headed “Substantial Shareholders” in this document.

Save as set out above, as of the Latest Practicable Date, our Directors were not aware of any persons who would, immediately following completion of the [REDACTED], be interested, directly or indirectly, in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of our Group or had option in respect of such share capital.

4. Disclaimers

Save as disclosed in the sections headed “Directors and Senior Management”, “Financial Information”, “[REDACTED]”, “Substantial Shareholders” and “Appendix IV – Statutory and General Information – C. Further Information about Our Directors” in this document:

- (i) there are no existing or proposed service contracts (excluding contracts expiring or determinable by the employer within one year without payment of compensation (other than statutory compensation)) between the Directors and any member of the Group;
- (ii) none of the Directors or the experts named in the sub-section headed “G. Other Information – 4. Consents of Experts” in this section below has any direct or indirect interest in the promotion of, or in any assets which have been, within the two years immediately preceding the date of this document, acquired or disposed of by or leased to any member of the Group, or are proposed to be acquired or disposed of by or leased to any member of the Group;
- (iii) no commissions, discounts, brokerages or other special terms have been granted in connection with the issue or sale of any Shares in or debentures of our Company within the two years ended on the date of this Document;
- (iv) none of the Directors is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of the Group taken as a whole;

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- (v) taking no account of any Shares which may be taken up under the [REDACTED], so far as is known to any Director or chief executive of our Company, no other person (other than a Director or chief executive of our Company) will, immediately following completion of the [REDACTED], have interests or short positions in the Shares or underlying shares which would fall to be disclosed to the Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO or (not being a member of the Group), be interested, directly or indirectly, in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of the Group; and
- (vi) none of the Directors or chief executive of our Company has any interests or short positions in the Shares, underlying shares or debentures of our Company or its associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to the Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which he is taken or deemed to have under such provisions of the SFO) or which will be required, pursuant to section 352 of the SFO, to be entered into the register referred to therein, or will be required, pursuant to the Model Code, to be notified to the Company and the Stock Exchange.

D. [REDACTED] EQUITY INCENTIVE PLAN

In April 2016, the board of directors of CANbridge Life Sciences approved an equity incentive plan, under which 1,250,000 shares of CANbridge Life Sciences were reserved for granting options to its employees (the “CANbridge Beijing Equity Incentive Plan”).

Pursuant to a resolution passed by the Board on July 25, 2019, the 2019 equity incentive plan (the “[REDACTED] Equity Incentive Plan”) was adopted to inherit and replace the CANbridge Beijing Equity Incentive Plan and Shares were granted under the [REDACTED] Equity Incentive Plan to replace the shares of CANbridge Life Sciences previously granted. The terms of the [REDACTED] Equity Incentive Plan are not subject to the provisions of Chapter 17 of the Listing Rules as they (i) do not involve any grant of options by our Company to subscribe for new Shares after the [REDACTED] and (ii) only involves the grant of restricted shares after the [REDACTED].

The following is a summary of the principal terms of the [REDACTED] Equity Incentive Plan.

(a) Summary of terms

Purpose. The purpose of the [REDACTED] Equity Incentive Plan is to provide incentives to Directors and employees of the Company or any other third party that the Board considers as contributed or will contribute to the Company. The [REDACTED] Equity Incentive Plan allow our Company to provide such persons with opportunities to (i) acquire Shares of the Company pursuant to options granted, (ii) receive restricted share units and (iii) purchase restricted shares (collectively, the “Awards”).

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Eligible Participants. Any Director and employee of the Company, or any advisor, consultant, distributor, contractor, customer, supplier, agent, business partner, joint venture business partner, service provider or other third parties who the Board considers, in its sole discretion, has contributed or will contribute to the Company are eligible to participate in the [REDACTED] Equity Incentive Plan. Reference factors for the selection of participants include: (i) the Company's long-term development strategy; (ii) the status of the Company's business development; (iii) the Company's human resources strategy; (iv) the functional characteristics of the participant's position; (v) the length of service of the participant; and (vi) the job performance of the participant.

Duration. Unless terminated sooner in accordance with the terms of the [REDACTED] Equity Incentive Plan, the [REDACTED] Equity Incentive Plan will continue in effect, with regard to the making of Awards, for a term of ten years from their respective effective date. Awards granted during the term of the [REDACTED] Equity Incentive Plan may continue to be valid and exercisable in accordance with their terms of grant.

Maximum Number of Shares. As at the Latest Practicable Date, the maximum number of Shares that may be subject to the Awards granted and sold under the 2019 Equity Incentive Plan is 5,454,923 Shares and Share Options to subscribe for 5,584,800 Shares thereof had been granted, with (i) Share Options to subscribe for 129,877 Shares having lapsed following the resignation of certain grantees; (ii) Share Options corresponding to 686,005 Shares having been exercised; and (iii) Share Options corresponding to the remaining [4,768,918] Shares being outstanding. The Company amended the 2019 Equity Incentive Plan to increase the maximum number of Shares that may be subject to the Awards to 5,454,923 Shares, and granted additional Share Options to subscribe for an aggregate of 2,867,886 Shares in [and after July 2021]. No Shares remain available for grant under the [REDACTED] Equity Incentive Plan. At all times during the term of the [REDACTED] Equity Incentive Plan and while any Awards are outstanding, the Company will retain as authorized and unissued Shares at least the number of Shares from time to time required to satisfy the terms of the [REDACTED] Equity Incentive Plan and such Awards, or otherwise assure itself of its ability to perform its obligations thereunder.

Administration. The [REDACTED] Equity Incentive Plan will be administered by the Board. The Board will be responsible for the approval, amendment to and termination of the [REDACTED] Equity Incentive Plan, as well as other major decisions such as determining the types of Awards to be granted, determining the number of Shares or restricted share units to be covered by each Award granted, approving the forms of Award agreements, determining the performance review targets for the eligible participants and determining the terms and conditions of any Award. A committee will be appointed by the Board to be responsible for the actual implementation of the [REDACTED] Equity Incentive Plan.

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Awards. Grant of Awards shall be made in accordance with the [REDACTED] Equity Incentive Plan and in compliance with applicable laws and regulations. Each recipient of an Award shall enter into an Award agreement and any other agreements as determined by the Board. The date of grant of an Award shall be determined by the Company and the recipient at the execution of the Award agreement. The term of each option, restricted share unit or other Award will be stated in the Award agreement.

(i) Options. Subject to terms stating otherwise in the relevant Award agreement or as otherwise determined by the Board, the exercise price for Shares to be issued upon exercise of an option granted under the [REDACTED] Equity Incentive Plan is as below:

For the pool of 1,250,000 Shares reserved under the 2019 Equity Incentive Plan to substitute the shares of CANbridge Life Sciences previously granted under the CANbridge Beijing Equity Incentive Plan

Time of Grant	Exercise Price
Within 2014	RMB1 or fair market value or otherwise determined by the Board
Within 2015	RMB1.5 or fair market value or otherwise determined by the Board
Within 2016	No less than the corresponding portion of the Company's net asset by the end of 2015 or fair market value or otherwise determined by the Board
Within 2017	No less than the corresponding portion of the Company's net asset by the end of 2016 or fair market value or otherwise determined by the Board
Within 2018	No less than the corresponding portion of the Company's net asset by the end of 2017 or fair market value or otherwise determined by the Board
Within 2019 or onwards	No less than the corresponding portion of the Company's net asset by the end of 2018 or fair market value or otherwise determined by the Board

For the remaining pool of 4,204,923 Shares under the 2019 Equity Incentive Plan

Time of Grant	Exercise Price
Within 2019 or onwards	No less than 50% of the last round financing of the Company or fair market value or otherwise determined by the Board

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(ii) Restricted share units and restricted shares. Under the 2019 Equity Incentive Plan, unless otherwise determined by the Board, for awards or restricted share units and restricted shares made within 2019 or onwards, the price to be paid for the granting of restricted share units and the purchase price of restricted shares will be no less than 50% of the last round financing of the Company or fair market value or otherwise determined by the Board.

The consideration to be paid for Shares to be issued upon exercise of an option granted, the granting of a restricted share unit, or the purchase of restricted shares, including the method of payment, will be determined by the Board.

Vesting. Options granted will become vested and exercisable, any restricted share units granted will vest and be settled, and any restricted shares issued pursuant to the [REDACTED] Equity Incentive Plan will be released and no longer be subject to forfeiture or a right of repurchase by the Company, according to the terms set out in the [REDACTED] Equity Incentive Plan, and under such conditions as determined by the Board and set forth in an Award agreement.

Rights. With respect to options granted, notwithstanding the exercise of such option, no right to vote or receive dividends or any other rights as a shareholder will exist until the issuance of the underlying Shares.

Change of Control. In the event a holder of Awards ceases to be an eligible participant upon a change of control event as defined under the [REDACTED] Equity Incentive Plan, any options granted will become vested and exercisable, any restricted units granted will vest and be settled, and any restricted shares issued will be released and no longer be subject to forfeiture or repurchase right of the Company, according to the terms at such times and under such conditions as determined by the Board and set forth in an Award agreement, unless the Board determines otherwise.

Change of Position and Retirement. In the event the position of a holder of Awards is changed as a part of the Company's normal course of business, or ceases to be an eligible participant upon his or her retirement, the Awards granted to him or her, whether vested or released or not, will remain valid in accordance with the terms and conditions of the [REDACTED] Equity Incentive Plan and the Award agreement.

Resignation and Loss of Ability to Work. In the event the holder of Awards leaves the Company due to non-renewal of the individual's employment or other agreement upon expiration or voluntary resignation, or the holder of Awards loses the ability to work for any reason other than the performance of his or her duty for the Company, (i) the unvested or unreleased portion of the Awards shall be immediately forfeited; (ii) the vested and unexercised portion of the Awards shall be exercisable in accordance with the terms and conditions of the [REDACTED] Equity Incentive Plan and the Award agreement.

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Dismissal. In the event a holder of Awards is dismissed by the Company due to his or her unqualified personal assessment, incompetence at work, breach of the individual's employment or other agreement with the Company, violation of any rule or policy of the Company, violation of any law, or code of business conduct, or divulgence of any secret of the Company, dereliction or neglect of duty or any other similar action that materially damage the interest or reputation of the Company, (i) all Awards, whether vested or released or not, shall be immediately forfeited, (ii) all issued Shares (if any) shall be repurchased by the Company at the price equal to the amount actually paid by the holder, and all other benefits received by the holder under the Awards shall be repaid/returned to the Company, and (iii) the Holder shall indemnify the Company against any loss suffered by the Company as a result thereof.

Death. In the event a holder of Awards dies due to the performance of his or her duty for the Company, the Awards granted to him or her, whether vested or released or not, shall be valid and shall be handled by the holder's estate or by a person who acquires the right to exercise the Awards by will or laws of succession in accordance with the terms and conditions of the [REDACTED] Equity Incentive Plan and the Award agreement. In the event a holder of Awards dies for any reason other than the performance of his or her duty for the Company, (i) the unvested or unreleased portion of the Awards shall be immediately forfeited; and (ii) the vested and unexercised portion of the Awards shall be exercisable by the holder's estate or by a person who acquires the right to exercise the Awards by will or laws of succession in accordance with the terms and conditions of the [REDACTED] Equity Incentive Plan and the Award agreement.

Buyout. The Board may at any time offer to buy out an Award previously granted for a payment in cash or Shares, based on such terms and conditions as the Board may establish.

Other circumstances. During the implementation of the [REDACTED] Equity Incentive Plan, upon occurrence of the following events to any holder of Awards: (i) all Awards, whether vested or released or not, shall be immediately forfeited, (ii) all issued Shares (if any) shall be repurchased by the Company at the price equal to the amount actually paid by the holder and all other benefits received by the Holder under the Awards shall be repaid/returned to the Company, and (iii) the Holder shall indemnify the Company against any loss suffered by the Company as a result thereof:

- (i) the holder is publicly condemned or announced as inappropriate candidate by any internationally recognized stock exchange as defined in the [REDACTED] Equity Incentive Plan;
- (ii) the holder is imposed on any administrative penalty or sentenced to any criminal punishment due to material violation of laws and regulations; or
- (iii) any other event specified in the Company Law of the People's Republic of China (implemented on January 1, 2006) as amended or any other applicable law or regulation upon the occurrence of which such Holder shall not assume the post of a director, supervisor or senior manager of any company.

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Changes in Capitalization. Subject to any required action by the Shareholders of the Company, the number of Shares covered by each outstanding Award, and the number of Shares which have been authorized for issuance under this Plan but as to which Awards have yet been granted or which have been returned to this Plan upon cancellation or expiration of an Award, as well as the price per Share covered by each such outstanding Award, will be proportionately adjusted for any increase or decrease in the number of issued Shares resulting from a reclassification of the Shares. Such adjustment will be made by the Board, whose determination in that respect will be final and binding. Except as expressly provided, no issuance by the Company of equity shares of any class, or securities convertible into equity shares of any class, will affect, and no adjustment by reason thereof will be made with respect to, the number or price of Shares subject to an Award.

Adjustments for Share Splits and Share Dividends. If the Company at any time increases or decreases the number of its outstanding Shares, whether through a Share dividend or any other distribution of Shares upon such Shares, or through a share split, subdivision, consolidation, combination, reclassification or recapitalization involving the Shares, then in relation to the Shares that are affected by one or more of the above events, (i) the number of Shares as to which Awards may be made under this Plan and (ii) the Shares included in each outstanding Award made will be increased or decreased in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the [REDACTED] Equity Incentive Plan.

Dissolution or Liquidation. In the event of the proposed dissolution or liquidation of the Company, the Board will notify each holder as soon as practicable prior to the effective date of such proposed transaction. The Board in its discretion may provide for a holder to have the right to exercise his or her Awards until such number of days prior to such transaction as is determined by the Board as to all of the underlying Shares covered thereby. To the extent it has not been previously exercised, an Award will terminate immediately prior to the consummation of the dissolution or liquidation.

Restrictions on Transfer. Unless otherwise determined by the Board, Awards may not be transferred in a manner other than as provided in the applicable Award agreement, the terms of the [REDACTED] Equity Incentive Plan, in compliance with the applicable laws and regulations, by will or by the laws of succession. Awards may only be exercised during the lifetime of the holders and only by the holder. Unless otherwise approved by the Board, after the [REDACTED], holders may transfer Shares underlying the Awards held by them in accordance with applicable laws and regulations (including any lock-up restrictions), the terms of the [REDACTED] Equity Incentive Plan and the Award agreement.

Amendment and Termination. Subject to the limitations set out in the [REDACTED] Equity Incentive Plan, the Memorandum and Articles, the relevant shareholders agreement and any applicable law and regulation, the Board may at any time amend, suspend or terminate the [REDACTED] Equity Incentive Plan at its discretion.

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(b) Outstanding Share Options granted under the [REDACTED] Equity Incentive Plan

As at the Latest Practicable Date, our Company had granted Share Options under the [REDACTED] Equity Incentive Plan to [177] grantees to subscribe for an aggregate of 5,584,800 Shares (or 55,848,000 Shares as adjusted after the Share Subdivision). Share Options to subscribe for 129,877 Shares (or 1,298,770 Shares as adjusted after the Share Subdivision) had lapsed following the resignation of certain grantees and Share Options corresponding to [686,005] Shares (or [6,860,050] Shares as adjusted after the Share Subdivision) had been exercised. Accordingly, as of the Latest Practicable Date, Share Options to acquire an aggregate of [4,768,918] Shares (or [47,689,180] Shares as adjusted after the Share Subdivision), representing approximately [REDACTED]% of our Shares in issue immediately following completion of the [REDACTED] (assuming that the Share Options outstanding as at the Latest Practicable Date and the [REDACTED] are not exercised), were outstanding under the [REDACTED] Equity Incentive Plan.

As of the Latest Practicable Date, the grantees of Share Options under the [REDACTED] Equity Incentive Plan include Dr. Xue as our CEO and [3] other Directors, [3] members of the senior management and [170] other grantees of our Group. Below is a list of grantees of outstanding Share Options (excluding lapsed and exercised Share Options) under the [REDACTED] Equity Incentive Plan. No Share Option under the [REDACTED] Equity Incentive Plan has been granted to other connected persons of the Company.

Name of grantee	Position held within our Group	Address	Exercise price (per share) <i>(Note 1)</i>	Number of Shares underlying the outstanding Share Options (as adjusted after the Share Subdivision)	Date of grant	Vesting period	Approximate percentage of equity interest in the Company underlying the outstanding Share Options <i>(Note 2)</i>
DIRECTORS							
Dr. Xue	Chairman of the Board, executive Director and Chief Executive Officer	No. 118 Lane 1500 Sizhuan South Rd. Songjiang District Shanghai PRC	USD1.85	620,280	October 17, 2018	<i>(Note 3)</i>	[REDACTED]
			USD5.20	3,861,140	October 17, 2018	<i>(Note 3)</i>	[REDACTED]
Mr. James Arthur Geraghty	Independent non-executive Director	10 Charlesgate East 601 Boston Massachusetts 02215 United States of America	USD11.79 RMB1.00	5,000,000 -	June 11, 2021 December 31, 2018	<i>(Note 3)</i> <i>(Note 4)</i>	[REDACTED] [REDACTED]
			RMB6.22	-	December 31, 2018	<i>(Note 4)</i>	[REDACTED]

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Name of grantee	Position held within our Group	Address	Exercise price (per share) <i>(Note 1)</i>	Number of Shares underlying the outstanding Share Options (as adjusted after the Share Subdivision)	Date of grant	Vesting period	Approximate percentage of equity interest in the Company underlying the outstanding Share Options <i>(Note 2)</i>
			RMB6.22	50,000	December 31, 2018	<i>(Note 5)</i>	[REDACTED]
			USD5.89	1,000,000	July 25, 2019	<i>(Note 3)</i>	[REDACTED]
			USD11.79	250,000	June 11, 2021	<i>(Note 3)</i>	[REDACTED]
Mr. Richard James Gregory	Independent non-executive Director	166 Tower Road Lincoln Massachusetts 01773 United States of America	USD7.06	300,000	April 7, 2020	<i>(Note 6)</i>	[REDACTED]
Mr. Peng Kuan Chan	Independent non-executive Director	Flat B8, 14/F, Block B Viking Garden 40-42 Hing Fat Street Tin Hau Hong Kong	USD7.53	250,000	June 11, 2021	<i>(Note 3)</i>	[REDACTED]
SENIOR MANAGEMENT							
Mr. Glenn Hassan	Chief Financial Officer	699 Boston Post Rd. Weston, MA 02493, United States of America	USD5.20	3,214,540	March 25, 2019	<i>(Note 3)</i>	[REDACTED]
			USD11.79	1,750,000	June 11, 2021	<i>(Note 3)</i>	[REDACTED]
Dr. Yunxiang Zhu	Vice President, Head of Global Research	17 Bayfield Road, Wayland, MA 01778, United States of America	USD11.79	1,200,000	September 15, 2020 and [November] [●] 2021	<i>(Note 3)</i>	[REDACTED]
Mr. Yijun Lu	General Manager of CANbridge China	Room 1002, No.17, Lane 88, Ping Ji Road, Shanghai, the PRC	USD7.53	2,000,000	November 9, 2020	<i>(Note 3)</i>	[REDACTED]
OTHER [170] GRANTEES OR THEIR SUCCESSOR(S)							
			RMB1.00	350,000	May 2013 – [November 2021]	One month from date of grant to five years from date of grant	[REDACTED]
			RMB1.50	300,000		Three years from date of grant to five years from date of grant	[REDACTED]

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Name of grantee	Position held within our Group	Address	Exercise price (per share) <i>(Note 1)</i>	Number of Shares underlying the outstanding Share Options (as adjusted after the Share Subdivision)	Date of grant	Vesting period	Approximate percentage of equity interest in the Company underlying the outstanding Share Options <i>(Note 2)</i>
			USD1.85	400,000		One year from date of grant to four years from date of grant	[REDACTED]
			USD5.20	2,928,230		One year from date of grant to five years from date of grant	[REDACTED]
			RMB5.38	795,500		Six months from date of grant to five years from date of grant	[REDACTED]
			USD5.43	500,000		One year from date of grant to four years from date of grant	[REDACTED]
			USD5.89	2,140,630		One year from date of grant to four years from date of grant	[REDACTED]
			RMB6.22	10,000		One year from date of grant to four years from date of grant	[REDACTED]
			RMB12.70	500,000		One year from date of grant to five years from date of grant	[REDACTED]
			Nil	50,000		Date of grant to three years from date of grant	[REDACTED]

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Name of grantee	Position held within our Group	Address	Exercise price (per share) <i>(Note 1)</i>	Number of Shares underlying the outstanding Share Options (as adjusted after the Share Subdivision)	Date of grant	Vesting period	Approximate percentage of equity interest in the Company underlying the outstanding Share Options <i>(Note 2)</i>
			USD11.79	2,365,000		One year from the date of grant to five years from the date of grant	[REDACTED]
			USD7.53	17,853,860		One year from the date of grant to five years from the date of grant	[REDACTED]
Subtotal of the [170] grantees or their successor(s):				28,193,220			[REDACTED]
Total:				[47,689,180]			[REDACTED]

Notes:

1. The exercise price per share is based on the number of shares before the Share Subdivision.
2. These percentages are calculated on the basis of [REDACTED] Shares in issue immediately following the completion of the Share Subdivision and the [REDACTED] and assuming that the [REDACTED] is not exercised and without taking into account any additional Shares to be issued upon the exercise of the Share Options outstanding as at the Latest Practicable Date.
3. The vesting schedule for these options is: (i) 25% to be vested one year from the date of grant and (ii) 75% to be vested in equal monthly installments over the subsequent 36 months thereafter.
4. The vesting schedule for these options is: 100% to be vested on the date of grant.
5. The vesting schedule for these options is: 100% to be vested in equal monthly installments over the 30 months from the date of grant.
6. The vesting schedule for these options is: 100% to be vested in equal monthly installments over the 36 months from the date of grant.

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(c) Dilution Effect

Assuming full exercise of the Share Options outstanding as at [the Latest Practicable Date], the shareholding of our Shareholders immediately following the [REDACTED] will be diluted by approximately [REDACTED]% if calculated on the basis of [REDACTED] Shares in issue immediately following completion of the [REDACTED] and assuming that the [REDACTED] is not exercised. There is no consequent impact on the earnings per ordinary share for the two years ended December 31, 2019 and 2020 and the six months ended June 30, 2021 as the options would not be included in the calculation of diluted earnings per share due to anti-dilution.

Waiver and Exemption

We have applied for, and have [been granted] (i) a waiver from the Stock Exchange from strict compliance with the disclosure requirements under Rule 17.02(1)(b) of an paragraph 27 of Appendix 1A to the Listing Rules and (ii) an exemption from the SFC from strict compliance with the disclosure requirements under paragraph 10(d) of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance in connection with the information of the options granted under the [REDACTED] Equity Incentive Plan. For further details, please refer to the section headed “Waivers from Strict Compliance with the Listing Rules and Exemptions from Compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance – Waiver and Exemption in relation to the [REDACTED] Equity Incentive Plan” in this document.

(e) Restricted share units and restricted shares

As at the Latest Practicable Date, no restricted share units or restricted shares have been granted under the [REDACTED] Equity Incentive Plan.

(f) General

Application has been made to the Stock Exchange for the [REDACTED] of and permission to deal in the Shares issued and to be issued pursuant to the exercise of any options under [REDACTED] Equity Incentive Plan.

E. [REDACTED] RSU SCHEME

The Company [has] conditionally adopted the [REDACTED] RSU Scheme by Shareholders’ resolutions dated [●], 2021. The [REDACTED] RSU Scheme is not subject to the provisions of Chapter 17 of the Listing Rules as the [REDACTED] RSU Scheme does not involve the grant of options by our Company. The Company may appoint a trustee (the “**RSU Trustee**”) to administer the [REDACTED] RSU Scheme with respect to the grant of any Award (as defined below), by way of restricted share unit(s) (“**RSU(s)**”), which may vest in the form of Shares (the “**Award Shares**”) or the actual selling price of the Award Shares in cash in accordance with the [REDACTED] RSU Scheme.

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1. Eligible Persons to the [REDACTED] RSU Scheme

Any individual, being an employee, director (including executive Directors, non-executive Directors and independent non-executive Directors) or officer, consultant or advisor of any member of the Group or any affiliate (including nominees and/or trustees of any employee benefit trust established for them) (an “**Eligible Person**” and, collectively “**Eligible Persons**”) who the Board considers, in its sole discretion, to have contributed or will contribute to the Group or any affiliate is eligible to receive an award granted by the Board (an “**Award**”), by way of RSUs, which may vest in the form of Award Shares or the actual selling price of the Award Shares of RSUs in cash in accordance with the [REDACTED] RSU Scheme.

2. Purpose of the [REDACTED] RSU Scheme

The purpose of the [REDACTED] RSU Scheme is to align the interests of Eligible Persons’ with those of our Group through ownership of Shares, dividends and other distributions paid on Shares and/or the increase in value of the Shares, and to encourage and retain Eligible Persons to make contributions to the long-term growth and profits of our Group.

3. Awards

An Award gives a selected participant a conditional right, when the RSU vests, to obtain the Award Share or, if in the absolute discretion of the Board, it is not practicable for the selected participant to receive the Award in Shares, the cash equivalent from the sale of the Award Shares. For the avoidance of doubt, the Board at its discretion may from time to time determine that any dividends declared and paid by our Company in relation to the Award Shares be paid to the selected participant even though the Award Shares have not yet vested.

4. Grant of Award

(i) Making the Grant

The Board may, from time to time, at their absolute discretion, grant an Award to a selected participant by way of an award letter (“**Award Letter**”). The Award Letter will specify the Grant Date, the number of Award Shares underlying the Award, the vesting criteria and conditions, the Vesting Date and such other details as the Board may consider necessary.

Each grant of an Award to any Director, chief executive or substantial shareholder of our Company or any of their respective associates shall be subject to the prior approval of the independent non-executive Directors of our Company (excluding any independent non-executive Director who is a proposed recipient of an Award). Our Company will comply with the relevant requirements under Chapter 14A of the Listing Rules for any grant of Shares to connected persons of our Company.

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(ii) Restrictions on Grants and Timing of Grants

The Board may not grant any Award to any selected participant in any of the following circumstances:

- (A) where any requisite approval from any applicable regulatory authorities has not been granted;
- (B) where any member of our Group will be required under applicable securities laws, rules or regulations to issue a document or other [REDACTED] documents in respect of such Award or the [REDACTED] RSU Scheme, unless the Board determines otherwise;
- (C) where such Award would result in a breach by any member of our Group or its directors of any applicable securities laws, rules or regulations in any jurisdiction;
- (D) where such grant of Award would result in a breach of the [REDACTED] RSU Limit (as defined below) or the 25% minimum public float requirement as required under the Listing Rules (or such other percentage as approved or agreed by the Stock Exchange), or would otherwise cause our Company to issue Shares in excess of the permitted amount in the mandate approved by the Shareholders;
- (E) where an Award is to be satisfied by way of issue of new Shares to the RSU Trustee, in any circumstances that cause the total Shares issued or allotted to connected persons to be in excess of the amount permitted in the mandate approved by the Shareholders;
- (F) after inside information has become to our Company's knowledge until (and including) the trading day after our Company has announced the information;
- (G) during the period commencing one month immediately before the earlier of:
 - (1) the date of the Board meeting (as such date is first notified to the Stock Exchange under the Listing Rules) for approving the results of the Company for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules); and
 - (2) the deadline for the Company to announce its results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules), and ending on the date of the results announcement;

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- (H) during the period of 60 days immediately preceding the publication of the annual results of our Company or, if shorter, the period from the end of the relevant financial year up to the publication date of the results;
- (I) during the period of 30 days immediately preceding the publication date of the quarterly (if any) or half-yearly results or, if shorter, the period from the end of the relevant quarterly or half-year period up to the publication of the results; and
- (J) during any period of delay in the publication of a results announcement.

5. Maximum Number of Shares to be Granted

The aggregate number of Shares underlying all grants made pursuant to the [REDACTED] RSU Scheme (excluding Award which have been forfeited in accordance with the [REDACTED] RSU Scheme) will not exceed 5% of the issued share capital of the Company as of the date of approval of the [REDACTED] RSU Scheme without Shareholders' approval (the "[REDACTED] RSU Scheme Limit"), further subject to an annual limit of 5% of the total number of issued share capital of the Company at the relevant time.

6. Rights attached to the Award

Save that the Board at its discretion may from time to time determine that any dividends declared and paid by our Company in relation to the Award Shares be paid to the selected participants even though the RSUs have not yet vested, the selected participant only has a contingent interest in the Award underlying an Award unless and until such Award are actually transferred to the selected participant, nor does he/she have any rights to any related income until the RSUs are vested.

Neither the RSU Trustee nor the selected participants may exercise any voting rights in respect of any Award Shares that have not yet vested.

7. Issue of Shares and/or transfer of funds to the RSU Trustee

Our Company shall, as soon as reasonably practicable and no later than 30 business days from the Grant Date, (i) issue and allot Shares to the RSU Trustee and/or (ii) transfer to the RSU Trustee the necessary funds and instruct the RSU Trustee to acquire Shares through on-market transactions at the prevailing market price, so as to satisfy the Awards.

Our Company shall not issue or allot Award Shares nor instruct the RSU Trustee to acquire Shares through on-market transactions at the prevailing market price, where such action (as applicable) is prohibited under the Listing Rules, the Securities and Futures Ordinance or other applicable laws from time to time. Where such a prohibition causes the prescribed timing imposed by the [REDACTED] RSU Scheme Rules or the trust deed to be missed, such prescribed timing shall be treated as extended until as soon as reasonably practicable after the first Business Day on which the prohibition no longer prevents the relevant action.

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8. Assignment of Awards

Unless express written consent is obtained from the Board, any Award granted under the [REDACTED] RSU Scheme but not yet vested are personal to the selected participants to whom they are granted and cannot be assigned or transferred. A selected participant shall not in any way sell, transfer, charge, mortgage, encumber or create any interest in favor of any other person over or in relation to any Award, or enter into any agreement to do so.

9. Vesting of Awards

The Board may from time to time while the [REDACTED] RSU Scheme is in force and subject to all applicable laws, determine such vesting criteria and conditions or periods for the Award to be vested.

Within a reasonable time period as agreed between the RSU Trustee and the Board from time to time prior to any Vesting Date, the Board will send a vesting notice to the relevant selected participant and instruct the RSU Trustee the extent to which the Award Shares held in the trust shall be transferred and released from the trust to the selected participant or be sold as soon as practicable from the Vesting Date. Subject to the receipt of the vesting notice and notification from the Board, the RSU Trustee will transfer and release the relevant Award in the manner as determined by the Board or sell the relevant Award Shares and pay the Actual Selling Price to the selected participant within a reasonable time period (in both cases with the related income, if any).

If there is an event of change in control of our Company by way of a merger, a privatization of our Company by way of a scheme or by way of an offer, all Awards will become vested and exercisable immediately and no longer be subject to forfeiture or repurchase right of our Company, according to the terms of the [REDACTED] RSU Scheme at such times and under such conditions as determined by the Board and set forth in the letter containing the offer or grant of the relevant Awards unless the Board determines otherwise.

10. Consolidation, subdivision, bonus issue and other distribution

In the event our Company undertakes a subdivision or consolidation of the Shares, corresponding changes will be made to the number of outstanding RSUs that have been granted provided that the adjustments shall be made in such manner as the Board determines to be fair and reasonable in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the [REDACTED] RSU Scheme for the selected participants. All fractional shares (if any) arising out of such consolidation or subdivision in respect of the Award Shares of a selected participant shall be deemed as returned shares and shall not be transferred to the relevant selected participant on the relevant Vesting Date. The RSU Trustee shall hold returned shares to be applied towards future Awards in accordance with the provisions of the [REDACTED] RSU Scheme rules for the purpose of the [REDACTED] RSU Scheme.

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In the event of an issue of Shares by our Company credited as fully paid to the holders of the Shares by way of capitalization of profits or reserves (including share premium account), the Shares attributable to any Award Shares held by the RSU Trustee shall be deemed to be an accretion to such Award Shares and shall be held by the RSU Trustee as if they were Award Shares purchased by the RSU Trustee hereunder and all the provisions hereof in relation to the original Award Shares shall apply to such additional Shares.

In the event of any non-cash distribution or other events not referred to above by reason of which the Board considers an adjustment to an outstanding Award to be fair and reasonable, an adjustment shall be made to the number of outstanding RSUs of each selected participant as the Board shall consider as fair and reasonable, in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the [REDACTED] RSU Scheme for the selected participants. Our Company shall provide such funds, or such directions on application of the returned shares or returned trust funds, as may be required to enable the RSU Trustee to purchase Shares on-market at the prevailing market price to satisfy the additional Award.

In the event of other non-cash and non-scrip distributions made by our Company not otherwise referred to in the [REDACTED] RSU Scheme rules in respect of the Shares held upon trust, the RSU Trustee shall sell such distribution and the net sale proceeds thereof shall be deemed as related income of the Award Shares or returned trust funds of the returned Shares held upon trust as the case may be.

11. Cessation of employment and other events

In the event that a selected participant ceases to be an eligible person of the Company by reason of the summary termination of his employment or office or service on any one or more of the grounds that he has been guilty of gross misconduct, or has been convicted of any criminal offense involving his integrity or honesty that seriously impair the interests and benefits of the relevant company in the Group or (if so determined by the Board in its absolute discretion) on any other ground on which the relevant company in the Group would be entitled to terminate his employment or office summarily at common law or pursuant to any applicable laws or under the selected participant's service contract with relevant company in our Group, (i) all Awards that are at that time unvested shall be immediately forfeited; and (ii) as the Board may determine and to the extent it is practicable and permissible under the Listing Rules and any other applicable laws and regulations, all issued Shares (if any) shall be repurchased by our Company at the price equal to the amount actually paid by the Selected Participant (if any) and all other cash and benefits received by the Selected Participant (if any) under the granting of Awards shall be repaid/returned to our Company or its subsidiaries as determined by the Board.

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12. Alteration of the [REDACTED] RSU Scheme

The [REDACTED] RSU Scheme may be altered in any respect (save for the [REDACTED] RSU Scheme Limit) by a resolution of the Board provided that no such alteration shall operate to affect adversely any subsisting rights of any selected participant unless otherwise provided for in the rules of the [REDACTED] RSU Scheme, except:

- (i) with the consent in writing of selected participants amounting to three-fourths in nominal value of all RSUs held by the RSU Trustee on that date; or
- (ii) with the sanction of a special resolution that is passed at a meeting of the selected participants amounting to three-fourths in nominal value of all RSUs held by the RSU Trustee on that date.

13. Termination

The [REDACTED] RSU Scheme shall terminate on the earlier of:

- (i) the end of the period of ten years commencing on the date on which this scheme is adopted except in respect of any non-vested RSUs granted hereunder prior to the expiration of the [REDACTED] RSU Scheme, for the purpose of giving effect to the vesting in the form of Award Shares of such RSUs or otherwise as may be required in accordance with the provisions of the [REDACTED] RSU Scheme; and
- (ii) such date of early termination as determined by the Board provided that such termination shall not affect any subsisting rights of any selected participant under the rules of the [REDACTED] RSU Scheme, provided further that for the avoidance of doubt, the change in the subsisting rights of a selected participant in this paragraph refers solely to any change in the rights in respect of the RSUs already granted to a selected participant.

14. Administration of the [REDACTED] RSU Scheme

The [REDACTED] RSU Scheme shall be subject to the administration of the Board in accordance with the [REDACTED] RSU Scheme and, where applicable, the Trust Deed. The authority to administer the scheme may be delegated by the Board to a committee of the Board or any person(s) as deemed appropriate at the sole discretion of the Board.

15. General

As of the Latest Practicable Date, no RSU had been granted or agreed to be granted under the [REDACTED] RSU Scheme.

An application has been submitted to the [REDACTED] for the [REDACTED] of, and permission to deal in, the Shares which may be issued pursuant to the [REDACTED] RSU Scheme.

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F. [REDACTED] SHARE OPTION SCHEME

A summary of the principal terms of the [REDACTED] Share Option Scheme conditionally approved and adopted in compliance with Chapter 17 of the Listing Rules by resolutions of our Shareholders on [●], 2021 is as follows.

1. Purpose

The purpose of the [REDACTED] Share Option Scheme is to align the interests of Eligible Persons with those of our Group through ownership of Shares, dividends and other distributions paid on Shares and/or the increase in value of the Shares, and to encourage and retain Eligible Persons to make contributions to the long-term growth and profits of our Group.

2. Selected participants

Any individual, being an employee, director, officer, consultant or advisor of any member of our Group or any affiliate (including nominees and/or trustees of any employee benefit trust established for them) (“**Eligible Person**”) who the Board may in its absolute discretion select to grant an Option to subscribe for such number of Shares as the Board may determine at the Subscription Price (as defined below).

3. Maximum number of Shares

The maximum number of Shares in respect of which Options may be granted under the [REDACTED] Share Option Scheme when aggregated with the maximum number of Shares in respect of which Options may be granted under any other option scheme over Shares shall not exceed 10% of the issued share capital of the same class of the Company as of the date of approval of the [REDACTED] Share Option Scheme (or of the refreshing of the 10% limit) by the shareholders of the Company. Options lapsed in accordance with the terms of the [REDACTED] Share Option Scheme shall not be counted for the purpose of calculating the 10% limit. Within the aforesaid 10% limit (or alternatively subject to the approval of shareholders of the Company in general meeting), the maximum number of Shares to be issued upon exercise of all outstanding Options under this [REDACTED] Share Option Scheme may be increased by increments as determined by the Board, provided that the total number of Shares to be issued upon exercise of all outstanding Options under the [REDACTED] Share Option Scheme and all other schemes of the Company granted and yet to be exercised does not exceed 30% of all the Shares of the same class in issue from time to time. No Option may be granted under the [REDACTED] Share Option Scheme if this will result in the limit being exceeded.

The maximum number of Shares shall be adjusted, in such manner as the auditor of the Company shall certify in writing to the Board to be fair and reasonable, in the event of any alteration in the capital structure of the Company whether by way of capitalization of profits or reserves, rights issue, consolidation, subdivision or reduction of the share capital of the Company provided that no such adjustment shall be made in the event of an issue of Shares as consideration in respect of a transaction to which the Company is a party.

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4. Maximum entitlement of a grantee

Except with the approval of shareholders in general meeting with the prospective Grantee and his associates abstaining from voting, no Option may be granted to any one person such that the total number of Shares issued and to be issued upon exercise of Options and any other Option over the Shares (including exercised, canceled and outstanding Options) granted and to be granted to such person in any 12-month period up to the date of the latest grant exceeds 1% of the Shares in issue from time to time. The Company shall send a circular to its shareholders containing the information required under the Listing Rules. The number and terms of the Options to be granted to such prospective Grantee shall be fixed before the shareholders' approval of the grant of such Options and the date of Board meeting for proposing such further grant should be taken as the Offer Date for the purpose of calculating the Subscription Price.

5. Performance target

Subject to the provisions of the Listing Rules, the Board may in its absolute discretion specify such event, time limit or conditions (if any) as it thinks fit including, without limitation, conditions as to performance criteria to be satisfied and/or the Company and/or the Group which must be satisfied before an Option can be exercised, provided such terms and conditions shall not be inconsistent with any other terms and conditions of the [REDACTED] Share Option Scheme.

6. Subscription price

The amount payable for each Share to be subscribed for under an option ("**Subscription Price**") in the event of the option being exercised shall be determined by the Board at its absolute discretion, but shall be not less than the highest of:

- (i) the closing price of a Share as stated in the daily quotations sheet issued by the Stock Exchange on the date of grant which must be a business day;
- (ii) the average closing price of our Shares as stated in the daily quotations sheets issued by the Stock Exchange for the five business days immediately preceding the date of grant; and
- (iii) the nominal value of a Share on the date of grant,

provided that, for the purpose of determining the Subscription Price where the Shares have been [REDACTED] on the Stock Exchange for less than five business days, the issue price of the Shares in the Company's [REDACTED] of the Shares shall be used as the closing price of the Shares for any business day falling within the period before the [REDACTED] of the Shares on the Stock Exchange.

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7. Rights are personal to grantee

An Option is personal to the grantee and shall not be assignable and no grantee shall in any way sell, transfer, charge, mortgage, encumber or create any interest (legal or beneficial) in favor of any third party over or in relation to any option, except that this clause shall not prejudice the operation of any general provision of law regarding the appointment and capacity of a nominee, attorney, trustee or other personal representative.

8. Options granted to Connected Persons

The approval of independent non-executive Directors of the Company (excluding any independent non-executive director of the Company who is intended to be a grantee of the Option) will be required for each grant of Options to a director, chief executive, or substantial shareholder of the Company or any of their respective associates.

If a grant of Option(s) to a substantial shareholder or an independent non-executive Director of the Company or their respective associates will result in the total number of Shares issued and to be issued upon exercise of all the options granted and to be granted (including options exercised, canceled and outstanding) to such person under the [REDACTED] Share Option Scheme and any other scheme in the 12-month period up to and including the date of such grant:

- (i) representing in aggregate over 0.1% of the Shares in issue from time to time; and
- (ii) having an aggregate value, based on the closing price of the Shares as stated in the Stock Exchange's daily quotations sheet at the date of each grant, in excess of HK\$5 million,

such further grant of Option(s) must be approved by the shareholders of the Company, voting by way of poll. In this case the Board shall procure that all the requirements of the Listing Rules relating to sending a circular to shareholders are complied with. All Connected Persons of the Company shall abstain from voting in favor of the resolution at such general meeting.

9. Grant offer letter and notification of grant of options

An offer of the grant of an Option shall be made to any Grantee by letter in such form as the Board may from time to time determine specifying the number of Shares, the Subscription Price, the Option Period, the date by which the grant must be accepted being a date not more than 28 days after the Offer Date (provided such offer shall be open for acceptance after the effective period of the [REDACTED] Share Option Scheme) and further requiring the Grantee to hold the Option on the terms on which it is to be granted and to be bound by the provisions of the [REDACTED] Share Option Scheme. The letter shall also state that the offer of an Option shall be personal to the Grantee concerned and shall not be

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transferable. The inadvertent non-compliance with the requirements of the above shall not render the grant of an Option invalid if the Board so determines and makes such remedial action, if any, as it deems appropriate in its absolute discretion.

An Option shall be deemed to have been granted and accepted and to have taken effect when (i) the grant is accepted by the Grantee through the online platform maintained by the trustee or any other party designated by the Company or (ii) the duplicate letter comprising acceptance of the offer of the grant of the Option duly signed by the Grantee is received by the Company within the time period specified in the offer of the grant of the Option.

Any offer of the grant of an Option may be accepted or deemed to have been accepted in respect of any number of Shares up to the number in respect of which the Option is offered provided that it is accepted in respect of a Board Lot or an integral multiple thereof. To the extent that the offer of the grant of an Option is not accepted within 28 days after the Offer Date, it will be deemed to have been irrevocably declined and will lapse, unless the Board in its absolute discretion determines otherwise.

10. Restriction of grant of options

No Option shall be offered or granted:

- (a) to any Eligible Person after inside information has become to the Company's knowledge until (and including) the trading day after the Company has announced the information;
- (b) to any Eligible Person during the period commencing one month immediately before the earlier of:
 - (i) the date of the Board meeting (as such date is first notified to the Stock Exchange under the Listing Rules) for approving the results of the Company for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules); and
 - (ii) the deadline for the Company to announce its results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules), and ending on the date of the results announcement. No Option shall be granted during any period of delay in publishing a results announcement.
- (c) to any director of the Company (except where the Subscription Price is to be determined by the Board at the time of exercise of the Option):
 - (i) during the period of 60 days immediately preceding the publication of the annual results of the Company or, if shorter, the period from the end of the relevant financial year up to the publication of the results; or

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- (ii) during the period of 30 days immediately preceding the publication of the quarterly (if any) or half-yearly results or, if shorter, the period from the end of the relevant quarterly or half-year period up to the publication of the results.

11. Time of exercise of an Option

Subject as provided in the [REDACTED] Share Option Scheme and any conditions specified by the Board, an Option may, subject to the terms and conditions upon which such option is granted, be exercised in whole or in part by the grantee giving notice in writing to our Company in such form as the Board may from time to time determine stating that the option is thereby exercised and the number of Shares in respect of which it is exercised.

12. Lapse of Option

Any Option shall elapse automatically and not be exercisable on the earliest of:

- (a) the expiry of the Option Period or other applicable exercisable periods under the [REDACTED] Share Option Scheme;
- (b) the date of the commencement of the winding-up of the Company;
- (c) the date on which the Grantee ceases to be an Eligible Person of the Company by reason of the summary termination of his employment or office or service on any one or more of the grounds that he has been guilty of gross misconduct, or has been convicted of any criminal offense involving his integrity or honesty that seriously impair the interests or benefits of the relevant company in the Group or (if so determined by the Board in its absolute discretion) on any other ground on which the relevant company in the Group would be entitled to terminate his employment or office summarily at common law or pursuant to any applicable laws or under the Grantee's service contract with relevant company in the Group;
- (d) where the Grantee is an Eligible Person of a subsidiary or a consolidated affiliated entity of the Company, the date on which such subsidiary or consolidated affiliated entity of the Company ceases to be a member of the Group;
- (e) the date on which the Option is canceled by the Board;
- (f) the date on which the Grantee commits a breach of relevant clauses that rights are personal to the Grantees; or
- (g) the occurrence or non-occurrence of any event, expiry of any period, or non-satisfaction of any condition, as specified in the letter containing the offer or grant of the relevant Option.

13. Voting and dividend rights

No dividends shall be payable and no voting rights shall be exercisable in relation to any options or Shares that are the subject of options that have not been exercised.

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14. Effects of alterations in the capital structure of our Company

In the event of any alteration in the capital structure of the Company whilst any Option remains exercisable, whether by way of capitalization of profits or reserves, rights issue, consolidation, subdivision or reduction of the share capital of the Company in accordance with applicable laws and regulatory requirements (other than an issue of Shares as consideration in respect of a transaction to which the Company is a party), such corresponding adjustments (if any) shall be made to:

- (a) the number or nominal amount of Shares, the subject matter of the Option (insofar as it is unexercised); and/or
- (b) the aggregate number of Shares subject to outstanding Options; and/or
- (c) the Subscription Price; and/or
- (d) the method of exercise of the Option,

as the auditor of the Company shall certify in writing to the Board to be in their opinion fair and reasonable, provided that any adjustment shall be made on the basis that the proportion of the issued share capital of the Company to which a Grantee is entitled after such adjustment shall remain the same, or as nearly as possible the same as that to which he was entitled to subscribe had he exercised all the Options held by him immediately before such adjustment, but so that no such adjustment shall be made the effect of which would be to enable any Share to be issued at less than its nominal value, or to alter any terms of the relevant Option to the advantage of the Grantee without the approval of the shareholders of the Company.

If there has been any alteration in the capital structure of the Company as referred to above the Company shall, upon receipt of a notice from the Grantee, inform the Grantee of such alteration and shall either inform the Grantee of the adjustment to be made pursuant to the certificate of the auditor of the Company obtained by the Company for such purpose, or if no such certificate has yet been obtained, inform the Grantee of such fact and instruct the auditor of the Company to issue a certificate in that regard.

15. Rights on takeover and schemes of compromise or arrangement

If a general or partial offer (whether by way of take-over offer, share repurchase offer or otherwise in like manner other than by way of a scheme of arrangement) is made to all the holders of Shares (or all such holders other than the offeror and/or any person controlled by the offeror and/or any person acting in association or in concert with the offeror) the Company shall use its best endeavors to procure that such offer is extended to all the Grantees (on the same terms mutatis mutandis, and assuming that they will become, by the exercise in full of the Options granted to them, shareholders of the Company). If such offer becomes or is

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declared unconditional, the Grantee (or his legal personal representative(s)) shall be entitled to exercise his outstanding Option(s) in full at any time within 14 days after the date on which such general offer becomes or is declared unconditional.

16. Rights on a voluntary winding up

In the event of an effective resolution being passed for the voluntary winding-up of the Company or an order of the court being made for the winding-up of the Company, notice thereof shall be given by the Company to Grantees with Options outstanding in full or in part at such date. If a Grantee immediately prior to such event had any outstanding Options, the Grantee (or his legal personal representative(s)) may by notice in writing to the Company within 21 days after the date of such resolution elect to be treated as if the Options had been exercised immediately before the passing of such resolution either to its full extent or to the extent specified in the notice, such notice to be accompanied by a remittance for the full amount of the aggregate Subscription Price for the Shares in respect of which the notice is given, whereupon the Grantee shall be duly issued and allotted with the relevant Shares (or treated as such by the Company) and entitled to receive out of the assets available in the liquidation *pari passu* with the holders of Shares such sum as would have been received in respect of the Shares that are the subject of such election.

17. Ranking of Shares

The Shares to be allotted upon the exercise of an Option will be subject to all the provisions of the Articles of Association of the Company for the time being in force and will rank *pari passu* with the fully paid Shares in issue on the date of allotment and accordingly will entitle the holders to participate in all dividends and other distributions paid or made on or after the date of allotment other than any dividend or other distribution previously declared or recommended or resolved to be paid or made if the record date therefor falls before the date of allotment.

18. Duration

The [REDACTED] Share Option Scheme shall be valid and effective for a period of 10 years commencing on the date when the [REDACTED] Share Option Scheme becomes unconditional, after which period no further Options will be granted by the provisions of the [REDACTED] Share Option Scheme, but the provisions of this [REDACTED] Share Option Scheme shall remain in full force and effect to the extent necessary to give effect to the exercise of any Options granted prior thereto or otherwise as may be required in accordance with the provisions of the [REDACTED] Share Option Scheme.

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19. Alteration of the [REDACTED] Share Option Scheme

The Board may subject to the rules of the [REDACTED] Share Option Scheme amend any of the provisions of the [REDACTED] Share Option Scheme (including without limitation amendments in order to comply with changes in legal or regulatory requirements and amendments in order to waive any restrictions, imposed by the provisions of the [REDACTED] Share Option Scheme, which are not found in Chapter 17 of the Listing Rules) at any time (but not so as to affect adversely any rights which have accrued to any grantee at that date).

Those specific provisions of the [REDACTED] Share Option Scheme which relate to the matters set out in Rule 17.03 of the Listing Rules cannot be altered to the advantage of selected participants, and no changes to the authority of the administrator of the [REDACTED] Share Option Scheme in relation to any alteration of the terms of the [REDACTED] Share Option Scheme shall be made, without the prior approval of Shareholders in general meeting. Any alterations to the terms of the [REDACTED] Share Option Scheme which are of a material nature, or any change to the terms and conditions of options granted (including those granted to a substantial shareholder or an independent non-executive director of the Company, or any of their respective associates), must also, to be effective, be approved by our Shareholders in general meeting, except where the alterations take effect automatically under the existing terms of the [REDACTED] Share Option Scheme. The options and the [REDACTED] Share Option Scheme so altered must comply with Chapter 17 of the Listing Rules. Any change to the authority of the Directors or [REDACTED] Share Option Scheme administrators in relation to any alteration to the terms of the [REDACTED] Share Option Scheme must be approved by Shareholders in general meeting.

20. Termination

The Company by an ordinary resolution in general meeting or the Board may at any time terminate the operation of the [REDACTED] Share Option Scheme and in such event no further Options will be offered but the provisions of the [REDACTED] Share Option Scheme shall remain in full force in all other respects. All Options granted but unexercised prior to such termination shall continue to be valid and exercisable in accordance with their terms of issue after the termination of the [REDACTED] Share Option Scheme.

21. Value of Option

Our Directors consider it inappropriate to disclose the value of options which may be granted under the [REDACTED] Share Option Scheme as if they had been granted as of the Latest Practicable Date. Any such valuation will have to be made on the basis of a certain option pricing model or other method that depends on various assumptions including the exercise price, the exercise period, interest rate, expected volatility and other variables. As no options have been granted, certain variables are not available for calculating the value of options. Our Directors believe that any calculation of the value of options granted as of the Latest Practicable Date would be based on a number of speculative assumptions that are not meaningful and would be misleading to investors.

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22. Administration of the [REDACTED] Share Option Scheme

The [REDACTED] Share Option Scheme shall be subject to the administration of the Board who may delegate all or part of such administration to a committee or any other authorised agent(s) as deemed appropriate at the sole discretion of the Board.

23. General

As of the Latest Practicable Date, no option had been granted or agreed to be granted under the [REDACTED] Share Option Scheme.

[An application has been made to the [REDACTED] of the Stock Exchange for [REDACTED] of and permission to deal in the Shares which may be issued pursuant to the exercise of any options which may be granted under the [REDACTED] Share Option Scheme.]

G. 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

Save as disclosed in the section headed "Risk Factors" in this document and so far as our Directors are aware, no litigation or claim of material importance is pending or threatened against any member of our Group.

3. Joint Sponsors

The Joint Sponsors have made an application on our behalf to the Stock Exchange for the [REDACTED] of, and permission to deal in, the Shares in issue (including the Shares or conversion of Preferred Shares) and to be issued pursuant to (i) the [REDACTED], (ii) the [REDACTED] and (iii) the [REDACTED] Equity Incentive Plan.

The Joint Sponsors satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules. Each of the Joint Sponsors will receive a fee of US\$[REDACTED] for acting as a sponsor for the [REDACTED].

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4. Consents of Experts

The following experts have each given and have not withdrawn their respective written consents to the issue of this document with copies of their reports, letters, opinions or summaries of opinions (as the case may be) and the references to their names included herein in the form and context in which they are respectively included.

Name	Qualification
Morgan Stanley Asia Limited	Licensed corporation to conduct Type 1 (dealing in securities), Type 4 (advising on securities), Type 5 (advising on futures contracts), Type 6 (advising on corporate finance) and Type 9 (asset management) regulated activities as defined under the SFO
Jefferies Hong Kong Limited	Licensed corporation to conduct Type 1 (dealing in securities), Type 4 (advising on securities) and Type 6 (advising on corporate finance) regulated activities as defined under the SFO
Ernst & Young	Certified Public Accountant under the Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong) Registered Public Interest Entity Auditor under Financial Reporting Council Ordinance (Chapter 588 of the Laws of Hong Kong)
King & Wood Mallesons	Legal adviser to our Company as to PRC law
Harney Westwood & Riegels	Legal adviser to our Company as to Cayman Islands 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.

5. Binding Effect

This document shall have the effect, if an application is made in pursuance hereof, of rendering all persons concerned bound by all the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

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6. Bilingual Document

The English language and Chinese language versions of this document are being published separately in reliance upon the exemption provided by section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

7. Preliminary expenses

We have not incurred any material preliminary expense.

8. Other Disclaimers

(a) Save as disclosed in the sections headed “Financial Information” and “[REDACTED]” in this document, within the two years immediately preceding the date of this document:

- (i) no share or loan capital or debenture of our Company or any of our subsidiaries has been issued or agreed to be issued or is proposed to be issued for cash or as fully or partly paid other than in cash or otherwise;
- (ii) no share or loan capital of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option; and
- (iii) no commissions, discounts, brokerages or other special terms have been granted or agreed to be granted in connection with the issue or sale of any share or loan capital of our Company or any of our subsidiaries

(b) Save as disclosed in the sections headed “Financial Information”, “[REDACTED]” and “Risk Factors” in this document, within the two years immediately preceding the date of this document:

- (i) there are no founder, management or deferred shares nor any debentures in our Company or any of our subsidiaries;
- (ii) no share or loan capital or debenture of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option; and
- (iii) no commissions, discounts, brokerages or other special terms have been granted in connection with the issue or sale of any share or loan capital of our Company or any of its subsidiaries by our Company for subscribing or agreeing to subscribe, or procuring or agreeing to procure subscriptions, for any shares in or debentures of our Company or any of our subsidiaries.

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- (c) Save as disclosed in the sub-section headed “B. Further Information about our Business – 1. Summary of Material Contracts” in this section, none of our Directors or proposed Directors or experts (as named in this document), have any interest, direct or indirect, in any assets which have been, within the two years immediately preceding the date of this document, acquired or disposed of by or leased to, any member of our Group, or are proposed to be acquired or disposed of by or leased to any member of our Group.

- (d) We do not have any promoters. No cash, securities or other benefit has been paid, allotted or given nor are any proposed to be paid, allotted or given to any promoters in connection with the [REDACTED] and the related transactions described in this document within the two years immediately preceding the date of this Document.

- (e) There is no restriction affecting the remittance of profits or repatriation of capital of our Company into Hong Kong from outside Hong Kong.

- (f) None of our Directors or their respective close associates or any Shareholders of our Company (who to the knowledge of our Directors owns more than 5% of the number of our issued shares) has any interest in our five largest suppliers or our five largest customers.

**APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR
OF COMPANIES AND AVAILABLE ON DISPLAY**

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES

The documents attached to the copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were:

- (a) a copy of the [REDACTED],
- (b) the written consents referred to in the section headed “Appendix IV – Statutory and General Information – G. Other Information – 4. Consents of Experts” in this document, and
- (c) a copy of each of the material contracts referred to in the section headed “Appendix IV – Statutory and General Information – B. Further Information about our Business – 1. Summary of Material Contracts” in this document.

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 and our website at www.canbridgepharma.com during a period of 14 days from the date of this document:

- (a) our Memorandum and the Articles;
- (b) the Cayman Companies Act;
- (c) the Accountants’ Report and the unaudited [REDACTED] financial information of our Group prepared by Ernst & Young, the texts of which are set out in Appendices I and II;
- (d) the audited consolidated financial statements of our Company for the two financial years ended December 31, 2019 and 2020 and the six months ended June 30, 2021;
- (e) the PRC legal opinions issued by King & Wood Mallesons, our PRC legal adviser in respect of certain general corporate matters and property interests of our Group;
- (f) the letter of advice prepared by Harney Westwood & Riegels, our legal adviser on Cayman Islands law, summarising the constitution of our Company and certain aspects of the Cayman Companies Act referred to in Appendix III;
- (g) the industry report prepared by Frost & Sullivan referred to in the section headed “Industry Overview” in this document;

**APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR
OF COMPANIES AND AVAILABLE ON DISPLAY**

- (h) the material contracts referred to under the section headed “Appendix IV – Statutory and General Information – B. Further Information about Our Business – 1. Summary of Material Contracts” in this document;
- (i) the service agreements and the letters of appointment with our Directors referred to in the section headed “Appendix IV – Statutory and General Information – C. Further Information about our Directors – 1. Particulars of Directors’ Service Contracts and Appointment Letters” in this document;
- (j) the written consents referred to under the section headed “Appendix IV – Statutory and General Information – G. Other Information – 4. Consents of Experts” in this document;
- (k) the terms of the [REDACTED] Equity Incentive Plan;
- (l) the terms of the [REDACTED] RSU Scheme; and
- (m) the terms of the [REDACTED] Share Option Scheme.

DOCUMENT AVAILABLE FOR INSPECTION

[A copy of a list of grantees under the [REDACTED] Equity Incentive Plan, containing all details as required under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance, will be available for inspection at the office of Davis Polk & Wardwell, Hong Kong Solicitors, at The Hong Kong Club Building, 3A Chater Road, Central, Hong Kong, during normal business hours up to and including the date which is 14 days from the date of this document.]