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Application Proof of

Laekna, Inc.
來凱醫藥有限公司

(Incorporated in the Cayman Islands with limited liability)

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Laekna, Inc.

來凱醫藥有限公司

(Incorporated in the Cayman Islands with limited liability)

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[REDACTED]

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[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.

BUSINESS OVERVIEW

Founded in 2016, we are a science-driven, clinical-stage biotechnology company. We have two Core Products and 13 other pipeline product candidates. Both of our Core Products are in-licensed from Novartis. Core Product LAE002 is an adenosine triphosphate (ATP) competitive AKT inhibitor for the treatment of ovarian cancer, prostate cancer, breast cancer and PD-1/PD-L1 drug-resistant solid tumors. The other Core Product LAE001 is an androgen synthesis inhibitor that simultaneously inhibits cytochrome P450 family 17 subfamily A member 1 (CYP17A1) and cytochrome P450 family 11 subfamily B member 2 (CYP11B2) for the treatment of prostate cancer. We have initiated one registrational clinical trial and another five clinical trials for our Core Products LAE002 and LAE001. Among these six clinical trials, three are multi-regional clinical trials (MRCTs) designed to address medical needs in the standard of care (SOC)-resistant cancers. As of the Latest Practicable Date, we owned 163 patents and patent applications (including in-licensed patents and patent applications with global rights).

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCTS AND OTHER PIPELINE PRODUCTS.

Our Pipeline

We have obtained global rights to develop, manufacture and commercialize LAE002, LAE001, LAE005 and LAE003 under our licensing agreement with Novartis Pharma AG (“Novartis”). The following chart summarizes the development status of our clinical-stage drug candidates and selected pre-clinical-stage drug candidates as of the Latest Practicable Date.

SUMMARY

Drug Candidate	Target Mechanism	Indications	Lead Discovery	Proof of Mechanism	CMC IND Enabling	Phase I	Phase II	Commercial Rights	Upcoming Major Milestones	Licensors/Partner
Cancer	+ Paclitaxel	AKT + Chemotherapy PROC (second- to sixth-line treatment)	MRCT (U.S. and China) <i>Registration⁽¹⁾</i>					Global	NDA submission with the FDA and NMPA in 4Q 2023	NOVARTIS
	+ LAE001 + Prednisone	AKT + CYP17A mCRPC following SOC Treatment (second- to fourth-line treatment)	MRCT (U.S. and South Korea) ⁽²⁾						Phase II read-out in 2Q 2023	NOVARTIS
	+ Sintilimab + Chemotherapy	AKT + PD-1 PD-/PD-L1 Resistant Solid Tumors							Phase I read-out in 4Q 2023	NOVARTIS Innovvent
	LAE002 + Chemotherapy	AKT + PD-L1 TNBC (second- to third-line treatment)							Phase I read-out in 1Q 2023	NOVARTIS
	+ Nab-Paclitaxel	AKT + PD-L1 + chemotherapy Locally Advanced or Metastatic HR+/HER2-Breast Cancer (second- to third-line treatment)							NDA submission with the FDA and NMPA in 2H 2025	NOVARTIS
	+ Fulvestrant	AKT + ER							Phase II read-out in 3Q 2023	NOVARTIS
	LAE001	CYP17A/CYP11B2 (first-line treatment) mHSPC							Progression into clinical stages in the U.S. by 1Q 2023	NOVARTIS
	LAE102	ActRIIA Cancer							IND application with FDA or NMPA by 4Q 2024	
	LAE109	NK / T regulator Cancer							IND application with FDA or NMPA by 2Q 2024	
	LAE111	NK / Ø regulator Cancer							IND application with FDA or NMPA by 2Q 2024	
LAE113	NK / T regulator Cancer							IND application with FDA or NMPA by 2Q 2024		
LAE117	NK / T regulator Cancer							IND application with FDA or NMPA by 2025		
LAE112	TAA Cancer							IND application with FDA or NMPA by 3Q 2024		
LAE119	Low molecular weight compounds Cancer							IND application with FDA or NMPA by 4Q 2024		
LAE120	Low molecular weight compounds Cancer							IND application with FDA or NMPA by 4Q 2024		
LAE104	aHSC depletion Liver Fibrosis								IND application with FDA or TGA by 2025	
LAE105	aHSC depletion Liver Fibrosis								IND application with FDA or TGA by 2025	
LAE106	Conditional TGFβ blocker Liver Fibrosis								IND application with FDA or TGA by 2025	
LAE003 ⁽³⁾	AKT HHT/Proteus Syndrome								IND application with FDA and/or NMPA by 3Q 2023	NOVARTIS
Rare Disease										



Core Product

 Internally Discovered

 Global Rights Exclusively Licensed

SUMMARY

Notes:

- (1) The global MRCT Phase II trial would be the registrational trial and appropriate to support product registration. According to the written confirmation issued by FDA in February 2019 and by NMPA in February 2020, FDA and NMPA agreed that this global MRCT Phase II trial would be the registrational trial and appropriate to support drug registration if the clinical results demonstrate good efficacy and safety profile. We aim to make NDA submissions to the FDA and NMPA in the fourth quarter of 2023.
- (2) The trial is a Phase I/II MRCT covering clinical sites in the U.S. and South Korea. Phase I study was completed in the U.S. in February 2021. We plan to complete the patient recruitment in both the U.S. and South Korea by March 2023, and obtain the preliminary clinical results from the U.S. and South Korea in the second quarter of 2023. Furthermore, the Phase III registrational trial for the same indication is planned to be a MRCT in the U.S., Asia and Europe, and we expect to initiate this MRCT in the U.S. first in the second half of 2023 and submit an NDA to the FDA and NMPA in 2025.
- (3) This is a Phase I/II study with collaboration with Innovent in China, and currently in Phase I stage with patients enrolling. We plan to complete the Phase I study with preliminary results in the fourth quarter of 2023.
- (4) This is a Phase I/II study in China, and currently in Phase I stage with patients enrolling. We plan to initiate the Phase II study in China in the first quarter of 2024 and complete the Phase II study in China in the fourth quarter of 2025. This study is planned to be expanded to a MRCT in China and the U.S. at the registrational stage.
- (5) LAE002+fulvestrant Phase Ib/III study does not require a Phase II clinical trial prior to beginning registrational III clinical trials. This is a Phase Ib/III study in China and the U.S., and currently in Phase Ib stage in China and the U.S. with patients enrolling. We plan to complete the Phase Ib part in China and the U.S. with preliminary results in the second quarter of 2023 and initiate the MRCT Phase III study in China and the U.S. in the second half of 2023, with top-line results expected in the first half of 2025 and NDA submissions to the FDA and the NMPA in the second half of 2025.
- (6) This is a Phase I/II study of LAE001 for mCRPC conducted only in China. We completed the Phase I study of LAE001 for mCRPC in China on September 13, 2021. We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC. As part of our clinical development strategy for LAE001 in prostate cancer and based on the clinical data from trials on mCRPC, we plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S. and apply the NDA for mHSPC with the NMPA and the FDA in 2027.
- (7) LAE003 has been conducted in several Phase I, Phase II clinical trials in various cancer indications prior to our in-licensing. We plan to repurpose the drug for rare disease indications with partners.

Glossary & abbreviations:

PROC: platinum-resistant ovarian cancer; mCRPC: metastatic castration-resistant prostate cancer; mHSPC: metastatic hormone-sensitive prostate cancer; ER: estrogen receptor; TNBC: triple negative breast cancer; HHT: hereditary hemorrhagic telangiectasia

SUMMARY

Drug Candidates	Highlights
Core Product LAE002	LAE002 is an ATP competitive AKT inhibitor. We in-licensed LAE002 from Novartis in 2018. Prior to our in-licensing, 11 clinical trials had been conducted to demonstrate the safety and efficacy profiles of LAE002 by Novartis and GlaxoSmithKline plc. In the Phase I/II study conducted by Novartis, LAE002 showed potential anti-tumor efficacy in PROC patients. In pre-clinical studies, LAE002 demonstrated its ability to restore platinum/paclitaxel sensitivity in PROC cell lines. After the in-licensing, we also identified the therapeutic potential of combining LAE002, prednisone and LAE001 and observed their synergistic anti-tumor efficacy in mCRPC patients as second- to fourth-line treatments. According to Frost & Sullivan, there are two AKT inhibitors that have entered registrational clinical trials globally.
Core Product LAE001	LAE001 is an androgen synthesis inhibitor that inhibits both CYP17A1 and CYP11B2. We in-licensed LAE001 from Novartis in 2017. According to Frost & Sullivan, LAE001 is the only dual CYP17A1/CYP11B2 inhibitor in clinical trial for the treatment of prostate cancer globally. Abiraterone acetate, a CYP17A1 enzyme inhibitor, is currently approved only for use in combination with prednisone. Prolonged cumulative doses or short-term high dose exposure to prednisone may lead to adverse events. Our completed Phase I study showed safety, preliminary anti-tumor efficacy and potential clinical benefits for LAE001 monotherapy without the use of prednisone in mCRPC patients. We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC.
LAE005	LAE005 is developed to be a highly affinitive, ligand-blocking, humanized anti-PD-L1 IgG4 antibody. In pre-clinical and clinical studies, LAE005 demonstrated its binding ability to PD-L1 and anti-tumor activities. Specifically, we are evaluating the therapeutic potential of the combination therapy of LAE002 and LAE005 in patients with TNBC.
LAE003	LAE003 is developed to be a potent ATP competitive AKT inhibitor. In pre-clinical studies, LAE003 showed potency and selectivity to AKT1, AKT2 and AKT3. LAE003 is currently in clinical stage development as a treatment of cancer and we plan to reposition it as a treatment of hereditary hemorrhagic telangiectasia and proteus syndrome.

SUMMARY

Drug Candidates	Highlights
LAE102	LAE102 is our most advanced internally discovered drug candidate for cancer treatment. It is a potent and selective activin receptor type IIA (ActRIIA) monoclonal antibody (mAb) that shows anti-tumor activity and ability to increase the bodyweight of cancer-bearing animals in pre-clinical animal models.
LAE105	LAE105 is our most advanced internally discovered drug candidate for liver fibrosis treatment, which targets activated hepatic stellate cells (aHSC) depletion and has entered into proof-of-mechanism pre-clinical studies.

Our Market Opportunities

Although the field of cancer treatment has developed significantly in the past decade, a large proportion of cancer patients find themselves in the absence of effective or safe treatments. The quality of life of those patients is severely affected primarily attributable to SOC resistance and/or intolerable toxicity, resulting in a large unmet medical need and socioeconomic burden. Among those cancers of unmet medical needs, platinum-resistant ovarian cancer (PROC), metastatic castration-resistant prostate cancer (mCRPC), HR+/HER2- metastatic breast cancer (HR+/HER2- mBC) and triple negative breast cancer (TNBC) are some of the diseases with limited SOC options and unsatisfactory treatment outcomes.

- PROC. According to Frost & Sullivan, the global and China incidence of ovarian cancer is expected to increase from 319.8 thousand and 56.2 thousand in 2021 to 374.2 thousand and 62.7 thousand in 2030, respectively. The SOC mainly consists of debulking surgery and platinum-based chemotherapy. Although platinum-based chemotherapy is normally effective at inducing an initial response, more than 80% of patients with epithelial ovarian cancer who achieve a full remission following first-line therapy will develop recurrent disease. PROC is broadly defined as ovarian cancer recurrence within six months of completing platinum-based chemotherapy, either in the primary or recurrent setting. PROC is generally associated with low response rates to standard chemotherapy with the ORR of 10% to 15%, and median PFS of 3.5 months only, indicating limited effective treatment options and poor prognosis. Treatment options are limited for PROC. The only approved PARP inhibitor is only recommended for BRCA-mutated ovarian cancer. Survival data from a clinical trial signaled that PARP inhibitors may not work as well as chemotherapy for patients with recurrent ovarian cancer who have received three or more lines of treatment. As a result, FDA approvals have been withdrawn for PARP inhibitors as third-line or later treatment for recurrent ovarian cancer, thereby leaving great unmet needs for effective therapies for late line ovarian cancer. Our preliminary clinical results of Phase II MRCT of LAE002 in combination with chemotherapy for PROC indicated LAE002’s therapeutic potential for PROC as a late line treatment.

SUMMARY

- mCRPC. According to Frost & Sullivan, the global and China incidence of prostate cancer is expected to increase from 1,451.5 thousand and 120.9 thousand in 2021 to 1,815.1 thousand and 199.3 thousand in 2030, respectively. Patients with prostate cancer that have relapsed after local therapy or that have distant metastasis usually respond to androgen deprivation therapy (ADT). However, despite receiving ADT, most of these patients eventually experience disease progression and develop castration-resistant prostate cancer (CRPC) within a median of 18 to 24 months from receiving ADT. A substantial majority of CRPC will develop into mCRPC. The current treatment regimen for mCRPC comprises of abiraterone acetate or enzalutamide, and abiraterone acetate requires co-medication with corticosteroids to manage adverse effects. Ultimately, almost all mCRPC patients who received SOC treatments will develop drug resistance with limited treatment options. To address the unmet needs of mCRPC patients who become resistant or not responsive to novel anti-androgen therapy, we are developing LAE002 for mCRPC patients who failed first to third line prior standard treatments that contain at least one novel anti-androgen treatment (i.e., abiraterone, enzalutamide, apalutamide, or darolutamide) with no more than one chemotherapy.
- HR+/HER2- mBC and TNBC. According to Frost & Sullivan, the global and China incidence of breast cancer is expected to increase from 2,301.2 thousand and 336.3 thousand in 2021 to 2,666.4 thousand and 372.4 thousand in 2030, respectively. It is estimated that 60% of patients with breast cancer have HR+/HER2- molecular signature in China. The endocrine/anti-estrogen therapies in combination with CDK4/6 inhibitors have emerged as first- and second-line treatment for patients with HR+/HER2- breast cancer. However, 15% to 20% of patients are intrinsically resistant to treatment, and another 30% to 40% patients will develop acquired resistance to treatment over time, according to Frost & Sullivan. TNBC is a type of breast cancer that is estrogen receptor negative, progesterone receptor negative and human epidermal growth factor receptor 2 negative based on immunohistochemistry, which accounted for approximately 15% of the total breast cancer population globally. TNBC is primarily treated with systemic therapies (chemotherapies) and immune checkpoint inhibitors (ICIs). However, current treatments have relatively poor prognosis, high risk of recurrence, and no significant survival benefit, indicating huge unmet medical needs for the treatment of TNBC. For advanced breast cancer patients with limited treatment options and resistant to current therapies, LAE002 represents a potential new treatment option.

SUMMARY

We plan to use LAE002 as second to sixth line treatment of PROC, second to fourth line treatment of mCRPC, second to third line treatment of TNBC and second to third line treatment of locally advanced or metastatic HR+/HER2- breast cancer. The clinical data obtained by Novartis suggest that LAE002 has a manageable and favorable safety profile for solid tumors, consistent with AKT pathway inhibition. Based on Novartis’ study, we designed a registrational Phase II MRCT to assess the efficacy and safety of LAE002 plus paclitaxel versus paclitaxel in patients with PROC. Based on the results of Roche’s AKT inhibitor study for mCRPC and AstraZeneca’s AKT inhibitor study for breast cancer, we designed clinical studies of LAE002 to evaluate its therapeutic potential on the treatment of mCRPC and breast cancer, respectively. The projected addressable patient pool of LAE002 in 2030 is shown below.

LAE002 indication	Projected addressable patient pool in 2030		
	China	US	Global
PROC (2L to 6L of treatment)	35,000	13,000	160,000
mCRPC (2L to 4L of treatment)	45,000	54,000	314,000
TNBC (2L to 3L treatment)	5,000	3,000	27,000
locally advanced or metastatic HR+/HER2- breast cancer (2L to 3L of treatment)	90,000	91,000	545,000

Source: Frost & Sullivan analysis

Currently, there is no AKT inhibitor approved for commercialization globally, according to Frost & Sullivan. There are seven AKT inhibitor candidates under clinical development for the treatment of cancer globally.

Pipeline Globally				
INN/Drug Code	Company	Phase*	First Post Date**	Indication***
Capivasertib	AstraZeneca	III	2019/6/25	Prostate Cancer (III, HSPC), locally advanced or metastatic breast cancer (III), triple negative breast neoplasms (III), Non-Hodgkin Lymphoma (II), endometrial cancer (II), meningioma (II)
LAE002 (Afuresertib)	Laekna	II (Registrational)	2020/5/5	PROC (II), mCRPC(II), Locally advanced or metastatic HR+/HER2-breast cancer (Ib/III), PD-1/PD-L1 inhibitor resistant solid tumor (I/II)
Ipatasertib	Roche	II	2020/07/13	NSCLC (II), gastric cancer (II), ovarian cancer (II, R/R epithelial OC), glioblastoma multiforme (I/II), endometrial cancer (I/II)
TAS-117	Taiho Oncology	II	2021/2/25	Advanced or metastatic solid tumors (excluding primary brain tumors) harboring germline PTEN inactivating mutations
M2698	EMD Serono	I	2013/10/29	Solid tumors
TAS0612	Taiho Oncology	I	2020/10/14	Advanced or metastatic solid tumors
WGI-0301	HaichangBiotech	I	2022/3/07	Advanced Solid Tumors

SUMMARY

Notes:

- * Phase refers to the drug’s most advanced phase stage of all ongoing studies.
- ** First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced. Information as of March 6, 2023.
- *** The chart shows cancer indications only.

Source: ClinicalTrials.gov, Frost & Sullivan analysis

Currently, there are three AKT inhibitor candidates under clinical development in China, according to Frost & Sullivan.

Pipeline in China				
INN/Drug Code	Company	Phase*	First Post Date**	Indication***
Capivasertib	AstraZeneca	III	2020/10/9	Metastatic CSPC (III), Metastatic CRPC (III), TNBC (III), HR+/HER2-Locally Advanced or Metastatic Breast Cancer (III)
LAE002 (Afuresertib)	Laekna	II (Registrational)	2020/11/19	PROC (including fallopian tube carcinoma and primary peritoneal carcinoma) (II), TNBC (I/II), HR+/HER2- Locally Advanced or Metastatic Breast Cancer (Ib/III), PD-1/P1-L1 resistant solid tumor (I/II)
NTQ1062	Chia Tai Tianqing	I	2021-08-18	Advanced solid tumor

Notes:

- * Phase refers to the drug’s most advanced phase stage of all ongoing studies.
- ** First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced. Information as of March 6, 2023.
- *** The chart shows cancer indications only.

Source: CDE, Frost & Sullivan analysis

SUMMARY

Only one PARP inhibitor (pamiparib) is approved by the NMPA for PROC in China. Two PARP inhibitors (olaparib and niraparib) and an anti-VEGF monoclonal antibody (bevacizumab), are only recommended by the Chinese Society of Clinical Oncology Guideline (“CSCO Guideline”) but have not been approved by the NMPA for the treatment of PROC. The following table sets forth the approved therapy as well as other therapies recommended by the CSCO Guideline for the treatment of PROC in China.

Drug name	Olaparib	Niraparib	Pamiparib	Bevacizumab
NMPA approval status	Y	Y	Y	Y
NMPA approved indications	<p>First-line maintenance treatment for adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD)-positive status</p> <p>Maintenance therapy of platinum-sensitive recurrent ovarian cancer</p> <p>Patients with BRCA-mutated metastatic castration-resistant prostate cancer</p>	<p>First-line maintenance treatment in adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who achieve a complete or partial response to first-line platinum-based chemotherapy</p> <p>Maintenance treatment for platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who achieve a complete or partial response to platinum-based chemotherapy</p>	<p>Treatment of patients with recurrent advanced ovarian, fallopian tube, or primary peritoneal cancer with germline BRCA (gBRCA) mutation who have previously received second-line or more chemotherapy</p>	<p>Metastatic colorectal cancer, with intravenous 5-fluorouracil-based chemotherapy for first- or second-line treatment.</p> <p>Glioblastoma, as a single agent for adult patients with progressive disease following prior therapy.</p> <p>Non-squamous non-small cell lung cancer, with platinum-based chemotherapy for first line treatment of unresectable, locally advanced, recurrent or metastatic disease</p> <p>Combination of atezolizumab (Tecentriq) plus bevacizumab (Avastin) for use in patients with advanced or unresectable hepatocellular carcinoma (HCC)</p> <p>In combination with carboplatin and paclitaxel as the first-line treatment for patients with Stage III or Stage IV epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer after the initial surgical resection</p> <p>In combination with paclitaxel and cisplatin or paclitaxel and topotecan for the treatment of patients with persistent, recurrent or metastatic cervical cancer</p>
China NRDL inclusion	Category B	Category B	Category B	Category B
China NRDL indications	<p>First-line maintenance treatment for adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency (HRD)-positive status</p> <p>Maintenance therapy of platinum-sensitive recurrent ovarian cancer</p>	<p>First-line maintenance treatment in adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who achieve a complete or partial response to first-line platinum-based chemotherapy</p> <p>Maintenance treatment for platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who achieve a complete or partial response to platinum-based chemotherapy</p>	<p>Treatment of patients with recurrent advanced ovarian, fallopian tube, or primary peritoneal cancer with germline BRCA (gBRCA) mutation who have previously received second-line or more chemotherapy</p>	<p>Metastatic colorectal cancer, with intravenous 5-fluorouracil-based chemotherapy for first- or second-line treatment.</p> <p>Glioblastoma, as a single agent for adult patients with progressive disease following prior therapy.</p> <p>Non-squamous non-small cell lung cancer, with platinum-based chemotherapy for first line treatment of unresectable, locally advanced, recurrent or metastatic disease</p> <p>Combination of atezolizumab (Tecentriq) plus bevacizumab (Avastin) for use in patients with advanced or unresectable hepatocellular carcinoma (HCC)</p>
NRDL reimbursement ratio	50-90%	50-90%	50-90%	50-90%
China generic drug approval status	N	N	N	Y
China 2021 median price of original drug (RMB)	102(150mg)	200(100mg)	117(20mg)	1,500(4ml:100mg)
China 2021 median price of generic drug (RMB)	NA	NA	NA	1,150(4ml:100mg)
2021 China original drug monthly treatment cost (thousand RMB)*	12.2	12.0-18.0	21.1	9.0(mCRC) 27.0(NSCLC) 18.0(rGBM) 27.0(HCC) 27.0(OC) 27.0(CC)
2021 China generic drug monthly treatment cost (thousand RMB)*	NA	NA	NA	6.9(mCRC) 20.7(NSCLC) 13.8(rGBM) 20.7(HCC) 20.7(OC) 20.7(CC)

Note*: Assume the patient weighs 60kg.

Source: Frost & Sullivan analysis

SUMMARY

LAE001 faces fierce competition from a number of potential competitors. Currently, there are seven anti-androgen drugs approved for commercialization globally (ex-China) and there are seven anti-androgen drugs approved in China.

Marketed Anti-androgen Drug in the US and China

Approved drug	Flutamide	Bicalutamide	Nilutamide	Abiraterone	Enzalutamide	Apalutamide	Darolutamide	Rezvitutamide
Commercial name	Fugerel	Casodex	Nilandron	Zytiga	Xtandi	Erlada	Nubeqa	艾瑞恩
Mechanism	AR inhibitor	AR inhibitor	AR inhibitor	CYP17A1 inhibitor	AR inhibitor	AR inhibitor	AR inhibitor	AR inhibitor
Company	Ferring	Astra Zeneca	Concordia	Janssen Biotech	Astellas	Janssen Biotech	Bayer	Hengrui Medicine
US approval time	1989*	1995	1996	2011	2012	2018	2019	Not approved
2020 global revenue (million US dollar)	NA	388.3	NA	2,767.6	5,134.3	760.0	317.0	NA
2022 US market price (US dollar)	NA	115.0 (50mg)	285.8 (150mg)	94.8 (250mg)	113.8 (40mg)	117.8 (60mg)	106.7 (300mg)	NA
2022 US monthly treatment cost (thousand US dollar)	NA	3.5 (PFS:NA)	3.5 (PFS:21.1)	11.4 (PFS:NA)	13.6 (mCRPC PFS:19.5 nmCRPC PFS:36.6 mCSPC PFS:NA)	14.1 (mCSPC PFS:NA nmCRPC PFS:40.5)	12.8 (PFS:40.4)	NA
FDA approved indications	B2-C stage prostate cancer, D2 stage metastasis prostate cancer	Metastatic prostate cancer	Metastatic prostate cancer	mCRPC, CSPC	CRPC, mCSPC	mCSPC, nmCRPC	nmCRPC	NA
China approval time	2003	1999	Not approved	2015	2019	2019	2021	2022
NMPA approved indications	Prostate cancer	Late stage Prostate cancer	NA	mCRPC, mCSPC	mCRPC, nmCRPC	nmCRPC, mCSPC	nmCRPC	mCSPC
China NRDL inclusion	Category B	Category B	NA	Category B	Category B	Category B	Category B	Category B
China generic drug approval status	Y	Y	NA	Y	Y	N	N	N
2020 China revenue (million RMB)	20.5	776.6	NA	1,614.3	141.5	38.9	NA	NA
2021 China market price (RMB)	NA	31.0 (50mg)	NA	108.5 (250mg)	69.6 (40mg)	332.5 (60mg)	196.7 (300mg)	NA
2021 China generic drug market price (RMB)	3.8 (250mg)	25.0 (50mg)	NA	30.0 (250mg)	48.2 (40mg)	NA	NA	NA
2021 China monthly treatment cost (thousand RMB)	NA	0.9 (PFS:NA)	NA	13.0 (PFS:NA)	8.4 (mCRPC PFS:19.5 nmCRPC PFS:36.6)	39.9 (mCSPC PFS:NA nmCRPC PFS:40.5)	23.6 (PFS:40.4)	NA
2021 China generic drug monthly treatment cost (thousand RMB)	0.3 (PFS:NA)	0.8 (PFS:NA)	NA	3.6 (PFS:NA)	5.8 (mCRPC PFS:19.5 nmCRPC PFS:36.6)	NA	NA	NA

Notes:

1. There were over 15 generic competitors of the approved anti-androgen drugs as of March 6, 2023. If the generic name of a drug is listed in the NRDL, both the original drug and the generics under such generic name will be included in the NRDL and available for reimbursement. Once a drug is included in the NRDL, it will be subject to volume-based purchasing in China.
2. The revenue refers to the overall sales under the generic name.
3. The chart does not include androgen deprivation therapy (ADT) drugs. Flutamide original drug has been withdrawn from China and the US market.
4. Information as of March 6, 2023.

Source: NMPA, FDA, Frost & Sullivan analysis.

SUMMARY

The following set forth the global and China competitive landscape of pipeline of novel anti-androgen drugs under clinical trials:

Global Pipeline					
Drug name	Target	Company	Indication	Phase	First posted date
SHR3680	AR inhibitor	Hengrui Medicine	CSPC, mCRPC, advanced breast cancer	III	2018-05-09
HC-1119	AR inhibitor	Hinova Pharmaceuticals Inc.	mCRPC	III	2019-02-22
Seviteronel/VT-464	Dual CYP17A1 and AR inhibitor	Innocrin Pharmaceuticals	CRPC, HR+ breast cancer, TNBC	II	2013-12-17
Proxalutamide/GT0918	AR inhibitor	Kintor Pharma	mCRPC	II	2019-04-02
TRC253	AR inhibitor	Tracon	mCRPC	I/II	2016-12-09
ODM-208	CYP11A1	Orion Corporation/Merck	mCRPC	I/II	2018-02-19
LAE001	Dual CYP17A1 and CYP11B2 inhibitor	Laekna	mHSPC*	II	2019-02-18
ODM-209	CYP11A1	Orion Corporation	Metastatic/advanced prostate cancer, metastatic/advanced breast cancer	I/II	2019-03-18
EPI-7386	AR inhibitor	ESSA Pharmaceuticals	mCRPC	I/II	2021-10-13
TAS3681	AR inhibitor	Taiho Oncology	mCRPC	I	2015-10-02
ONC1-0013B	AR inhibitor	Avionco LLC	mCRPC	I	2017-03-03

Note: Only includes oncology drugs. First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced. The chart does not include androgen deprivation therapy (ADT) drugs or PROTAC. Information as of March 6, 2023.

* We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC. As part of our clinical development strategy for LAE001 in prostate cancer and based on the clinical data from trials on mCRPC, we plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S. and submit the NDA for mHSPC.

Pipeline in China					
Drug name	Mechanism/Target	Company	Indication	Phase	First posted date
Proxalutamide	AR inhibitor	Kintor Pharma	mCRPC	III	2018-07-02
HC-1119	AR inhibitor	Hinova Pharmaceuticals	mCRPC	III	2019-03-01
ISIS560131/AZD5312	AR inhibitor	Pyramid Laboratories	AR-V7 positive mCRPC	II	2021-04-29
LAE001	Dual CYP17A1 and CYP11B2 inhibitor	Laekna	mHSPC*	II	2019-04-25
TQB3720	AR inhibitor	Chia Tai-Tianqing Pharmaceutical	mCRPC	I	2021-01-26

Note: Only includes oncology drugs. First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced. The chart does not include ADT drugs or PROTAC. Information as of March 6, 2023.

* We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC. As part of our clinical development strategy for LAE001 in prostate cancer and based on the clinical data from trials on mCRPC, we plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S. and submit the NDA for mHSPC.

Source: ClinicalTrials.gov, CDE, Frost & Sullivan analysis

SUMMARY

Our LAE005 also faces fierce competition from marketed PD-1/PD-L1 products. In addition to approved PD-1/PD-L1 options, there are a large number of competing drug candidates currently under different clinical stages. For the competitive landscape of LAE005, see “Business – LAE005: A High-Affinity, Ligand-Blocking, Humanized Anti-PD-L1 IgG4 Antibody – Advantages and Market Opportunities.”

We may also face challenges in obtaining regulatory approval from the NMPA pursuant to the Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》), or the Clinical Principles, launched by the CDE. The Clinical Principles discourage repetitive research and development of “me-too drugs” and disorderly waste of research resources.

We believe that the Clinical Principles are expected to raise the regulatory bar for oncology drug innovation, and cool down the R&D activities of “me-too” drug. As a biotechnology company with drug development capabilities as well as an experienced development team dedicated to innovation, we believe we are well positioned to take advantage of the measures and provisions in the Clinical Principles and the likelihood of the NMPA approving our product candidates would not be affected because: (i) LAE001 is the only CYP17A1 and CYP11B2 dual inhibitor candidate in clinical trial stage globally, according to Frost & Sullivan. Based on non-head-to-head studies, LAE001 has demonstrated an advantage over current abiraterone combination therapies; (ii) globally, LAE002 is one of the only two AKT inhibitors that have entered into registrational clinical trial, and based on non-head-to-head studies, LAE002 has the potential to be the best-in-class AKT inhibitor, according to Frost & Sullivan; (iii) we have established collaboration with various multi-national pharmaceutical companies in developing potential superior combination cancer therapies over SOC; and (iv) we plan to optimize our current drug discovery and clinical development criteria and procedures to ensure that our research and development activities are value-oriented and focus on patient needs, in accordance with the Clinical Principles.

For details, see “Risk Factors – Risks Relating to 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.”

OUR COMPETITIVE STRENGTHS

We believe the following strengths differentiate us from our competitors:

- ATP competitive AKT inhibitor LAE002 in registrational clinical trials with potentially better clinical efficacy and favorable safety profile
- CYP17A1/CYP11B2 inhibitor LAE001 exhibits favorable efficacy profile for prostate cancer

SUMMARY

- Deep understanding into fundamental disease biology and clinical practice that empowers our internal discovery, business development and translational research
- Highly integrated operation that well-positions us to capture international business opportunities
- Seasoned management team has a proven track record of R&D, supported by strategic investors and healthcare specialists

OUR STRATEGIES

We plan to pursue the following significant opportunities and execute our key strategies accordingly:

- Rapidly advance the development of our existing drug candidates and portfolio towards commercialization
- Actively explore potential combination therapy opportunities to fully unlock clinical value of our product pipeline
- Consistently expand our innovative drug pipeline through in-house discovery to address broader underserved patients
- Further enhance our capabilities as our clinical studies progress and business develops
- Continue to attract and retain top talents and become a world-class organization

RESEARCH AND DEVELOPMENT

We have developed our clinical and pre-clinical pipeline through a combination of internally discovered and in-licensed products. Leveraging our know-how and R&D approach, we have implemented a “Tri-Pillar” product development model that consists of internal discovery, business development and translational research.

- Internal discovery. Our internal drug discovery primarily focuses on identifying innovative immunology therapies for cancer and liver fibrosis. LAE102, is our most advanced internally discovered drug candidate for cancer treatment, is a potent and selective ActRIIA mAb that has demonstrated anti-tumor activity in pre-clinical animal models and body weight gain in cancer-bearing animals. LAE105 is our most advanced internally discovered drug candidate for liver fibrosis treatment, which targets aHSC depletion and has advanced into proof-of-mechanism pre-clinical studies.

SUMMARY

- Business development. We apply a disciplined approach for bolstering our existing pipeline and expanding our capabilities. We focus on novel and clinically proven assets for drug-resistant cancers of which we have accumulated specialized knowledge and experience. As such, we obtained global rights from Novartis on four drug candidates with a clinical proof-of-concept, namely LAE001, LAE002, LAE005 and LAE003. We will continue to expand our drug portfolio and explore partnership through strategic collaborations to maximize the value of our pipeline.
- Translational research. We devote substantial resources to conducting translational research on our in-licensed product candidates to expand their clinical applications. Our translational studies include indication expansions through combination therapies or providing targeted treatments through patient stratification. Specifically, we are conducting a Phase I/II trial for LAE001, prednisone and LAE002 combination therapy targeting drug-resistant mCRPC patients as second- to fourth-line treatments and a Phase I/II trial for LAE002 and LAE005 combination therapy for TNBC patients. We also redesigned LAE001’s Phase I/II clinical trials to specifically target mCRPC patients without prior abiraterone acetate treatment.

We are dedicated to enhance our pipeline by leveraging our in-house R&D capabilities, from early stage drug discovery to clinical development. As of the Latest Practicable Date, our R&D team consisted of approximately 60 employees including 17 holding doctorate degrees and 28 holding master degrees. Our R&D team members have extensive pre-clinical and clinical development experience, focusing on oncology and liver diseases.

Our drug discovery and pre-clinical development team is led by Dr. Justin Gu, who has over 20 years of experience in early-stage drug discovery. The primary goal of our discovery team is to identify new targets and novel drug candidates in the oncology and liver fibrosis disease areas; and the key activities span from target discovery, hit to lead generation, PCC selection, IND enabling studies to IND filing. In addition, our team also conducts pre-clinical translational research to support the clinical development of our drug candidates. To complement our internal capabilities, the team works closely with the local CROs which have significantly increased the speed and efficiency of our internal discovery effort.

Our clinical development team is led by Dr. Yong Yue, who has over 20 years of experience in oncology clinical development and ample clinical practice experience in China, Europe and the United States. The clinical development team covers most of the key functions, from clinical development strategy, clinical development planning, setting up quality assurance and control system, to clinical trial design, trial operations, safety monitoring, data management, data analysis and programming, clinical supply, procurement, etc.

For 2021 and 2022, our R&D expenses were RMB173.3 million and RMB313.4 million, respectively. The R&D expenses attributable to the Core Products were RMB130.8 million and RMB195.0 million in the same periods, respectively.

SUMMARY

INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we hold 163 patents and patent applications (including in-licensed patents and patent applications with global rights). The following table sets forth an overview of our material granted patents and filed patent applications in connection with our Core Products as of the Latest Practicable Date:

Product	Subject Matter of Patent Family ⁽¹⁾	Jurisdiction	Legal Status	Applicant/Assignee	Expected Patent Expiration ⁽²⁾	Market Commercial Rights of the Company
LAE002	Composition of matter	U.S.	issued	Novartis AG	2031	exclusive license rights
		Argentina, Australia, Brazil, Canada, mainland China, EPO (Austria, Belgium, Denmark, France, Germany, Greece, Hong Kong, Ireland, Italy, Netherlands, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, UK), India, Israel, Japan, South Korea, Mexico, Singapore, South Africa	issued	Novartis AG	2028	exclusive license rights
	Crystalline N-((1)-2-amino-1-((3-fluorophenyl)methyl)ethyl)-5-chloro-4-(4-chloro-1-methyl-1h-pyrazol-5-yl)-2-thiophenecarboxamide hydrochloride	U.S.	issued	Novartis AG	2031	exclusive license rights
		Australia, Brazil, Canada, mainland China, Israel, Japan, South Korea, Mexico, Singapore, South Africa	issued	Novartis AG	2030	exclusive license rights
		EPO, Hong Kong	pending	Novartis AG	2030	exclusive license rights
	Combination of bortezomib with afuresertib and use thereof in the treatment of cancer	U.S., mainland China, EPO (France, Germany, UK), Japan	issued	Novartis AG	2032	exclusive license rights

SUMMARY

Product	Subject Matter of Patent Family ⁽¹⁾	Jurisdiction	Legal Status	Applicant/Assignee	Expected Patent Expiration ⁽²⁾	Market Commercial Rights of the Company
	Combinations for treating cancer and use thereof	Japan	issued	Novartis AG	2034	exclusive license rights
		U.S., mainland China, EPO, Hong Kong, Japan	pending	Novartis AG	2034	exclusive license rights
	Enzalutamide in combination with afuresertib for the treatment of cancer	Mainland China, EPO (France, Germany, UK), Japan	issued	Novartis AG	2034	exclusive license rights
LAE001	Composition of matter	U.S.	issued	Novartis AG	2031	exclusive license rights
		Australia, Brazil, Canada, mainland China, EPO (Austria, Belgium, France, Germany, Greece, Italy, Netherlands, Poland, Portugal, Spain, Switzerland, Turkey, UK), India, Japan, South Korea, Mexico	issued	Novartis AG	2030	exclusive license rights

Abbreviation: EPO = European Patent Office; UK = United Kingdom; U.S. = United States

Notes:

- (1) Unless otherwise indicated, the patent for applications within the same family is the same and is therefore disclosed once.
- (2) The expected patent expiration date is estimated based on current filing status on the assumption that a patent is granted to a pending application, without taking into account any possible patent term adjustments or extensions except as noted for the U.S. patents, the expiration date of which takes into account the patent term adjustments and terminal disclaimers as shown in the U.S. Patent and Trademark Office database, assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

We conduct our business under the brand name “LAEKNA”. As of the Latest Practicable Date, we had 15 registered trademarks and filed two trademark applications in mainland China and Hong Kong. We are also the registered owner of three domain names.

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent.

SUMMARY

COLLABORATION AND LICENSING ARRANGEMENTS

Collaboration with Novartis

We have a long working relationship with Novartis and have been collaborating with Novartis since 2017. Several members of our senior management team also previously worked for Novartis’ affiliates. Dr. Lu, our Chairman, executive Director and Chief Executive Officer, worked at Novartis Institutes for BioMedical Research and China Novartis Institutes for BioMedical Research Co., Ltd. from 2003 to 2016 with the last position as an Executive Director. Ms. Xie, our executive Director and senior vice president, worked at China Novartis Institutes for BioMedical Research Co., Ltd. as an executive assistant from 2008 to 2017. Dr. Gu, our executive Director and Chief Scientific Officer, served first as a scientist and then as a group leader at Genomics Institute of the Novartis Research Foundation from 2001 to 2008. Although our three executive Directors were all employed by Novartis’ affiliates previously and have known each other well since then, they have made and will make decisions independently of each other to carry out their fiduciary duties as Directors to the Company.

LAE001 License Agreement

On June 30, 2017, we entered into a license agreement (“**LAE001 License Agreement**”) with Novartis, a subsidiary of Novartis AG (NYSE: NVS), a multinational group of companies specializing in the research, development, manufacturing and marketing of healthcare products led by innovative pharmaceuticals and also including high-quality generic pharmaceuticals. Its major therapeutic focus includes cancer, cardiovascular, renal & metabolism diseases, immunology & dermatology, ophthalmology, neuroscience, and respiratory diseases. Its principal place of business locates in Basel, Switzerland. Novartis is one of our shareholders. Unless terminated earlier, the LAE001 License Agreement shall continue in full force and effect in perpetuity.

According to the LAE001 License Agreement, Novartis grants to us an exclusive, royalty-bearing, sub-licensable and assignable license regarding the licensed patents and data to develop, use, manufacture or have manufactured and/or commercialize LAE001 in any and all therapeutic, prophylactic and/or diagnostic uses in humans (“**LAE001 Field**”) worldwide. Novartis grants to us a non-exclusive, sublicensable, assignable license regarding the manufacturing technology to manufacture or have manufactured the LAE001 for development or commercialization of LAE001 in the LAE001 Field worldwide. The non-exclusive license of manufacturing technology of LAE001 granted by Novartis is in line with market practice and Novartis utilizes the same manufacturing technology for many of the products it manufactures. No other company has the legal right to manufacture LAE001 as we have the sole and exclusive manufacturing rights to the compounds of LAE001.

SUMMARY

In consideration of the licenses and rights granted to us, the upfront payment and the maximum milestone payments payable by us amount to US\$33.5 million in the aggregate, which include US\$1.0 million of non-refundable upfront payment and US\$32.5 million of milestone payments, consisting of development milestone payments divided into individual payments between US\$5.0 million to US\$10.0 million upon (a) receipt of regulatory approval for two different indications in China, (b) receipt of regulatory approval for the use in the LAE001 Field in the U.S., (c) receipt of regulatory approval for the use in the LAE001 Field in one or more major EU markets, and (d) receipt of regulatory approval in Japan. We are also obligated to pay tiered royalties ranging from a single-digit percentage to a low teen percentage of annual net sales of LAE001. As of December 31, 2022, we have paid US\$1.0 million under the LAE001 License Agreement.

According to the 2017 Shareholders Agreement, (i) we should issue 3,288 shares to Novartis AG so that Novartis AG can indirectly hold 5% equity interest in Laekna Therapeutics upon closing of the LAE001 License Agreement; and (ii) Novartis AG’s ultimate beneficial interest in Laekna Therapeutics shall be maintained at 5% until the valuation of Laekna Therapeutics reaches US\$70 million, above which, Novartis AG’s ultimate beneficial interest in Laekna Therapeutics shall be diluted on a pro rata basis. We granted 776,437 ordinary shares to Novartis AG and Novartis to fulfill our obligations under the 2017 Shareholders Agreement and on April 4, 2018, Novartis AG transferred all its beneficial interest in Laekna Therapeutics to Novartis. The 2017 Shareholders Agreement had been superseded by the 2018 Shareholders Agreement.

As of the Latest Practicable Date, we had no intention or plan to out-license LAE001 in the domestic and overseas markets.

LAE002 and LAE003 License Agreement

On May 9, 2018, we entered into a license agreement (“**LAE002 and LAE003 License Agreement**”) with Novartis. According to the LAE002 and LAE003 License Agreement, Novartis grants to us a royalty-bearing, sub-licensable and assignable exclusive license to develop, use, manufacture or have manufactured and/or commercialize LAE002 and LAE003 in any and all therapeutic, prophylactic and/or diagnostic uses in humans (“**LAE002 and LAE003 Field**”) worldwide. Novartis grants to us a non-exclusive, sublicensable, assignable license regarding the manufacturing technology to manufacture or have manufactured the LAE002 and LAE003 for development or commercialization of LAE002 and LAE003 in the LAE002 and LAE003 Field worldwide. The non-exclusive license of manufacturing technology of LAE002 and LAE003 granted by Novartis is in line with market practice and Novartis utilizes the same manufacturing technology for many of the products it manufactures. No other company has the legal right to manufacture LAE002 and LAE003 as we have the sole and exclusive manufacturing rights to the compounds of LAE002 and LAE003. Unless terminated earlier, the LAE002 and LAE003 License Agreement shall continue in full force and effect in perpetuity.

SUMMARY

In consideration of the licenses and rights granted to us, we are required to pay the non-refundable upfront payment of US\$5.0 million and for the LAE002 and LAE003, US\$242.5 million in milestone payments, consisting of (i) development milestone payments of up to US\$57.5 million divided into individual payments between US\$2.5 million to US\$10.0 million upon (a) dosing of the first patient in the first visit in the first Phase III registrational clinical trial, (b) the first NDA acceptance; (c) receipt of regulatory approval for three different indications in China, (d) receipt of regulatory approval for three different indications in the U.S., (e) receipt of regulatory approval for three different indications in one or more EU markets; and (ii) sales milestone payments of up to US\$185.0 million divided into individual payments upon achieving four different sales targets. We are also obligated to pay tiered royalties ranging from a single-digit percentage to a low teen percentage of annual net sales of LAE002 and LAE003. As of December 31, 2022, we have paid US\$5.0 million under the LAE002 and LAE003 License Agreement.

According to the 2018 Shareholders Agreement, (i) we should issue 165,200 shares to Novartis so that Novartis can indirectly hold 6% equity interest in Laekna Therapeutics upon closing of the LAE002 and LAE003 License Agreement; and (ii) Novartis’ ultimate beneficial interest in Laekna Therapeutics shall be maintained at 6% until the valuation of Laekna Therapeutics reaches US\$70 million, above which, Novartis’ ultimate beneficial interest in Laekna Therapeutics shall be diluted on a pro rata basis. We granted 165,200 ordinary shares to Novartis to fulfill our obligations under the 2018 Shareholders Agreement. Since the date of the Series B financing, Laekna Therapeutics has been valued at over US\$70 million. We are not obligated to issue additional shares to Novartis in the future to maintain the agreed equity interest percentage should the valuation of Laekna Therapeutics subsequently fall below US\$70 million as the 2017 Shareholders Agreement had been superseded by the 2018 Shareholders Agreement, which had then been superseded by the Series D Shareholders Agreement. The Series D Shareholders Agreement does not contain such anti-dilution mechanism.

As of the Latest Practicable Date, we had no intention or plan to out-license LAE002 in the domestic and overseas markets.

LAE005 License Agreement

On February 4, 2020, we entered into a license agreement (“**LAE005 License Agreement**”) with Novartis. According to the LAE005 License Agreement, Novartis grants to us an exclusive and sub-licensable license to practice Novartis’ and its affiliates’ interest in the licensed know-how and patents to research, develop and commercialize LAE005 worldwide. The manufacturing technology of LAE005 is not licensed to us and we can use our own manufacturing process for LAE005. As the manufacturing of LAE005 is not exclusively dependent on Novartis’ manufacturing technology and Novartis has transferred the analytical manufacturing method to us, we cooperated with CDMOs on the manufacturing of LAE005 during the Track Record Period. As of the Latest Practicable Date, we did not experience any obstacles in the manufacturing of LAE005.

SUMMARY

In consideration of the licenses and rights granted to us, the upfront payment and the maximum milestone payments payable by us amount to US\$128.0 million in the aggregate, which consist of US\$10.0 million in upfront payment, and US\$118.0 million in milestone payments, consisting of (i) development milestone payments of up to US\$28.0 million divided into individual payments between US\$2.0 million to US\$10.0 million upon (a) the first visit of the first patient to the first registrational trial, (b) acceptance of a biologic license application in any jurisdiction or application for the authorization to market the product in any country or group of countries outside the U.S., (c) regulatory approval for three different indications; and (ii) sales milestone payments of up to US\$90.0 million divided into individual payments upon achieving three different sales targets. We are also obligated to pay tiered royalties calculated ranging from a single-digit percentage to a low teen percentage of annual net sales of LAE005. As of December 31, 2022, we have paid US\$10.0 million under the LAE005 License Agreement.

Collaboration with Innovent

On July 6, 2021, we entered into a collaboration agreement (“**Innovent Collaboration Agreement**”) with Innovent Biologics (Suzhou) Co. Ltd. (“**Innovent**”), a subsidiary of Innovent Biologics, Inc. (HK: 1801), a Hong Kong-listed Chinese biopharmaceutical company. Innovent is an Independent Third Party to us.

According to the Innovent Collaboration Agreement, Innovent and we will collaborate in a clinical combination trial to evaluate the safety, pharmacokinetics, pharmacodynamics and preliminary efficacy of the concomitant and sequenced administration of LAE002 and sintilimab injection in subjects with solid tumors. Innovent will supply the sintilimab injection for free for our use in the combination therapy study. Our collaboration is non-exclusive other than that, during the term of the Innovent Collaboration Agreement, (i) we, including through our affiliates, shall not collaborate with any third-party to conduct any clinical trial of combination therapy of LAE002 and any anti-PD-1 antibody in mainland China and (ii) Innovent, including through its affiliates, shall not collaborate with any third party to conduct clinical trial of combination therapy of sintilimab injection and any AKT inhibitor in mainland China. Innovent will remain as the sole owner of all know-how and patents of sintilimab injection controlled by Innovent that are necessary for sintilimab injection’s development. All know-how that is created, conceived or reduced to practice by us or Innovent, in the performance of the development activities under the Innovent Collaboration Agreement, and all patent rights claiming such know-how (other than these that solely relates to sintilimab injection or LAE002), shall be jointly owned by us and Innovent.

SUPPLIERS

During the Track Record Period, we primarily procured services and raw materials to develop our drug candidates from highly reputable manufacturers and suppliers. Our purchases mainly include third-party contracting services for pre-clinical evaluation and clinical trials of our drug candidates, raw materials, and consumables. Our purchases from our five largest suppliers in the aggregate in each period during the Track Record Period amounted to

SUMMARY

RMB78.7 million and RMB152.6 million, representing 63.4% and 67.2% of our total purchases (excluding value-added tax), respectively. Our purchases from our largest supplier in each period during the Track Record Period amounted to RMB27.7 million and RMB80.4 million, representing 22.3% and 35.4% of our total purchases (excluding value-added tax), respectively.

To the best of our knowledge, all of our five largest suppliers during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates or any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers during the Track Record Period.

OUR MAJOR SHAREHOLDERS

The Company had no immediate and ultimate controlling party nor controlling shareholder as defined under the Listing Rules as at the Latest Practicable Date. Immediately following the completion of the [REDACTED] and the [REDACTED] (assuming the [REDACTED] is not exercised), major Shareholders of our Company include (i) OrbiMed Asia Partners III, L.P., which is interested in approximately [REDACTED]% of our issued share capital; (ii) Dr. Lu, our executive Director, Chairman and Chief Executive Officer, who is interested in approximately [REDACTED]% of our issued share capital through the Shares held by himself and under the Family Trust as the settlor; (iii) GP Healthcare Capital Co., Ltd. (上海金浦醫療健康股權投資基金管理有限公司), which is deemed to be interested in approximately [REDACTED]% of our issued share capital through GP Healthcare Capital, Inc. and Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership); and (iv) Ms. Xie, our executive Director, who is entitled to control the voting rights attached to the Shares held by the ESOP Trusts and Linbell Technology Holdings Limited (which are interested in approximately [REDACTED]% and [REDACTED]% of our issued share capital, respectively). For further details, see “Substantial Shareholders”.

OUR [REDACTED] INVESTORS

Between January 2018 and April 2022, we conducted five rounds of [REDACTED] Investments and secured [REDACTED] Investments of an aggregate amount of approximately US\$168 million. Our [REDACTED] Investors includes certain Sophisticated Investors who made meaningful investments in the Company, including OrbiMed Asia Partners III, L.P. (controlling approximately [REDACTED]% of the voting rights of our Company upon completion of the [REDACTED]), GP Healthcare Capital, Inc. (controlling approximately [REDACTED]% of the voting rights of our Company upon completion of the [REDACTED]) and Shenzhen Capital Group Company, Ltd. (controlling approximately [REDACTED]% of the voting rights of our Company upon completion of the [REDACTED]). The Shares held by the [REDACTED] Investors are expected to be subject to [REDACTED] for a period of six months commencing from the [REDACTED]. For further details, see “History, Development and Corporate Structure – [REDACTED] Investments”.

SUMMARY

SUMMARY OF KEY FINANCIAL INFORMATION

This summary of key financial information set forth below have been derived from, and should be read in conjunction with, our historical financial information, including the accompanying notes, set forth in the Accountants’ Report set out in Appendix I to this document, as well as the information set forth in “Financial Information” of this document. Our historical financial information was prepared in accordance with IFRSs.

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

The table below sets forth summary of our consolidated statements of profit or loss and other comprehensive income for the periods indicated:

	For the Year Ended	
	December 31,	
	2021	2022
	RMB'000	RMB'000
Other income	520	4,798
Other losses	(990)	(4,353)
Administrative expenses	(51,884)	(80,238)
Research and development expenses	<u>(173,256)</u>	<u>(313,356)</u>
Loss from operations	(225,610)	(393,149)
Finance costs	(922)	(1,389)
Fair value changes on financial instruments issued to investors	<u>(522,432)</u>	<u>(387,056)</u>
Loss before taxation	(748,964)	(781,594)
Income tax	<u>—</u>	<u>—</u>
Loss for the year	<u>(748,964)</u>	<u>(781,594)</u>

SUMMARY

	For the Year Ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Other comprehensive income for the year		
(after tax and reclassification adjustments)		
<i>Items that will not be reclassified to profit or loss:</i>		
Exchange differences on translation of financial statements of the Company	10,781	(71,656)
<i>Item that may be reclassified subsequently to profit or loss:</i>		
Exchange differences on translation of financial statements of foreign subsidiaries	8,156	(48,947)
Total comprehensive income for the year	(730,027)	(902,197)

We currently have no products approved for commercial sale and have not generated any revenue from product sales. We have incurred operating losses during the Track Record Period. Our loss before taxation was RMB749.0 million and RMB781.6 million in 2021 and 2022, respectively. Substantially all of our loss resulted from research and development expenses, administrative expenses and fair value changes on financial instruments issued to investors. Our administrative expenses increased by 54.5% from RMB51.9 million in 2021 to RMB80.2 million in 2022, primarily due to (i) an increase of RMB10.9 million in staff costs due to an increase in our total headcount to support growth of our business, and (ii) an increase of RMB[REDACTED] in [REDACTED] expenses. Our research and development expenses increased by 80.8% from RMB173.3 million in 2021 to RMB313.4 million in 2022, primarily due to (i) increases of RMB102.7 million in clinical development expenses and discovery research expenses incurred mainly from clinical trials for our Core Products, especially Phase II clinical trials for LAE002, and pre-clinical trials for our drug candidates such as LAE102, (ii) an increase of RMB24.9 million in staff costs mainly as a result of the expansion of our R&D staff size by 55% from 2021 to 2022, and (iii) an increase of RMB10.4 million in equity settled share-based payments due to increases in the number and value of Share Options granted in 2022. We expect to incur significant expenses, in particular increasing research and development expenses and administrative expenses, and operating losses for at least the next several years as we progress our pre-clinical research and development, continue the clinical development of, and seek regulatory approval for, our product candidates, launch commercialization of our pipeline products, and add personnel necessary to operate our business. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a [REDACTED] company. We expect that our financial performance will fluctuate from period to period due to the development status of our product candidates, regulatory approval timeline and commercialization of our product candidates after approval.

SUMMARY

Summary of Consolidated Statements of Financial Position

During the Track Record Period, we maintained a net liabilities position, primarily due to the recognition of financial instruments issued to investors as our non-current liabilities. We have significant amount of intangible assets. Our intangible assets consist of (i) our in-licensed rights in relation to LAE001, LAE002, LAE003 and LAE005, and (ii) the clinical data analysis software we purchased in 2021 and the molecular operating environment software and a series of software for clinical development we purchased in 2022. Our intangible assets were RMB110.3 million and RMB123.6 million as of December 31, 2021 and 2022, respectively. The table below sets forth summary of our consolidated statements of financial position as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Total non-current assets	149,948	145,233
Total current assets	308,897	334,631
Total current liabilities	41,990	97,509
NET CURRENT ASSETS	266,907	237,122
Total assets less current liabilities	416,855	382,355
Total non-current liabilities	1,528,024	2,287,441
NET LIABILITIES	(1,111,169)	(1,905,086)

We recorded net current assets of RMB266.9 million and RMB237.1 million as of December 31, 2021 and 2022, respectively. The decrease in net current assets during the Track Record Period were primarily due to the increase in other payables. For more details on the change in our other payables, please see “Financial Information – Discussion of Certain Selected Items From the Consolidated Statements of Financial Position – Other Payables.” As of January 31, 2023, our current assets and current liabilities were RMB299.2 million and RMB89.5 million, respectively.

We recorded net liabilities of RMB1,111.2 million and RMB1,905.1 million as of December 31, 2021 and 2022, respectively, primarily due to our financial instruments issued to investors that we recorded as financial liabilities of RMB1,500.5 million and RMB2,277.3 million as of December 31, 2021 and 2022, respectively. All Preferred Shares will be reclassified from financial liabilities to equity as a result of the automatic conversion into our Shares upon [REDACTED], which will reverse our net liability position to a net asset position.

SUMMARY

Summary of Consolidated Statements of Cash Flows

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

	For the Year Ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Net cash used in operating activities	(198,007)	(306,283)
Net cash used in investing activities	(8,712)	(4,220)
Net cash generated from financing activities	412,414	312,580
Net increase in cash and cash equivalents	205,695	2,077
Cash and cash equivalents at January 1	94,760	296,412
Effect of foreign exchange rate changes	(4,043)	24,581
Cash and cash equivalents at December 31	<u>296,412</u>	<u>323,070</u>

Our primary use of cash was to fund pre-clinical and clinical research and development of our drug candidates. Our net cash used in operating activities was RMB198.0 million and RMB306.3 million in 2021 and 2022. Our negative cash flows from operating activities were primarily attributable to cash used in paying research and development expenses and administrative expenses we incurred during the Track Record Period while we had not generated any revenue from sales of our drug candidates. As our product candidates in pipeline advance further in clinical trials and obtain regulatory approvals for commercialization, we believe we will be able to generate operating cash inflow from an increasing number of drug products, thus improving our operating cash outflow position.

Our Directors are of the opinion that, taking into account the financial resources available to us, including cash and cash equivalents and the estimated net [REDACTED] from the [REDACTED], and considering our cash burn rate, we have sufficient working capital to cover at least 125% of our costs, including research and development expenses and administrative expenses for at least the next 12 months from the expected date of this document.

SUMMARY

Our cash burn rate refers to our average monthly (i) net cash used in operating activities; (ii) capital expenditures; and (iii) lease payments. Assuming that the average cash burn rate going forward of 1.3 times the level in 2022 (which is primarily based on the difference between the average monthly burn rate in 2022 and the prospective burn rate based on the average monthly net cash used in operating activities, capital expenditures and lease payments in 2023 and 2024), we estimate that our cash and cash equivalents as of December 31, 2022 for the purpose of the indebtedness statement, will be able to maintain our financial viability for approximately 9.9 months, or, if we taking into account the estimated net [REDACTED] (based on the lower end of the indicative [REDACTED] and assuming [REDACTED] is not exercised) from the [REDACTED], for at least 30.7 months. We will continue to closely monitor our working capital, cash flows, and our business development status.

Key Financial Ratios

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

	As of December 31,	
	2021	2022
Current Ratio ⁽¹⁾	7.36	3.43

Note:

(1) Current ratio equals current assets divided by current liabilities as of the end of the year/period.

The decrease in current ratio was primarily due to the increase in current liabilities from other payables. For more details on the change in our other payables, please see “Financial Information – Discussion of Certain Selected Items From the Consolidated Statements of Financial Position – Other Payables.”

[REDACTED]

SUMMARY

[REDACTED]

DIVIDEND

We have never declared or paid regular cash dividends on our Shares. Any declaration and payment as well as the amount of dividends will be subject to our Memorandum and Articles and the Cayman Companies Act. The declaration and payment of any dividends in the future will be determined by our Board of Directors, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. In addition, 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 counsel, 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 the 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.

If we pay dividends in the future, in order for us to distribute dividends to our Shareholders, we will rely to some extent on any dividends distributed by our PRC subsidiaries. Any dividend distributions from our PRC subsidiaries to us will be subject to PRC withholding tax. In addition, regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China. See “Risk Factors – Risks Relating to Doing Business in China” in this document.

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] stated in this document:

- (i) Approximately [REDACTED]% of the net [REDACTED], or approximately HK\$[REDACTED], is expected to be used for rapidly advancing the clinical development and approval of one of our Core Products LAE001;
- (ii) Approximately [REDACTED]% of the net [REDACTED], or approximately HK\$[REDACTED], is expected to be used for advancing the clinical development and approval of the other Core Product of the Company, LAE002;
- (iii) Approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for accelerating the research and development of other existing pipeline products and continuously advancing and improving innovative pipeline products;
- (iv) Approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for improving our production capabilities and developing our manufacturing capacities.
- (v) Approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for business development activities and enhancing our global reach. We plan to capture the underlying value of our assets through global collaboration including but not limited to merger and acquisition, as well as licensing opportunities, especially of assets with proven efficacy and safety profiles, validated mechanism of action, large addressable unmet medical needs and co-development partnerships, which strategy shall complement and diversify our pipeline to increase our competitiveness globally; and
- (vi) Approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for our working capital and other general corporate purposes.

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

SUMMARY

RISK FACTORS

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

- We face fierce competition from existing products and product candidates under development in the entire oncology market. Our competitors may discover, develop or commercialize competing drugs earlier or more successfully than we do. If we fail to effectively compete with our competitors, our competitive position in our target markets may be undermined, our drug candidates, if and when approved, may fail to be commercially successful and our business, financial condition, results of operations and prospects could be adversely affected.
- 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, results of operations and financial condition may be adversely affected.
- 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.
- 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 rely on third-party collaborators for some of our clinical development activities. In particular, sintilimab has been issued a CRL by the FDA and it may negatively affect our overseas development and commercialization of combination therapies involving sintilimab globally.
- We have no experience in manufacturing pharmaceutical products, 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.

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- 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.
- 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.
- Our business operations may in the future be affected by COVID-19 resurgence, and may be affected by other health epidemics or outbreaks of contagious diseases.
- We have incurred significant net losses since our inception, and expect to continue to incur net losses for the foreseeable future and may not be able to generate sufficient revenue to achieve profitability. Potential [REDACTED] are at risk of losing substantially all of their [REDACTED] in our Shares.
- Intangible assets represent a significant portion of the assets on our consolidated balance sheet. If we determine our intangible assets are impaired, our results of operations and financial condition may be adversely affected.

[REDACTED] EXPENSES

Our [REDACTED] expenses represent professional fees, [REDACTED] commissions and other fees incurred in connection with the [REDACTED]. Assuming an [REDACTED] of HK\$[REDACTED] per Share at the mid-point of the indicative [REDACTED] stated in this document and no [REDACTED] is exercised, we estimated that total [REDACTED] expenses for the [REDACTED] are approximately RMB[REDACTED], accounting for [REDACTED]% of the gross [REDACTED] from the [REDACTED], including RMB[REDACTED] that we have recognized as expenses for the year ended December 31, 2022, about RMB[REDACTED] that we expect to recognize as expenses after December 31, 2022 and about RMB[REDACTED] that we expect to deduct from equity upon [REDACTED]. The above [REDACTED] expenses are comprised of (i) [REDACTED] expenses, including [REDACTED] commission and other expenses, of RMB[REDACTED]; and (ii) [REDACTED] expenses of RMB[REDACTED], including (a) fee paid and payable to legal advisors and reporting accountants of RMB[REDACTED]; and (b) other fees and expenses, including sponsor fees, of RMB[REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

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RECENT DEVELOPMENTS

Impact of the COVID-19 Outbreak

In the end of December 2019, the outbreak of a novel strain of coronavirus named COVID-19 has materially and adversely affected the global economy. In response, countries and regions across the world, including China, imposed widespread lockdowns, closure of workplaces and restrictions on mobility and travel to constrain the spread of the virus. Since December 2022, the PRC government has started to relax substantially all of its restrictive measures nationwide. Many regions are experiencing a temporary surge in infection cases. The surge in COVID-19 infections since December 2022 has not materially impacted our business operations and financial performance as the majority of our infected employees have already recovered and returned to office within approximately two weeks of infection. As of the Latest Practicable Date, COVID-19 did not impose any material adverse impact on our clinical development, daily operation, supply chain and regulatory affairs.

- *Our clinical development.* Since many regions are facing a surge in COVID-19 cases in December 2022, many hospitals in China have allocated their resources to the prevention and treatment of COVID-19, thus our ongoing clinical trials of Core Products in a minority of hospital sites were temporarily delayed in December 2022. We have been closely monitoring the progress of our on-going clinical trials throughout China by maintaining frequent communication with the medical institutions that cooperate with us, and as of the Latest Practicable Date, we had not experienced and did not anticipate that there will be any material delay or suspension to our on-going clinical trials because of COVID-19.
- *Our daily operation.* Since the lifting of substantially all COVID-19 restrictions in China in December 2022, we experienced an increased number of COVID-19-related sick leaves from our employees. However, we continued to maintain normal business operations. As of the Latest Practicable Date, the surge of COVID-19 infections in the cities where a majority of our employees are located has largely stabilized and most of our infected employees have already recovered and returned to work.
- *Supply chain and cooperation with third parties.* Since the COVID-19 outbreak and up to the Latest Practicable Date, we had not experienced any material disruption to our supply chain or material adverse effect on our cooperation with third parties due to the COVID-19 outbreak.

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- *Regulatory affairs.* To the knowledge of our Directors, in December 2022, the evaluation process of the NMPA for applications were slower than usual, but the NMPA has resumed their normal review process since January 2023. In addition, as most foreign competent government authorities relevant to our clinical trials, particularly the FDA, are currently in normal operations, we do not expect that our communications and filings with these authorities will be significantly affected by COVID-19 in the future.

Overseas Listing

On February 17, 2023, the CSRC promulgated Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “Overseas Listing Trial Measures”) and relevant five guidelines, which will become effective on March 31, 2023.

The Overseas Listing Trial Measures will comprehensively improve and reform the existing regulatory regime for overseas offering and listing of the PRC domestic companies’ securities and will regulate both direct and indirect overseas offering and listing of the PRC domestic companies’ securities by adopting a filing-based regulatory regime.

According to the Overseas Listing Trial Measures, the PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provide that an overseas listing or offering is explicitly prohibited, in any of the following scenario: (i) such securities offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (ii) the intended securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law; (iii) the domestic company intending to make the securities offering and listing, or its controlling shareholder(s) and the actual controller, have committed relevant crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the last three years; (iv) the domestic company intending to make the securities offering and listing is currently under investigation for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has been made thereof; or (v) there are material ownership disputes over equity held by the domestic company’s controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller.

The Overseas Listing Trial Measures also provide that if the issuer meets both of the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as indirect overseas offering by the PRC domestic companies: (i) 50% or more of any of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (ii) the main parts of the issuer’s business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are PRC

SUMMARY

citizens or have their usual place(s) of residence located in mainland China. The determination of the indirect overseas offering by PRC domestic companies shall follow the principle of substance over form. Where an issuer submits an application for initial public offering to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted. The Overseas Listing Trial Measures also require subsequent reports to be filed with the CSRC on material events, such as change of control or voluntary or forced delisting of the issuer(s) who have completed overseas offerings and listings.

At a press conference held for these new regulations, officials from the CSRC clarified that the domestic companies that have already been listed overseas on or before the effective date of the Overseas Listing Trial Measures (i.e. March 31, 2023) shall be deemed as existing issuers, or the Existing Issuers. Existing Issuers are not required to complete the filing procedures immediately, and they shall be required to file with the CSRC when subsequent matters such as refinancing are involved. Furthermore, according to the officials from the CSRC, domestic companies that have obtained approval from overseas regulatory authorities or securities exchanges (for example, a contemplated offering and/or listing in Hong Kong has passed the hearing of the Stock Exchange) and do not need to re-obtain the approval from the relevant overseas regulatory authorities or securities exchanges for their indirect overseas offering and listing prior to the effective date of the Overseas Listing Trial Measures (i.e. March 31, 2023) but have not yet completed their indirect overseas issuance and listing, are granted a six-month transition period from March 31, 2023. Those who complete their overseas offering and listing within such six-month transition period are deemed as Existing Issuers and do not need to file with the CSRC. Within such six-month transition period, however, if such domestic companies need to reapply for offering and listing procedures to the overseas regulatory authorities or securities exchanges (such as requiring a new hearing of the Stock Exchange), or if they fail to complete their indirect overseas issuance and listing, such domestic companies shall complete the filing procedures with the CSRC.

Based on the foregoing and as advised by our PRC Legal Adviser, we may be deemed as a PRC domestic company and therefore subject to the Overseas Listing Trial Measures. If we fail to qualify as an Existing Issuer, we will be required to complete the filing procedures with the CSRC in connection with the [REDACTED] as required by the Overseas Listing Trial Measures. In any event, we will perform the reporting obligations to the CSRC in the event of occurrence of material events after the [REDACTED] as required. See “Risk Factors – Risks Relating to Doing Business in China – The approval of or filing with the CSRC may be required in connection with the [REDACTED], and, if required, we cannot predict whether we will be able to obtain such approval or complete such filing in a timely manner or at all.”

Expected Loss

We expect that we will continue to incur loss for the year ending December 31, 2022, primarily due to (i) increasing expenses for clinical development and pre-clinical research, (ii) fair value changes on financial instruments issued to [REDACTED], and (iii) [REDACTED] expenses.

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No Material Adverse Change

Our Directors confirm that, as of the date of this document, there has been no material adverse change in our financial position, indebtedness, mortgage, contingent liabilities, guarantees or prospects of our Group since December 31, 2022, the end of the period reported in the Accountants’ Report set out in Appendix I to this document.

DEFINITIONS

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

“2017 Shareholders Agreement”	the share subscription and shareholders’ agreement entered among our Company, Laekna HK, Laekna Therapeutics, Dr. Lu, Mr. Lin and Novartis AG dated June 30, 2017
“2018 Shareholders Agreement”	the share subscription and shareholders’ agreement entered among our Company, Laekna HK, Laekna Therapeutics, Dr. Lu, Mr. Lin, Tibet Longmaide, OrbiMed Asia Partners III, L.P. and Novartis dated May 9, 2018
“affiliate(s)”	with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“AFRC”	Accounting and Financial Reporting Council (會計及財務匯報局)
“Articles” or “Articles of Association”	the fifth amended and restated articles of association of our Company conditionally adopted by special resolution on [●] which shall become effective on the [REDACTED] and as amended from time to time, a summary of which is set out in “Summary of the Constitution of our Company and Cayman Companies Act” in Appendix III
“associate”	has the meaning ascribed to it under the Listing Rules
“Audit Committee”	the audit committee of the Board
“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
“BVI”	the British Virgin Islands

DEFINITIONS

“CAGR”	compound annual growth rate
“Cayman Companies Act” or “Companies Act”	the Companies Act (2023 Revision) of the Cayman Islands, Cap. 22 (Law 3 of 1961), as amended or supplemented or otherwise modified from time to time
“CCASS”	the Central Clearing and Settlement System established and operated by HKSCC
“CCASS Broker Participant”	a person admitted to participate in CCASS as a broker participant
“CCASS Clearing Participant”	a person admitted to participate in CCASS as a direct clearing participant or a general clearing participant
“CCASS Custodian Participant”	a person admitted to participate in CCASS as a custodian participant
“CCASS Investor Participant”	a person admitted to participate in CCASS as an investor participant, who may be an individual or joint individuals or a corporation
“CCASS Participant”	a CCASS Broker Participant, a CCASS Custodian Participant or a CCASS Investor Participant
“Chairman”	the chairman of the Board
“Chief Executive Officer”	the chief executive officer of our Company
“Chief Medical Officer”	the chief medical officer of our Company
“Chief Scientific Officer”	the chief scientific officer of our Company
“China” or “PRC”	the People’s Republic of China, but for the purpose of this document and for geographical reference only and except where the context requires otherwise, references in this document to “China” and the “PRC” do not apply to Hong Kong, Macau 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

DEFINITIONS

“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”	Laekna, Inc. (來凱醫藥有限公司), an exempted company incorporated in the Cayman Islands with limited liability on July 29, 2016
“Compliance Adviser”	Huajin Corporate Finance (International) 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
“Conversion”	conversion of each Preferred Share to a Share on a one-to-one basis
“core connected person(s)”	has the meaning ascribed to it under the Listing Rules
“Core Product”	LAE002 or LAE001, the designated “core product” as defined under Chapter 18A of the Listing Rules
“Corporate Governance Code”	the Corporate Governance Code set out in Appendix 14 to the Listing Rules
“CSRC”	China Securities Regulatory Commission
“Director(s)” or “our Director(s)”	the director(s) of our Company
“Dr. Lu”	Dr. LU Chris Xiangyang, the founder, Chairman, executive Director and the Chief Executive Officer of our Company
“ESOP Trusts”	Laekna Halley Trust and Laekna Wonderland Trust, being the trusts set up by the Company to facilitate the administration of the [REDACTED] Share Option Scheme
“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the government of Hong Kong
“Family Trust”	Ealex LLC, a trust set up by Dr. Lu as settlor, The Bryn Mawr Trust Company of Delaware as trustee and Dr. Lu’s certain family members as the beneficiaries

DEFINITIONS

“Frost & Sullivan” Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent market research and consulting company that provides market survey and consulting services

“Frost & Sullivan Report” an industry report prepared by Frost & Sullivan on the worldwide biologics market, which was commissioned by us

[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

“HKSCC” Hong Kong Securities Clearing Company Limited

“HKSCC Nominees” HKSCC Nominees Limited, a wholly-owned subsidiary of HKSCC

“Hong Kong” or “HK” the Hong Kong Special Administrative Region of the People’s Republic of China

[REDACTED]

DEFINITIONS

“Hong Kong Stock Exchange” or “Stock Exchange” The Stock Exchange of Hong Kong Limited

[REDACTED]

“Independent Third Party(ies)” any entity or person who is not a connected person of our Company or its subsidiaries

[REDACTED]

“Laekna HK” Laekna Limited, a limited liability company incorporated in Hong Kong on August 26, 2016 and one of our Company’s subsidiaries

DEFINITIONS

“Laekna Pharmaceutical” Laekna Pharmaceutical Shanghai Co., Ltd. (來凱製藥(上海)有限公司), a limited liability company established under the laws of the PRC on December 8, 2020 and one of our Company’s subsidiaries

“Laekna Therapeutics” Laekna Therapeutics Shanghai Co., Ltd. (來凱醫藥科技(上海)有限公司), a limited liability company established under the laws of the PRC on December 28, 2016 and one of our Company’s subsidiaries

“Latest Practicable Date” [March 6], 2023, being the latest practicable date for the purpose of ascertaining certain information contained in this document before its publication

[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

“Main Board” the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with GEM of the Stock Exchange

“Memorandum” or
“Memorandum of Association” the fifth amended and restated memorandum of association of our Company conditionally adopted by special resolution on [●], 2023 which shall become effective on the [REDACTED] and as amended from time to time, a summary of which is set out in “Summary of the Constitution of our Company and Cayman Companies Act” in Appendix III

“Mr. Lin” Mr. LIN Anpeng (林安鵬), one of our [REDACTED] Investors

DEFINITIONS

“Ms. Xie”	Ms. XIE Ling (謝玲), an executive Director and a senior vice president of our Company
“MOFCOM”	the Ministry of Commerce of the PRC (中華人民共和國商務部)
“MOST”	the Ministry of Science and Technology of the PRC (中華人民共和國科學技術部)
“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
“Novartis”	Novartis Pharma AG, a company organized under the laws of Switzerland and one of our [REDACTED] Investors

[REDACTED]

DEFINITIONS

[REDACTED]

“[REDACTED] Share Option Scheme”	the share option scheme adopted by our Company on [●] 2023, the principal terms of which are set out in “Statutory and General Information – E. [REDACTED] Share Option Scheme” in Appendix IV
“PRC Legal Adviser”	Jingtian & Gongcheng
“Preferred Share(s)”	convertible preferred share(s) in the share capital of our Company, including Series Seed Preferred Shares, Series A Preferred Shares, Series B Preferred Shares, Series C Preferred Shares and Series D Preferred Shares
“[REDACTED] Investments”	the investments made by the [REDACTED] Investors pursuant to the respective agreements, see “History, Development and Corporate Structure – [REDACTED] Investments” for further information
“[REDACTED] Investor(s)”	the investor(s) who made [REDACTED] Investments in our Company prior to our [REDACTED], see “History, Development and Corporate Structure – [REDACTED] Investments – 9. Information about the [REDACTED] Investors” for further information
“[REDACTED] Share Option Scheme”	the share option scheme adopted by our Company on April 11, 2018 and amended on October 30, 2019, April 20, 2021 and March 31, 2022, the principal terms of which are set out in “Statutory and General Information – D. [REDACTED] Share Option Scheme” in Appendix IV

DEFINITIONS

[REDACTED]

“QIB”	a qualified institutional buyer within the meaning of Rule 144A
“Regulation S”	Regulation S under the U.S. Securities Act
“Remuneration Committee”	the remuneration committee of the Board
“RMB” or “Renminbi”	Renminbi, the lawful currency of China
“Rule 144A”	Rule 144A under the U.S. Securities Act
“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
“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), currently known as the SAMR
“SAMR”	the State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局), formerly known as the SAIC
“Series A Preferred Share(s)”	the series A convertible preferred share(s) of our Company with a par value of US\$0.0001 per share as of the Latest Practicable Date, or the series A convertible preferred share(s) of our Company with a par value of US\$[0.00001] per share in the authorized share capital of our Company following the [REDACTED], details of which are described in the section headed “History, Development and Corporate Structure”
“Series A Preferred Shareholder(s)”	holder(s) of Series A Preferred Shares of our Company

DEFINITIONS

“Series B Preferred Share(s)”	the series B convertible preferred share(s) of our Company with a par value of US\$0.0001 per share as of the Latest Practicable Date, or the series B convertible preferred share(s) of our Company with a par value of US\$[0.00001] per share in the authorized share capital of our Company following the [REDACTED], details of which are described in the section headed “History, Development and Corporate Structure”
“Series B Preferred Shareholder(s)”	holder(s) of Series B Preferred Shares of our Company
“Series C Preferred Share(s)”	the series C convertible preferred share(s) of our Company with a par value of US\$0.0001 per share as of the Latest Practicable Date, or the series C convertible preferred share(s) of our Company with a par value of US\$[0.00001] per share in the authorized share capital of our Company following the [REDACTED], details of which are described in the section headed “History, Development and Corporate Structure”
“Series C Preferred Shareholder(s)”	holder(s) of Series C Preferred Shares of our Company
“Series D Preferred Share(s)”	the series D convertible preferred share(s) of our Company with a par value of US\$0.0001 per share as of the Latest Practicable Date, or the series D convertible preferred share(s) of our Company with a par value of US\$[0.00001] per share in the authorized share capital of our Company following the [REDACTED], details of which are described in the section headed “History, Development and Corporate Structure”
“Series D Preferred Shareholder(s)”	holder(s) of Series D Preferred Shares of our Company
“Series D Shareholders Agreement”	the third amended and restated shareholders agreement dated October 4, 2021 entered into by, among others, the [REDACTED] Investors and our Company
“Series Seed Preferred Shareholder(s)”	holder(s) of Series Seed Preferred Shares of our Company

DEFINITIONS

“Series Seed Preferred Share(s)” the series seed convertible preferred share(s) of our Company with a par value of US\$0.0001 per share as of the Latest Practicable Date, or the series seed convertible preferred share(s) of our Company with a par value of US\$[0.00001] per share in the authorized share capital of our Company following the [REDACTED], details of which are described in the section headed “History, Development and Corporate Structure”

“SFC” the Securities and Futures Commission of Hong Kong

“SFO” the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time

“Share Option(s)” the share option(s) granted or to be granted pursuant to the terms and conditions of the [REDACTED] Share Option Scheme

[REDACTED]

“Shareholder(s)” holder(s) of Shares

“Share(s)” ordinary share(s) in the share capital of our Company with a par value of [US\$0.00001] each following the [REDACTED] and the Conversion

[REDACTED]

“Sole Sponsor” China International Capital Corporation Hong Kong Securities Limited

DEFINITIONS

“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 OrbiMed Asia Partners III, L.P., GP Healthcare Capital, Inc. and Shenzhen Capital Group Company, Ltd.

“STA” the State Administration of Taxation of the PRC (國家稅務總局)

[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 Codes on Takeovers and Mergers and Share Buybacks issued by the SFC, as amended, supplemented or otherwise modified from time to time

“Tibet Longmaide” Tibet Longmaide Venture Capital Fund (Limited Partnership) (西藏龍脈得股權投資中心(有限合夥))

“Track Record Period” the periods comprising the two years ended December 31, 2021 and 2022

[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

[REDACTED]

“%” per cent

In this document:

- *Unless otherwise expressly stated or the context otherwise requires, all data in this document is as of the Latest Practicable Date.*
- *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 explanations of certain technical terms used in this document in connection with our Company and its business. Such terminology and meanings may not correspond to standard industry meanings or usages of those terms.

“ActRIIA”	activin receptor type IIA
“ADT”	androgen deprivation therapy
“AEs”	adverse events, any untoward medical occurrences in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials which do not necessarily have a causal relationship with the treatment
“aHSC”	activated hepatic stellate cells
“AKT”	a serine/threonine protein kinase with 3 isoforms (AKT1, AKT2 and AKT3) that participate in multiple pathways regulating several cellular processes, including survival, proliferation, tissue invasion, and metabolism
“antibody (Ab)”	also known as an immunoglobulin (Ig), a protein used by the immune system to recognize and bind an antigen
“antigen”	the substance that is capable of stimulating an immune response, specifically activating lymphocytes, which are the body’s infection-fighting white blood cells
“apoptosis”	a form of programmed cell death in which a programmed sequence of events leads to the elimination of cells
“ATP”	adenosine triphosphate, an organic compound
“AUC”	area under curve, a parameter of systemic exposure
“AR inhibitor”	anti-androgen receptor inhibitor
“BID”	twice-daily administration
“BT474”	a breast cancer cell line, characterized by the overexpression of HER2 and ER

GLOSSARY OF TECHNICAL TERMS

“BRAF”	a protein kinase involved in directing cell growth and shown to be mutated in some human cancers
“BRCA”	proteins involved in gene damage repair, including BRCA1 and BRCA2
“CDK”	cyclin-dependent kinases, a family of protein kinases regulating the cell cycle, also involved in regulating transcription, mRNA processing, and the differentiation of nerve cells
“CDMO”	contract development and manufacturing organization, a company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis
“cGCP”	current good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
“cGLP”	current good laboratory practice, a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) non-clinical studies
“cGMP”	current good manufacturing practice, containing minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have
“chemotherapy”	a category of cancer treatment that uses one or more anti-cancer cytotoxic agents
“clinical trial/study”	a research study for validating or finding the therapeutic effects and side effects of test drugs in order to determine the therapeutic value and safety of such drugs
“CMC”	chemistry, manufacture and control

GLOSSARY OF TECHNICAL TERMS

“CMO”	contract manufacturing organization, a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services of drug manufacturing
“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
“combination therapy”	treatment in which a patient is given two or more drugs (or other therapeutic agents) for a single disease
“CR”	complete response, the disappearance of all signs of cancer in response to treatment
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CSCO Guideline”	The Chinese Society of Clinical Oncology Guideline
“CYP17A1”	cytochrome P450 family 17 subfamily A member 1, an enzyme of the hydroxylase type that in humans is encoded by the CYP17A1 gene
“CYP11B2”	cytochrome P450 family 11 subfamily B member 2
“DOR”	duration of response, the length of time that a tumor continues to respond to treatment without the cancer growing or spreading
“EC ₅₀ ”	half maximal effective concentration, referring to the concentration of a drug, antibody or toxicant which induces a response halfway between the baseline and maximum after a specified exposure time
“FFS”	failure-free survival
“fibrosis”	a condition marked by increase of interstitial fibrous tissue

GLOSSARY OF TECHNICAL TERMS

“GMP”	good manufacturing practice, the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of products
“Grade – in relation to AE”	term used to refer to the severity of adverse events according to Common Terminology Criteria for Adverse Events (CTCAE) v4.03, using Grade 1, Grade 2, Grade 3, etc.
“HHT”	hereditary hemorrhagic telangiectasia
“HR+/HER2- breast cancer”	the most common type of breast cancer with overexpression of HR and without overexpression of HER2
“IC ₅₀ ”	concentration at half maximal inhibition, a measure of the potency of a substance in inhibiting a specific biological or biochemical function
“ICI”	immune checkpoint inhibitor
“immuno-oncology”	a type of immunotherapy that is specifically targeted to fight cancer
“immunology”	study of immune systems in an organism in biological science
“immunotherapy”	use of the immune system to treat disease
“ <i>in vivo</i> ”	studies in which the effects of various biological entities are tested on whole, living organisms, usually animals, including humans, and plants, as opposed to a tissue extract or dead organism
“ <i>in vitro</i> ”	studies that are performed with microorganisms, cells, or biological molecules outside their normal biological context
“IND”	investigational new drug, the application for which is the first step in the drug review process by regulatory authorities to decide whether to permit clinical trials; also known as clinical trial application, or CTA, in China

GLOSSARY OF TECHNICAL TERMS

“IV”	intravenous injection, an injection of a medication or another substance into a vein and directly into the bloodstream
“Ki* values”	inhibition constant, the dissociation constant for an enzyme inhibitor complex
“lines of treatment”	the order in which different therapies are given to patients as their disease progresses, such as first-line, second-line, third-line etc.
“liver cirrhosis”	a chronic liver disease marked by fibrous thickening of tissue
“mAb”	monoclonal antibody, an antibody generated by identical immune cells that are all clones of the same parent cell
“mCRPC”	metastatic castration resistant prostate cancer
“metastatic”	in reference to any disease, including cancer, disease-producing organisms or of malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
“mHSPC”	metastatic hormone-sensitive prostate cancer
“MOA”	mechanism of action, specific mechanism producing its pharmacological effect
“monotherapy”	therapy that uses a single drug to treat a disease or condition
“MTD”	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects
“MRCT”	multi-regional clinical trial, a clinical trial that is conducted in different regions under a common trial design for simultaneous global new drug development
“NAFLD”	non-alcoholic fatty liver disease
“NASH”	non-alcoholic steatohepatitis, liver inflammation and damage caused by accumulation of fat in the liver

GLOSSARY OF TECHNICAL TERMS

“NCCN Guideline”	The National Comprehensive Cancer Network Guideline
“NDA”	new drug application, a process required by an regulatory authority to approve a new drug for sale and marketing
“NSCLC”	non-small-cell lung cancer, any carcinoma (as an adenocarcinoma or squamous cell carcinoma) of the lungs that is not a small-cell lung carcinoma
“NGS”	next generation sequencing, a massively parallel sequencing technology that offers ultra-high throughput, scalability, and speed
“ORR”	overall response rate, the proportion of patients who have a partial or complete response to therapy
“OS”	overall survival, a length of time that a patient with a specific disease is still alive, used as a measurement of a drug’s effectiveness
“paclitaxel”	a chemotherapy medication used to treat a number of types of cancer, includes ovarian cancer, esophageal cancer, breast cancer, lung cancer, Kaposi’s sarcoma, cervical cancer, and pancreatic cancer
“PARP”	poly (ADP-ribose) polymerase, a family of proteins involved in a number of cellular processes, such as DNA repair, genomic stability, and programmed cell death
“PD”	pharmacodynamics, the branch of pharmacology concerned with the effects of drugs and the mechanism of their action
“PD-1”	programmed death-1, an immune checkpoint receptor expressed on T cells, B cells and macrophages, acting to turn off the T cell mediated immune response as part of the process that stops a healthy immune system from attacking other pathogenic cells in the body
“PD-L1”	programmed death ligand-1, a protein on the surface of a normal cell or a cancer cell that attaches to PD-1 on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell

GLOSSARY OF TECHNICAL TERMS

“PDX”	patient derived xenografts, a model of cancer where the tissue or cells from a patient’s tumor are implanted into an immune-deficient or humanized mouse
“PFS”	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives without the disease getting worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works
“PSOC”	platinum-sensitive ovarian cancer
“Phase I clinical trial(s)”	study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its efficacy
“Phase Ia clinical trial(s)”	study in which dose escalation is tested on the healthy human subjects or patients to primarily assess safety, dosage tolerance, and PK/PD at different dose levels
“Phase Ib clinical trial(s)”	study in which dose expansion is tested on the healthy human subjects or patients to primarily assess safety, dosage tolerance and PK/PD at different dose levels
“Phase II clinical trial(s)”	study in which a drug is administered to a limited patient population to preliminarily evaluate the efficacy of the product for specific targeted diseases, to identify possible adverse effects and safety risks, and to determine optimal dosage
“Phase III clinical trial(s)”	study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the labeling of the product
“PO”	(medication taken) by mouth
“PI3K”	phosphoinositide 3 kinase, an important signaling node for many cellular functions such as growth control, metabolism and translation initiation

GLOSSARY OF TECHNICAL TERMS

“PI3KCA”	PI3K catalytic subunit alpha
“PK”	pharmacokinetics, the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit, and adverse effects of the drug
“PKA”	protein kinase A, cAMP-dependent protein kinase
“PKC”	protein kinase C, a serine/threonine protein kinase, controlling function of other proteins through phosphorylation
“PKC θ ”	protein kinase C θ isoform
“PKC δ ”	protein kinase C δ isoform
“PKC η ”	protein kinase C η isoform
“PKC β 1”	protein kinase C β 1 isoform
“PKG”	protein kinase G or cGMP-dependent protein kinase, a serine/threonine protein kinase activated by cGMP
“PKG1 α ”	cGMP-dependent protein kinase 1, alpha isozyme
“PKG1 β ”	cGMP-dependent protein kinase 1, beta isozyme
“placebo”	a treatment or preparation with no specific pharmacological activity
“PR”	partial response, an at least 30% but less than 100% decrease in the size of a tumor or in the extent of cancer in the body in response to treatment per RESIST criteria
“PRAS40”	proline-rich Akt substrate of 40 kDa
“pre-clinical studies”	pre-clinical studies testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials
“primary endpoint”	the main or most important outcome at the end of a study to determine whether a new drug or treatment works

GLOSSARY OF TECHNICAL TERMS

“PROC”	platinum resistant ovarian cancer
“PROTAC”	proteolysis targeting chimera
“proof of concept (POC)”	an early stage of drug development used to demonstrate that a drug is likely to be successful
“PSA”	prostate specific antigen, a protein that may be present with elevated levels in a prostate cancer or other disease patient, which is commonly used as an efficacy indicator of anti-prostate cancer drugs
“PTEN”	phosphatase and tensin homolog deleted on chromosome ten, a negative regulator of PI3K
“p70S6K”	p70S6 kinase, a protein kinase encoded by the RPS6KB1 gene in humans
“QD”	once-daily administration
“refractory”	a disease that is resistant at the beginning of treatment or becomes resistant during treatment
“registrational clinical trial”	a clinical trial study to demonstrate clinical efficacy and safety evidence to support the marketing approval of a drug
“ROCK1”	a protein serine/threonine kinase, also known as rho-associated, coiled-coil-containing protein kinase 1
“RP2D”	recommended Phase II dose
“RSK”	ribosomal s6 kinase, a family of protein kinases involved in signal transduction
“SCID mice”	severe combined immunodeficient mice, often used in the research of human disease
“SD”	stable disease, in oncology, indicating a cancer that is neither decreasing at least 30% nor increasing at least 20% in the size of a tumor or in the extent of cancer in the body in response to treatment

GLOSSARY OF TECHNICAL TERMS

“standard of care (SOC)”	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
“TAA”	tumor associated antigen, a portion of intracellular molecules expressed on the cell surface that allows large proteins in immune system cells to identify compatible or foreign proteins to help the body make an immune response against cancer cells or to help boost the body’s immune system to kill more cancer cells
“TGF”	transforming growth factor, a family of proteins involved in regulating and mediating processes at the cellular level
“TGI”	tumor growth inhibition
“TNBC”	triple-negative breast cancer, any breast cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2
“TRAE”	treatment-related adverse event, undesirable events not present prior to medical treatment or an already present event that worsens in intensity or frequency following the treatment
“translational research”	the process by which the results of research done in the laboratory are used to develop new ways of diagnosis and treatment

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”, “Business”, “Risk Factors”, “Future Plans and Use of [REDACTED]”, “Financial Information” and “Industry Overview”. 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”, “target”, “expect”, “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;
- the effects of the on-going COVID-19 pandemic; 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”.

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 Latest Practicable Date. 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, as well as our financial statements and the related notes, and the “Financial Information” section, before deciding to [REDACTED] in our Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any such an event, the market price of our Shares could decline, and you may lose all or part of your [REDACTED]. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward-Looking Statements” in this document.

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

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

RISKS RELATING TO OUR PRE-CLINICAL AND CLINICAL DEVELOPMENT OF OUR DRUG CANDIDATES

We face fierce competition from existing products and product candidates under development in the entire oncology market. Our competitors may discover, develop or commercialize competing drugs earlier or more successfully than we do. If we fail to effectively compete with our competitors, our competitive position in our target markets may be undermined, our drug candidates, if and when approved, may fail to be commercially successful and our business, financial condition, results of operations and prospects could be adversely affected.

We face fierce competition from existing products and product candidates under development in the entire oncology market, in particular in the AKT inhibitor market. Competition in therapeutic areas such as oncology to which our Core Products and most of our other pipeline assets belong is intense given the abundance of existing competing oncology therapy options, approved drugs and drug candidates that continue to increase. In particular, for selective inhibitors, especially AKT inhibitors including our Core Product LAE002, there are a large number of competing drug candidates currently under different development stages.

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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.

In particular, the wide application of traditional cancer therapies, such as surgeries, radiotherapies and chemotherapies, also poses significant competition for our drug candidates. Surgery is a procedure in which a surgeon removes tumors and nearby tissues from the patient's body. Radiotherapies deliver high doses of radiation to kill cancer cells and shrink tumors, while chemotherapies use single or combination anti-cancer drugs to stop or slow the growth of cancer cells. Our drug candidates and lines of treatments may not be selected unless and until one or more of these more conventional and widely adopted cancer treatments have been adopted, which could potentially negatively affect the size of our total addressable market for our drug candidates.

Our commercial opportunities may deteriorate if our competitors develop and commercialize drugs that are safer, more effective, more convenient, or less expensive than any of the drugs that we may develop or commercialize. Our competitors also may obtain approval from the NMPA, the FDA, or other comparable regulatory authorities for their drugs more quickly than we do, which could result in our competitors establishing a strong market position before we are able to enter the market. This may render our drug candidates obsolete or less competitive before we can recover the expenses of developing and commercializing our drug candidates.

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 respective clinical development, obtain relevant regulatory approvals or achieve their commercialization, or if we experience significant delays in any of the foregoing, our business, results of operations and financial condition may be adversely affected.

Our ability to generate revenue and become profitable depends 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.

We face uncertainties in clinical trial development which are subject to a variety of factors, including satisfactory safety and efficacy results from clinical trials, successful enrollment of patients, and performance of CROs and other parties involved in clinical trial development and others. For example, perifosine, another AKT inhibitor, failed the Phase III clinical trial for treatment of colon cancer and relapsed and refractory multiple myeloma. Although we believe the risk of a similar discontinuation is not applicable to our LAE002 combination study because of the difference in AKT selectivity and target indications, our development of LAE002 may still be subject to other development risks.

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In addition to the completion of clinical trial development, the success of our drug candidates will depend on many other factors, including but not limited to:

- receipt of regulatory approvals;
- obtaining sufficient supplies of any qualified 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;
- establishing sufficient commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- avoiding infringement, misappropriation or violation of the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- successfully launching commercial sales of our 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.

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 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 strengthen our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop.

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For example, we have entered into license agreements with Novartis in relation to LAE001, LAE002, LAE005 and LAE003, and a collaboration agreement with Innovent in relation to LAE002. 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 otherwise adversely affect our business if such relationships were disrupted.

Our strategic collaboration with partners involves numerous risks. For example, Novartis may terminate the license agreements with us if we fail to demonstrate our commercially reasonable efforts in the R&D, manufacturing and commercialization of in-licensed products. In addition, we may not achieve the revenue and cost synergies expected from the transaction. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. Even if we achieve the expected benefits, they may not be achieved within the anticipated timeframe. 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. 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.

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 and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits.

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 our third-party collaborator is not successful, our revenue-generating growth potential will be adversely affected.

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. These license agreements impose diligence obligations in development or

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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 in-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 our expectations under 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.

We rely on certain third-party collaborators for some of our clinical development activities. In particular, sintilimab has been issued a CRL by the FDA and it may negatively affect our overseas development and commercialization of combination therapies involving sintilimab globally.

We rely on certain third parties for some of our clinical trials. In particular, we have initiated a Phase I/II clinical trial for LAE002 in combination with anti-PD-L1 antibody sintilimab supplied by Innovent. However, in March 2022, the FDA issued a complete response letter (CRL) indicating it cannot approve the biologics license application for sintilimab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of advanced NSCLC. The CRL also included a recommendation for an additional clinical study, specifically a multi-regional clinical trial comparing the first-line standard of care therapy for metastatic NSCLC to sintilimab with chemotherapy utilizing a non-inferiority design with an overall survival as the endpoint. As of the Latest Practicable Date, sintilimab was not an approved product in the U.S. If we plan to extend the combination study overseas and the FDA rejected our study plan in the U.S., our overseas development and commercialization of combination therapies involving sintilimab globally may be negatively affected.

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Furthermore, during the R&D and commercialization stages for the combination treatment of LAE002 with sintilimab, we cannot guarantee that Innovent or other potential third party partners will provide stable supply of the relevant compounds, or terminate the agreements altogether. In such cases, we may need to reevaluate our approaches with respect to these combination trials, and potentially find other compounds with combination potentials with our drug candidates. We cannot guarantee that we will be able to find such alternative combination trial opportunities, or that we will not incur significant costs and efforts in so doing. If the NMPA, the FDA or another comparable regulatory agency revokes or denies its approval of sintilimab, in either the clinical design, clinical administration, therapy approval or commercialization, we will be forced to terminate or redesign the clinical trials, experience significant regulatory delays or stop our commercialization efforts.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results and may be subject to adjustments.

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 clinical trial process. The results of pre-clinical studies and early clinical trials of our drug candidates 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. Moreover, a number of factors could affect the relevant clinical results and could render cross-trial comparison results less meaningful, including the different patient enrollment standards adopted in different trials (e.g., tumor size and status, prior treatment history, age group), dose regimen, and the other aspects of clinical trial design. 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 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, results of operations and prospects.

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If clinical trials of our drug candidates fail to meet the trial targets 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 meet the trial targets, including 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 obtain regulatory approval or commercialize our drug candidates, including but not limited to:

- regulators, institutional review boards or 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; and
- 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

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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. For example, we received IND approval for registrational Phase II MRCT study of LAE002 plus paclitaxel versus paclitaxel in patients with PROC from the FDA in the United States. The global Phase II MRCT would be the registrational trial and appropriate to support product registration. According to the written confirmation issued by the FDA in February 2019 and by the NMPA in February 2020, the FDA and the NMPA agreed that this global Phase II MRCT would be the registrational trial and appropriate to support drug registration if the clinical results demonstrate good efficacy and safety profile. However, if our Phase II clinical results are not favorable for registrational purpose, we need to conduct Phase III clinical trials, which may negatively affect our clinical development and commercialization plan.

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.

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

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

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- 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;
- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated; and
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated.

In addition, some of our drug candidates are still considered as emerging therapies for cancers and liver cirrhosis. 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, the FDA 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 affect our business, results of operations and prospects.

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

The 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. For example, 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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Our pre-clinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these drug candidates on a timely basis or at all, which would have an adverse effect on our business.

Some of our drug candidates are still in the pre-clinical development stage, and the risk of failure of pre-clinical programs is high. Before we can commence clinical trials for a drug candidate, we must complete extensive pre-clinical testing and studies to obtain regulatory clearance to initiate human clinical trials, including based on IND applications and clinical trial applications (CTAs) in China and the U.S., as applicable. We cannot be certain of the timely completion or outcome of our pre-clinical testing and studies and cannot predict (i) if the NMPA, the FDA or other regulatory authorities will accept our proposed clinical programs or (ii) if the outcome of our pre-clinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit IND applications or similar applications for our pre-clinical programs on the timelines that we expect, if at all, and we cannot be sure that submission of IND applications, CTAs or similar applications will result in the NMPA, the FDA or other regulatory authorities allowing clinical trials to begin.

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 clinical trial process. The results of pre-clinical studies and early clinical trials of our drug candidates 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 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, results of operations and prospects.

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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. In 2021 and 2022, our research and development expenses were RMB173.3 million and RMB313.4 million, respectively. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our clinical trials. We intend to continue to enhance our technical capabilities in drug discovery, development and manufacturing, which are capital-and-time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may make our techniques obsolete, which could materially and adversely affect our business and prospects.

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

We face an inherent risk of product liability as a result of the clinical trials and any future commercialization of our drug candidates inside and outside China. 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.

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 potential competition from many different sources working to develop therapies targeting the same indications against which we are developing our drug candidates. These include major pharmaceutical companies, academic institutions, government agencies and research institutions. Some of these competitors have better 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.

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Competition in therapeutic areas such as cancer and to which part of our product candidates belong is extremely 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 more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drugs that we may develop or commercialize. Our competitors also may obtain approval from the NMPA, the FDA, or other comparable regulatory authorities for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. They may render our drug candidates obsolete or non-competitive before we can recover expenses of developing and commercializing any of our drug candidates.

Mergers and acquisitions in the pharmaceutical 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.

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 on drug candidates or indications that may later prove to be more profitable, or for which there is a greater likelihood of success, that could materially and adversely affect our future growth and prospects.

Historically, we have in-licensed a number of drug candidates to develop and commercialize. These assets are important to our portfolio. We will continue to seek collaboration opportunities, including in-licensing, if certain drug candidate fits our development plan. However, we cannot guarantee that we will be able to successfully identify, discover 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;

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- 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.

RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

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 and SMOs to generate, monitor or manage data for our ongoing pre-clinical and clinical programs. We rely on these parties for execution of our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs and SMOs does not relieve us of our regulatory responsibilities. We, our CROs and SMOs 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 in China and the U.S. for all of our drugs in clinical development. If we or any of our CROs and SMOs or clinical investigators fail to comply with applicable GCPs, the clinical 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 registrational 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 and SMOs terminate, we may not be able to enter into arrangements with alternative CROs and SMOs on commercially reasonable terms, or at all. In addition, our CROs and SMOs are not our employees. Except for remedies available to us under our agreements with such CROs and SMOs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and non-clinical programs. If CROs and SMOs 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.

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Switching or adding CROs and SMOs 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.

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. 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, the FDA 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, the FDA 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;

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- 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;
- active pharmaceutical ingredients ("APIs") 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.

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

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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.

Our employees, collaborators, service providers, independent contractors, principal investigators, consultants, vendors, CROs, SMOs and CDMOs may engage in misconduct or other improper activities, and we may be unable to detect, deter and prevent all instances of misconduct.

We are exposed to the risk that our employees, collaborators, independent contractors, principal investigators, consultants, vendors, CROs, SMOs and CDMOs 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:

- regulations of the NMPA, the FDA or other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information;
- 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.

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RISKS RELATING TO MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

We have no experience in manufacturing pharmaceutical products, 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 no experience in manufacturing of our future approved 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 APIs;
- delays in the construction of new facilities as a result of changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements;
- changes in the types of products produced;
- advances in manufacturing techniques;
- physical limitations that could inhibit continuous supply; and
- man-made or natural disasters and other environmental factors.

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

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Manufacturing methods and formulations 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, the FDA or other comparable regulatory agency standards or specifications, and maintaining consistent and acceptable production costs. We may also experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to our facilities or 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, or not in compliance with the relevant requirements of the GMP and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

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We intend to manufacture at least a portion of our approved drug candidates ourselves in the future. Delays in commencing and completing construction of, 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 eastern China. These facilities may encounter unanticipated delays and expenses due to a number of factors, including regulatory requirements. If construction, regulatory evaluation and/or approval of our new facilities is delayed, we may not be able to manufacture sufficient quantities of our drug candidates and our drugs, if approved, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from 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, the FDA 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, the FDA 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, the FDA or other comparable regulatory agencies.

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 affect our business.

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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 affect our business, financial condition and operating results.

We rely on certain reagents, specialized equipment, and other specialty materials to manufacture our drug candidates. Such supplies may not be available to us on acceptable terms or at all, and an increase in the market price of such supplies may adversely affect our results of operations.

The manufacturing process of our drug candidates requires many reagents, specialized equipment and other specialty materials manufactured by other third parties. During the Track Record Period, we had not encountered material supply difficulties with respect to reagents, equipment or other materials necessary for our manufacturing of drug candidates. However, as we continue to develop and scale our manufacturing process and capacity, there is no assurance that we will be able to, at all times, procure such reagents, equipment and materials in adequate amount or on commercially reasonable terms, in a timely manner or at all. There is also no assurance that we will be able to identify alternative sources of supply or suitable substitutes for the reagents, equipment or other materials. If we encounter difficulties in procuring necessary reagents, equipment or other materials for manufacturing our drug candidates, we may be forced to delay or suspend our manufacturing activities, which may have a material adverse effect on our clinical development, regulatory approval, future commercialization efforts, results of operations and our prospects.

In addition, for some of these reagents and equipment, we may in the future rely on single source vendors or a limited number of vendors. We might in the future encounter temporary difficulties in sourcing key raw materials as a result of the COVID-19 outbreak, which could have a material impact on our business operations. For additional information on the impact of the COVID-19 outbreak, in particular due to recent Omicron variants, on our business, see

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"Summary – Recent Developments – Impact of the COVID-19 Outbreak." For the risks associated with the COVID-19 outbreak, see "– Risks Relating to Our Operations – Our business operations may in the future be affected by COVID-19 resurgence, and may be affected by other health epidemics or outbreaks of contagious diseases as well as natural disasters." We may not be able to continue to source product from any of these suppliers, which could be due to factors beyond our control, such as regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues. Failure to obtain sufficient supply of these reagents, equipment, and materials could adversely affect our ability to satisfy demand for our drug candidates, which could adversely and materially affect our development process, future commercialization efforts and operating results.

Furthermore, as our manufacturing processes require substantial amounts of supplies, and fluctuations in price of such supplies may directly and adversely impact on our gross margins. During the Track Record Period, we had not experienced significant fluctuations in prices of supplies, and they are generally available and in sufficient quantity to meet our demands. However, we cannot assure you that this will continue to be the case in the future. The prices of supplies we use in manufacturing our drug candidates may be affected by a number of factors, including market supply and demand, the PRC or international environmental and regulatory requirements, natural disasters such as fires, outbreak of epidemics or diseases, and the PRC and global economic conditions. A significant increase in the costs of supplies may directly and negatively affect our profit margins and, ultimately, our business, financial conditions, results of operation and prospects.

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

We are initially seeking approval of the use of some of our drug candidates in certain indications, such as mCRPC, PROC, TNBC, and other solid tumors as a therapy for patients who have progressed after other approved treatments. For example, we are currently and primarily developing LAE002 as a second or later lines of treatment of its target indications. However, there is no guarantee that our product candidates, even if initially approved as a second or later lines of treatment, would be approved as a first line therapy. To develop our drug candidates as a first line treatment, we may have to conduct additional clinical trials at a much larger scale, which may not be successful. As a result, even though the number of patients of the indications we are developing may be large, the actual addressable patients for our drug candidates may be limited to those that have failed prior treatments which may be small. Additionally, regulatory authorities may establish narrower definitions around when a patient is eligible for treatment using our products than we have used in our projections and the number of addressable patients may turn out to be lower than expected.

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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 treatments for cancers and liver cirrhosis 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 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;
- physicians, hospitals 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.

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We have no experience in launching and marketing drug candidates. If we are unable to maintain sufficient marketing and sales capabilities, or to effectively build and manage our sales network, we may not be able to generate product sales revenue as planned.

We have no track record in commercialization, and if we are unable to build sufficient sales and marketing capabilities, we may be unsuccessful to raise awareness and sell our drug candidates successfully. We have not yet demonstrated an ability to launch and commercialize any of our drug candidates. As a result, our ability to successfully commercialize our drug candidates may involve more inherent risks, take longer, and cost more than it would if we were a company with experience launching and marketing drug candidates.

If we fail to comply with applicable anti-bribery laws for commercialization, 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 relevant 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.

Other downward pressure in the pricing of our products when commercialized may have a material adverse effect on our business and results of operations.

In addition to governmental price control measures, we may experience downward pressure in pricing of our drug candidates from other sources, some of which may be beyond our control. For example, competing products, once approved for marketing, may allow our future customers to gain more bargaining power to lower the retail prices of our drug candidates in light of the availability of alternative products. Similarly, as more competing products that target the same indications as our drug candidates may become available for hospitals and patients to choose, therefore would decrease our bargaining power to set price for our drug candidates. Furthermore, with the development of technologies and increasing competition in the industry, we may need to lower the price for our drug candidates in light of the potential launch and commercialization of competing products that tackle similar indications with improved efficacy and safety profile. If we experience such downward pressure in the pricing of our drug candidates, our revenues from sales of drug candidates will decrease, which may have a material adverse effect on our business and results of operations.

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Guidelines, recommendations and studies published by various organizations could disfavor our drug candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors' drugs and drug candidates. Any such guidelines, recommendations or studies that reflect negatively on our drug candidates, either directly or relative to our competitive drug candidates, could result in current or potential decreased use, sales of, and revenues from one or more of our drug candidates. Furthermore, our success depends in part on our and our partners' ability to educate healthcare providers and patients about our drug candidates, and these education efforts could be rendered ineffective by, among other things, third-parties' guidelines, recommendations or studies.

RISKS RELATING TO EXTENSIVE GOVERNMENT REGULATION

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 adopt a global development strategy, and all of our key geopolitical areas 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

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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, the FDA 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, the FDA and other comparable regulatory authorities is unpredictable but typically takes 10 to 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. As of the Latest Practicable Date, we have not obtained qualifications for expedited registration pathways, breakthrough therapies or similar accelerated review channels in any jurisdictions for our drug candidates.

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, the FDA 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

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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 pre-clinical studies or clinical trials which would be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We 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 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 impact our business, financial condition and prospects.

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

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 patients and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations 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 during data storage and data transfer. 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 a number of ongoing clinical studies in China and the U.S. Any storage, transfer and/or use of clinical trial data

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concerning a certain amount of personal data or other critical data categories is subject to the applicable local data and privacy protection laws, including those in China and the U.S. 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. Furthermore, any change in such laws and regulations could affect our ability to store, transfer and/or use medical data and subject us to liability for the process of such data for previously permitted purposes. Complying with all applicable laws, regulations, standards and obligations relating to privacy and data security may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. Any failure to protect the confidentiality of patients’ medical records and personal data during data processing processes including data storage, transfer and/or use or any restriction on or liability as a result of our aforementioned data processing activities including data storage, transfer and/or use, could have a material adverse effect on our business, financial condition and results of operations.

Our [REDACTED] may be impeded and our business operations may be adversely affected by the Measures for Cybersecurity Review or the Regulation on the Administration of Cyber Data Security (Draft for Comments).

On December 28, 2021, the Cyberspace Administration of China (“CAC”), jointly with the other 12 governmental authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the “MCR”), which took effect on February 15, 2022. For details relating to the MCR, please refer to “Regulatory overview – Data Security, Cyber Security and Data Privacy Protection”. Pursuant to Article 2 of the MCR, besides the procurement of network products and services by critical information infrastructure operators, any data processing activity by network platform operators that affects or may affect national security shall be subject to the cybersecurity review. In accordance with Article 7 of the MCR, network platform operators mastering personal information of more than one million users must apply to the Cybersecurity Review Office for cybersecurity review when listing abroad (國外上市).

On November 14, 2021, CAC promulgated the Regulation on the Administration of Cyber Data Security (Draft for Comments) (《網絡數據安全管理條例(徵求意見稿)》) (the “**Draft Cyber Data Security Regulation**”). For details relating to the Draft Cyber Data Security Regulations, please refer to “Regulatory overview – Data Security, Cyber Security and Data

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Privacy Protection”. Given that the Draft Cyber Data Security Regulation had not come into force as of the Latest Practicable Date, the applicability of various requirements under the Draft Cyber Data Security Regulation is still subject to further official guidance and applicable implementation rules.

On May 17, 2022, our PRC Legal Adviser and Sponsors’ PRC legal adviser conducted an anonymous oral consultation with the China Cybersecurity Review Technology and Certification Center (the “**Center**”), which is authorized by the Cybersecurity Review Office of the CAC to accept public consultation and cybersecurity review submissions and is the competent authority to provide views and interpretation relating to the MCR. According to the Center, (i) the listing in Hong Kong does not fall within the scope of “listing abroad”; (ii) critical information infrastructure operators are identified by the governmental authorities of corresponding industry; (iii) if the platforms of the companies are not involved in the collection and processing activities of personal information, such companies would not be viewed as network platform operators; and (iv) at present, the CAC does not require the companies to make their own assessment of whether they affect or may affect national security, therefore it’s not necessary for the companies to take the initiative to declare a cybersecurity review according to the MCR. If the companies affect or may affect national security, the relevant governmental authorities will initiate cybersecurity review at their own discretion, the relevant companies shall cooperate with such cybersecurity review.

As of the Latest Practicable Date, (i) we have not been notified of the results of any determination that we have been identified as a critical information infrastructure operator or that any of our systems have been identified as critical information infrastructure by the relevant governmental authorities; (ii) the MCR does not clearly define “network platform operator”, and we believe that we should not be classified as network platform operator taking into consideration of the fact that we do not engage in business of providing network platform services; (iii) the MCR provides no further explanation or interpretation for “affect or may affect national security”, which remains to be clarified and elaborated by the CAC. As of the Latest Practicable Date, we have not received any notification of cybersecurity review from relevant governmental authorities due to our impact or potential impact on national security; and (iv) we have taken reasonable and adequate technical and management measures to ensure data security, we are of the view that the likelihood that our business operation or [REDACTED] might give rise to national security risks is relatively low.

Therefore, as advised by our PRC Legal Adviser, our Directors believe that as long as there is no material change to our current business and if no further rules are introduced and no significant changes to the enforcement of the MCR by governmental authorities, cybersecurity review under the article 2 and article 7 of the MCR shall not be applicable to us. Based on the above, with the support of our PRC Legal Adviser, we do not foresee any material obstacles to comply with the MCR in all material aspects and we believe the MCR would not have a material adverse impact on our business operations or our [REDACTED]. Given the aforementioned assessment regarding the limited application and implication of the MCR to our business operation or our [REDACTED], and also supported by the industry precedent, our PRC Legal Adviser and our Directors are of the opinion that an anonymous consultation with CAC is sufficient.

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We may be subject to evolving economic sanctions of the U.S., the European countries, the United Kingdom and other relevant sanctions authorities.

The U.S. and other jurisdictions or organizations, including the European countries, the United Kingdom, have, through executive order, passing of legislation or other governmental means, implemented measures that impose economic sanctions against such countries or against targeted industry sectors, groups of companies or persons, and/or organizations within such countries. We cannot provide assurances that our future business will be free of risk under sanctions implemented in these jurisdictions or that we will conform our business to the expectations and requirements of all government authorities, including those that do not have jurisdiction over our business but nevertheless assert the right to impose sanctions on an extraterritorial basis. Our business and reputation could be adversely affected if any government authority were to determine that any of our activities constitutes a violation of the sanctions they impose or provides a basis for a sanctions designation of our Company. In addition, because many sanctions program are evolving, new requirements or restrictions could come into effect which might increase scrutiny on our business or result in one or more of our business activities being deemed to have violated sanctions, or being sanctionable.

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, labeling, 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, the FDA 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, the FDA 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 GCP, for any clinical trials that we conduct subsequent to the approval.

The NMPA, the FDA and other regulatory authorities strictly regulate the marketing, labeling, 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, the FDA 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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Even if we are able to commercialize any approved drug candidates, the drugs may become subject to national and provincial 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 China and some markets outside China, 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.

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.

Our and/or others’ failure to make filings or 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 authorities, 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 make various filings with, or obtain and maintain various approvals, licenses, permits and certificates from, relevant authorities to operate our business. Some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to make filings or obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including fines or 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

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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 make any additional filings or 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 make such filings on time or obtain such approvals, permits, licenses or certificates. Our or these parties’ failure to make the additional filings or 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 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, the FDA 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. The lack of regulations presents uncertainties to our commercialization efforts and may have an adverse effect on our business and results of operations.

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

China imposes controls on the import and export of technology and software products. Under the Regulations on Administration of Imports and Exports of Technologies (《技術進出口管理條例》) promulgated by the State Council, which were amended in November 2020, technology import and export is defined to include, among others, the transfer or licensing of patents and know-how, and the provision of services related to technology. Depending on the nature of the relevant technology, the import and export of technology require either approvals by or registration with the relevant PRC governmental authorities. The Measures for the Administration of Registration of Technology Import and Export Contracts (《技術進出口合同登記管理辦法》), issued by the MOFCOM in February 2009, specify registration requirements related to the import and export of technology.

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We are also subject to export control and import laws and regulations in the U.S., including the U.S. Export Administration Regulations, U.S. Customs regulations, economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. The U.S. Department of Commerce Bureau of Industry and Security (BIS) regulates the export of certain biological and chemical agents, and an export license may be required for the exchange of certain equipment and information we need to operate our business. Approval of such export license applications is based on the technology involved, the destination, and current U.S. foreign policy. We have not received any notification from any U.S. governmental authority requesting any approval for our exports.

As of the Latest Practicable Date, our agreements in effect with CROs in the PRC were signed by our PRC subsidiaries, while our agreements with CROs outside the PRC (including in the U.S) were not signed by our PRC subsidiaries. Therefore, our PRC Legal Adviser is of the view that the relevant agreements with CROs in the PRC in effect as of the Latest Practicable Date did not constitute import or export of technology and were not subject to the Regulations on Administration of Imports and Exports of Technologies, and were not required to be registered with competent authorities. To our best knowledge, we have obtained the relevant approvals required from the U.S. governmental authorities regarding our operations in the U.S., and we are not aware of any violation of U.S. import law with respect to our in-licensing.

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 or individual privacy 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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If we participate in expanded access programs, compassionate use 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 industries, including healthcare reform in China, and compliance with new regulations may result in additional costs.

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 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, Former President Donald J. TRUMP threatened to impose additional tariffs on

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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 light of the current situations and the 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, and 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 to the extent that will have a material impact on the aforementioned aspects of our businesses, which may have a material adverse effect on our results of operations.

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, we formed licensing agreements with Novartis based in the Switzerland. 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. Any tensions and political concerns between China and the relevant foreign countries or regions, including the U.S. and Switzerland, may adversely affect our business, financial condition, results of operations, cash flows and prospects. If Novartis terminates these license agreements due to the international trade policies, our business, financial condition and results of operations will be materially and adversely impacted.

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

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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 Licensing Arrangements" in this document.

If we or our CROs, SMOs or CDMOs fail to comply with environmental, health and safety laws and regulations, we could become subject to fines, penalties, damages 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, 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, chemical hazards or personal injury at our facilities during the process of research, testing, development and manufacturing of pharmaceuticals. 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 affect 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 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.

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RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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.

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. 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.

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 and patent applications 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. Furthermore, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates. As of the Latest Practicable Date, we haven’t obtained patent protections for certain of our early-stage drug candidates. As of the Latest Practicable Date, our non-patented drug candidates included LAE102, LAE109, LAE111, LAE113, LAE117, LAE112, LAE119, LAE120, LAE104, LAE105 and LAE106. For further details of our non-patented drug candidates, please see “Business – Intellectual Property” in this document. Although we plan to initiate patent applications in due course, currently there is no patent protection available for such drug candidates until the relevant patent applications are successful.

The requirements for patentability differ in certain jurisdictions, particularly developing countries. For example, methods of treatment of diseases are not patentable subject matters in China. Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. For example, 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. The U.S. does not have any provisions for a compulsory license. 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

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value of such patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patent or patent application 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. To our best knowledge, as of the Latest Practicable Date, drug products belonging to the same class of our product candidates had not been subjects of compulsory licensing in China and the U.S.

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 and contract manufacturers, 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, in 2013 the U.S., have adopted the “first-to-file” system under which the first inventor to file 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 file in advance to China National Intellectual Property Administration (CNIPA), 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 or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. In addition, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Consequently, we do not know whether any of our platform advances and 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.

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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. The applied and issued patents of our licensing partners for our drug candidates are expected to expire on various dates as described in “Business – Intellectual Property” in this document. Upon the expiration of these and our future applied and issued 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 or license currently or in the future may be subject to a reservation of rights by one or more third parties.

Our in-licensed patents and intellectual property relating to our internally-discovered drug candidates may be subject to priority disputes or 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 narrowing of our or our licensing partners’ patent claims could limit our ability to stop others

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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.

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

The patent position of pharmaceutical 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 result in the issuance of patents at all, and even if were granted patents, they may not be issued 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 successfully result in the issuance of any 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 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 or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings challenging our patent rights or the patent rights of others. 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, 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

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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 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.

Despite measures we or our licensing partners take to obtain patent protection with respect to our major drug candidates and technologies, any of such issued patents could be challenged or invalidated. For example, if we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigations 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 patent invalidity 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. Even if a third party 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 such third party and others.

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 the U.S. law, when new technologies are developed with the 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 the 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 the U.S. industry. In addition, our rights in such government-funded inventions may be subject to certain requirements to manufacture products embodying such

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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.

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 CNIPA, USPTO and other governmental patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO and various other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and maintenance process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment 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.

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

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

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In China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in China. For example, the Standing Committee of the National People’s Congress (SCNPC) promulgated the Amendment to the PRC Patent Law (effective from June 1, 2021), which introduces patent extensions to eligible innovative drug patents and patent term adjustment. Patents owned by third parties may be extended, which may in turn affect our ability to commercialize our products without facing infringement risks. It may also enable the patent owner to submit applications for a patent term extension or enable CNIPA to adjust the patent term. The length of any such extension or adjustment is uncertain. 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 the U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications in the U.S. and the enforcement or defense of our issued patents, each of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Recent U.S. Supreme Court rulings have also changed the law surrounding patent eligibility and narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights 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.

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FIRRMA 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. Former President Trump signed the Foreign Investment Risk Review Modernization Act (“FIRRMA”) in August 2018. Pursuant to the FIRRMA, 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 the 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 the 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 FIRRMA currently grants CFIUS jurisdiction on only controlling and certain non-controlling investments made by foreign persons in the U.S. businesses in research and development in biotechnology, the CFIUS 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.

We may face intense competition from manufacturers of generic or biosimilar drugs after the expiration of patent protection periods.

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. For example, patents related to composition of matter of LAE002 or LAE003 may expire in 2028, and we plan to apply patent term extension for LAE002 or LAE003 in China, the U.S. and other jurisdictions. Upon the expiration of relevant patents, we may face fierce competition from generic or biosimilar products, including from the ATK inhibitors in generic or biosimilar form of LAE002 and LAE003. Although we plan to apply for an extension of the patent term of LAE002 or LAE003 after the patent expires and we have developed a commercialization strategy for LAE002 and LAE003 to compete with their potential competitors, there can be no assurance that our application and commercialization strategy will be successful. If we fail to extend the patent term of LAE002 and LAE003 or our commercialization strategy prove to unsuccessful, our results of operations may be adversely affected.

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If we are unable to protect the confidentiality of our trade secrets and other confidential information, including unpatented know-how upon which we rely on, 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. 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. In addition, some courts in China, the U.S. and other jurisdictions are less willing or unwilling to protect trade secrets. 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 companies, including our competitors or potential competitors. Some of these employees, consultants, and advisers, including each member of our senior management, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and advisers 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 individuals 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

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rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. An inability to incorporate such intellectual property rights would materially and adversely affect 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 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. If third parties succeed in registering or developing common law rights in trademarks similar or identical to our 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. 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.

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, the outcome of which would be uncertain, 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. The pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. 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.

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.

Parties making infringement, misappropriation, or other intellectual property claims against us may obtain injunctive or other equitable relief, which could block our ability to further develop and commercialize one or more of our drug candidates. Defense of these

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claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. In addition, even if we believe any third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of validity, enforceability, priority, or non-infringement. A court of competent jurisdiction could hold that such third party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any of our products or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such third-party U.S. patents in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent.

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 non-exclusive, which could result in our competitors gaining access to the same intellectual property, and it could require us to make substantial licensing and royalty payments. 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 trade name. As of the Latest Practicable Date, we owned 163 patents and patent applications (including in-licensed patents and patent applications with global rights), and we were also the registered owner of three domain names. 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;

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- 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;
- 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 or those that we may own in the future will not lead to issued patents;
- patents that may be issued from our pending patent applications may 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 OPERATIONS

Our business operations may in the future be affected by COVID-19 resurgence, and may be affected by other health epidemics or outbreaks of contagious diseases as well as natural disasters.

In March 2020, the World Health Organization characterized the COVID-19 outbreak as a global pandemic. Significant rises in COVID-19 cases have been reported since then, causing governments around the world to implement unprecedented measures such as city lockdowns, travel restrictions, quarantines and business shutdowns. The COVID-19 outbreak, including the emergence of its variants, has caused an unprecedented impact on the global economy as it has significantly reduced market liquidity and depressed economic activities.

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The COVID-19 outbreak has caused and may continue to cause a long-term adverse impact on the economy and social conditions in China and globally, which may have an adverse impact on our industry and cause temporary suspension of projects and shortage of labor and patients, which would severely disrupt our operations and clinical trial progress and have a material adverse effect on our business, financial condition and results of operations. Our operations could also be disrupted if any of our employees or employees of our suppliers and other business partners, including but not limited to CROs, SMOs and CDMOs, were suspected of contracting or contracted COVID-19, since this may require us and our suppliers and other business partners to quarantine some or all of these employees and disinfect facilities used for operations. In addition, the commencement of new clinical trials for drug candidates in our development pipeline could also be delayed or prevented by any delay or failure in subject recruitment or enrollment. Our commercialization plan for our approved products could also be disrupted and delayed.

Since the start of 2022, there have been resurgence of COVID-19 cases in certain cities of China, in response to which, the government has taken further mitigation measures and actions, including temporary lockdowns and other enhanced social distancing measures. The extent to which COVID-19 will impact our operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19, the scope and duration of restricted measures to contain COVID-19 or treat its impact, evolution of variants of the virus and effectiveness of the vaccines, among others. If the COVID-19 situation deteriorates, it may affect our clinical development, the sales of our future approved products and the supply of raw materials and production equipment. We cannot assure you that the resurgence will not persist, or that there will not be similar events in the future. If the COVID-19 resurgence continues, our business, results of operations and financial condition will be adversely affected.

In addition, any future occurrence of force majeure events, natural disasters or outbreaks of other epidemics and contagious diseases, including avian influenza, severe acute respiratory syndrome, swine influenza caused by the H1N1 virus, or H1N1 influenza or the Ebola virus, may materially and adversely affect our business, financial condition and results of operations. Moreover, the PRC has experienced natural disasters such as earthquakes, floods and droughts in the past few years. Any future occurrence of severe natural disasters or outbreaks of epidemics and contagious diseases in China or globally, or the measures taken by the Chinese government or other countries in response to such contagious diseases, may materially and adversely affect their economy and our business.

If we fail to maintain effective internal controls, we may not be able to accurately report our financial results or prevent fraud, and our business, financial condition, results of operation and reputation could be materially and adversely affected.

We will become a [REDACTED] company upon completion of the [REDACTED], and our internal controls will be essential to the integrity of our business and financial results. Our public reporting obligations are expected to place a strain on our management, operational and financial resources and systems in the foreseeable future. In order to address our internal

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controls issues and to generally enhance our internal controls and compliance environment, we have taken various measures to improve our internal controls and procedures including establishing a compliance program, adopting new policies, and providing extensive and ongoing training on our controls, procedures and policies to our employees. In addition, in preparation for the [REDACTED], we have implemented other measures to further enhance our internal controls, and plan to take steps to further improve our internal controls. If we encounter difficulties in improving our internal controls and management information systems, we may incur additional costs and management time in meeting our improvement goals. We cannot assure you that the measures taken to improve our internal controls will be effective. If we fail to maintain effective internal controls in the future, our business, financial condition, results of operation and reputation may be materially and adversely affected.

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 depend on principal members of our management and scientific teams. Our employment agreements with our executive officers 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.

To incentivize valuable employees, especially 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, obtain 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 companies for similar personnel. To compete effectively, we may need to offer higher compensation and other benefits, which could

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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, physicians or other technical personnel may have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

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

We had 95 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.

Increased labor costs could result in exceeding expenses, slow our growth and adversely affect our profitability.

Since our operations are labor-intensive and our operations, to a certain extent, require the use of technical skills and know-how of our employees, our success depends in part on our ability to attract, retain and motivate a sufficient number of qualified employees. We have implemented a number of initiatives in an effort to attract, retain and motivate our qualified and competent staff. There is no assurance that these measures will be effective or that supply of

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skilled labor in local markets will be sufficient to fulfill our needs. Competition for competent and skilled labor is intensive in the industry. Our failure to hire and retain enough skilled employees could delay the anticipated pre-clinical studies or clinical trials timeframe or receipt of regulatory approvals to commercialize our drug candidates, or result in our expenses exceeding our initial budget. Any of the foregoing changes could have a material adverse effect on our business, profitability and prospects.

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

We may be involved in lawsuits, claims, administrative proceedings or other legal proceedings against us, which could 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. 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.

Additionally, 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 third parties, they 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.

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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 recruit key employees away from companies during the integration phase of an acquisition. In

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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 the 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 Ministry Of Commerce, or 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.

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

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

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In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. Disruptions in our on-site systems and by our outsourced vendors could have a material adverse impact on us and our business, including loss of data and damage to equipment, among other things.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, system malfunction or intentional or accidental release or loss of information maintained in the information systems and networks of our Company and our vendors, including but not limited to personal information of our employees and patients, and company, vendor and the other users of our vendors' confidential data.

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 subject to regulatory actions or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations. As we engage in more electronic transactions with payers and patients, and collect and store an increasing volume of data, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

We 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 leased four properties in China with an aggregate GFA of approximately 5,493.3 sq.m. 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 may be subject to fines due to the lack of registration of our leases.

Pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, the lease agreements shall be filed for registration and property leasing filing certificates shall be obtained. As of the Latest Practicable Date, three of our lease agreements for properties in China have not been registered with relevant authorities in China. The registration of these relevant lease agreements requires additional steps to be taken by the lessors which are beyond our control. We cannot assure you that the lessors will be cooperative and that we can complete the registration of these lease agreements.

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We also maintain a pool of site candidates, and believe we would be able to relocate to a different site relatively easily should we be required to do so. As advised by our PRC Legal Adviser, if we cannot complete the registration of lease agreement, we may be subject to a fine ranging from RMB1,000 to RMB10,000 for each of the lease agreements. Such non-compliance does not affect the validity of the property lease agreement, and we believe such non-compliance is unlikely to have a material adverse effect on our business operations and financial performance.

We are subject to the risks of doing business, including risks relating to political and economic instability and changes in diplomatic and trade relationships, which may materially and adversely affect our business and results of operations.

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

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

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Furthermore, we are subject to general geopolitical risks in foreign countries where we operate, such as political and economic instability and changes in diplomatic and trade relationships, which could cause our results to fluctuate and our revenue to decline. The occurrence of any one or more of these risks of doing business internationally, individually or in the aggregate, could materially and adversely affect our business and 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 the U.S. dollars, most of our assets are cash and cash equivalents primarily denominated in RMB and the U.S. dollars, and our [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. Any significant change in the exchange rates of the Hong Kong dollar against RMB or U.S. dollars against RMB may materially and adversely affect the value of and any dividends payable on, our Shares in Hong Kong dollars.

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

We maintain insurance policies that are required under the PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. In line with industry practice in the PRC, we have elected not to maintain certain types of insurance. 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.

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 Shareholders, Directors, officers, employees, collaboration partners, suppliers or other third parties we work with or rely on were non-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. Any negative publicity regarding our industry could also affect our reputation and commercialization. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity that may or may not directly related to us, and may not be able to defuse them to the satisfaction of our current or future [REDACTED], customers, patients and business partners.

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RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

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

We are a development-stage pharmaceutical company. Our operations to date have focused on conducting pre-clinical studies and clinical trials of our drug candidates, establishing our intellectual property portfolio, organizing and staffing, business planning, and raising capital. As of the Latest Practicable Date, we had no product approved for commercial sale. Our limited operating history, particularly in light of the rapidly evolving pharmaceutical 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 have not generated any revenue, and our ability to generate revenue from future sales of our drug candidates and become profitable depends significantly on our success in a number of factors, including the success of our drug candidates.

As of the Latest Practicable Date, none of our drug candidates had been approved for commercial sale by any relevant regulatory authorities, and therefore we had not generated any revenue. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including:

- completing non-clinical and clinical research and development of our drug candidates;
- obtaining regulatory approvals and marketing authorizations for drug candidates for which we have completed clinical trials for;
- developing a sustainable and scalable manufacturing process for our drug candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- controlling the cost of production of our drug candidates;
- launching and commercializing drug candidates for which we obtain regulatory approvals and marketing authorizations;
- obtaining market acceptance of our drug candidates as viable treatment options to be paid as an out-of-pocket expense, and availability of adequate coverage, reimbursement, pricing by third-party payors and integrated delivery networks;

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- addressing any competing technological and market developments;
- maintaining, protecting, expanding and enforcing our portfolio of intellectual property rights, including patents, trademarks, trade secrets, and know-how;
- identifying, assessing, acquiring and/or developing new drug candidates, intellectual property and technologies;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the drug candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved drug candidate. Our expenses could increase beyond expectations if we are required by the NMPA, the FDA or other relevant regulatory authorities to modify our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those we currently anticipate. Even if we are successful in obtaining regulatory approvals to market one or more of our drug candidates, our revenue will be dependent, in part, upon the size of the market and competitive landscape for the relevant product in China, the United States or other relevant jurisdictions, the accepted price for the product to be paid with out-of-pocket expenses and the ability to get reimbursement for any amount. If the number of patients with our addressable disease is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

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

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

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

[REDACTED] in pharmaceutical drug development is highly speculative. Drug development entails substantial upfront capital expenditures and significant risk that a drug candidate fails to obtain 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 2021 and 2022, we recorded loss of RMB749.0 million and RMB781.6 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 losses on financial instruments issued to [REDACTED].

We expect to continue to incur significant 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 [REDACTED] company and in support of our growth as a development-stage or commercial-stage 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 obtain regulatory approval, or if approved, fails to achieve market acceptance, we may never become profitable. Even if we become profitable in the future, we may not be able to remain profitable 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. As a result, you may lose substantially all or part of your [REDACTED].

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

We had net cash used in operating activities of RMB198.0 million and RMB306.3 million in 2021 and 2022, respectively. While we believe we have sufficient working capital to fund our current operations for the next 12 months, we expect that we may continue to experience net cash outflows from our operating activities for the foreseeable future. If we are unable to maintain adequate working capital, we may default on our payment obligations such as the milestone payments under our licensing agreements, 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.

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

We had net liabilities of RMB1,111.2 million and RMB1,905.1 million as of December 31, 2021 and 2022, respectively. Our net liabilities are primarily attributable to our financial instruments issued to investors we recorded as non-current liabilities, which amounted to RMB1,500.5 million and RMB2,277.3 million as of December 31, 2021 and 2022, respectively. Although we expect our net liability position to be reversed after the automatic conversion of the Preferred Shares into Shares upon the [REDACTED], a net liabilities position can expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources such as external debt, which may not be available on terms favorable or commercially reasonable to us or at all. Any difficulty or failure to meet our liquidity needs as and when needed can have a material adverse effect on our 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 net cash used in operating activities mainly consists of (i) research and development costs including staff costs, discovery research expenses and clinical development expenses and (ii) workforce employment costs. In 2021 and 2022, we incurred total net cash used in operating activities of RMB198.0 million and RMB306.3 million, respectively. For further details of our net cash used in operating activities, please see “Financial Information – Cash Operating Costs.” We expect our net cash used in operating activities will increase significantly in light of our expanding clinical trial programs. Additionally, we are exposed to credit risk on the cash and cash equivalents deposited in financial institutions. In the event that any of them becomes insolvent and is taken into receivership by the relevant government agencies, there will be uncertainty as to the timing and extent to which we will be able to recover our cash on deposit at such financial institution. 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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Raising additional capital may cause dilution to our shareholders’ interest, restrict our operations or, when licensing of intellectual property rights is deployed as a means of financing our operations, 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. Incurring additional debt 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 collaboration 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.

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

We adopted the Laekna Inc. Employee Stock Option 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] Share Option Scheme” in this document. In 2021 and 2022, we incurred equity settled share-based payment expenses of RMB12.0 million and RMB26.5 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.

Intangible assets represent a significant portion of the assets on our consolidated balance sheet. If we determine our intangible assets are impaired, our results of operations and financial condition may be adversely affected.

As of December 31, 2022, we had intangible assets of RMB123.6 million which comprised of RMB118.7 million related to in-licensed rights and RMB4.9 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

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assumptions made by the management. For a detailed discussion on the intangible assets, see Note 11 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.

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 “Significant Accounting Policies – Intangible assets” and Note 3 “Accounting Judgments and Estimates – Impairment of intangible assets not ready for commercial use” to the Accountants’ Report in Appendix I to this document.

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

Our fair value changes on financial instruments issued to [REDACTED] resulted from changes in fair value of Preferred Shares and a warrant issued to [REDACTED]. In 2021 and 2022, our fair value changes on financial instruments issued to investors were RMB522.4 million and RMB387.1 million. Since 2018, we have issued a series of Series Seeds Preferred Shares, Series A Preferred Shares, Series B Preferred Shares, Series C Preferred Shares, and Series D Preferred Shares to our Series Seeds investors, Series A investors, Series B investors, Series C investors, and Series D investors, respectively. For more details regarding Preferred Shares, please see “History, Development and Corporate Structure – [REDACTED] Investments” in this document. We have designated the entire instrument of the Preferred Shares as financial liabilities at fair value through profit or loss. On January 31, 2019, we entered into a warrant agreement with an individual investor pursuant to which we issued a warrant to such investor for a cash consideration of RMB11.7 million. Pursuant to such warrant agreement, the warrant holder may exercise the warrant to purchase 1,166,525 ordinary shares and 338,273 Series Seeds Preferred Shares for nil consideration on or before the 90th day after our board approves to initiate an [REDACTED] of our shares. The warrant is initially recognized at fair value on the date of issuance and is subsequently re-measured to the fair value at the end of each reporting period. We have engaged an independent qualified professional valuer to determine the fair value of Preferred Shares and the warrant. For additional information, see Note 21(b) of the Accountants’ Report set out in Appendix I to this document. The respective fair value is determined by applying certain valuation techniques. Key valuation assumptions used to determine the fair value of the financial instruments are subject to various uncertainties. Any change in the assumptions may lead to different valuation results and, in turn, changes in the fair value of financial instruments issued to [REDACTED]. Fair value changes in our financial instruments issued to [REDACTED] and related valuation uncertainty may materially affect our financial condition and results of operations.

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The impairment of our prepayments and other receivables may affect our business operations.

Our prepayments and other receivables were RMB12.5 million and RMB11.6 million as of December 31, 2021 and 2022, respectively. Our current prepayments and other receivables include advances to third parties, deposits, interest receivables, VAT recoverable and other receivables. For more details, please see Note 15 of the Accountants’ Report set out in Appendix I to this document. We conduct assessments on the recoverability of prepayments and other receivables based on, among others, our historical settlement records, our relationship with relevant counterparties, payment terms, current economic trends and to a certain extent, the larger economic and regulatory environment, which involve the use of various judgments, assumptions and estimates by our management. However, there is no assurance that our expectations or estimates will be entirely accurate, or any precautions we take to prevent an impairment will be effective, as we are not in control of all the underlying factors affecting such prepayments and other receivables. If we are not able to recover the prepayments and other receivables as scheduled, our financial position and results of operations may be adversely affected.

RISKS RELATING TO 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 40 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

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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.

On November 19, 2021, the CDE launched the Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》), or the Clinical Principles, for anti-tumor drugs, which state that the fundamental purpose of the drug market is to address the needs of patients, and emphasize that drug research and development should be based on patient needs and clinical value. The Clinical Principles discourage repetitive research and development of “me-too drugs” (drugs with identical mechanisms of actions) and disorderly waste. If we are unable to comply with, or are deemed to be in violation of the Clinical Principles’ detailed provisions and principles, our clinical development activities and overall business operations may be materially 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.

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 non-binding nature of such decisions, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the 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.

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

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.

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 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.

In response to the persistent capital outflow in China and RMB’s depreciation against the U.S. dollar, the 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 [REDACTED] or other obligations to our suppliers, or otherwise fund and conduct our business.

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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 (《中華人民共和國外商投資法》), 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 (《中外合資經營企業法》), the Sino-foreign Cooperative Joint Venture Enterprise Law (《中外合作經營企業法》) and the Wholly Foreign-invested Enterprise Law (《外資企業法》), 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 《外商投資法實施條例》 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, 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.

More stringent restrictions on the remittance of RMB into and out of the PRC and governmental control over currency conversion may limit our ability to pay dividends and other obligations, and affect the value of your [REDACTED].

The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. 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 expected to be 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

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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 research and development activities. We recorded government grants of RMB0.1 million and RMB0.3 million in 2021 and 2022, respectively, which represent subsidies from local governments. 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.

The approval of or filing with the CSRC may be required in connection with the [REDACTED], and, if required, we cannot predict whether we will be able to obtain such approval or complete such filing in a timely manner or at all.

The M&A Rules require an overseas special purpose vehicle formed for [REDACTED] purposes through acquisitions of PRC domestic companies and controlled by PRC companies or individuals to obtain the approval of the China Securities Regulatory Commission, or the CSRC, prior to the [REDACTED] and trading of such special purpose vehicle’s securities on an overseas stock exchange. The interpretation and application of the regulations remain unclear, and the [REDACTED] may ultimately require approval from the CSRC. If the CSRC approval is required, it is uncertain how long it will take us to obtain such approval and any failure to obtain or delay in obtaining the approval for the [REDACTED] would subject us to sanctions imposed by the CSRC and other PRC regulatory agencies, which could include fines and penalties on our operations in China, restrictions or limitations on our ability to pay dividends outside of China. Our PRC Legal Adviser has advised us that, based on its understanding of the current PRC laws and regulations, we will not be required to submit an application to the CSRC for the aforementioned approval under the M&A Rules and [REDACTED] of our Shares on the Stock Exchange because (i) the CSRC currently has not

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issued any definitive rule or interpretation concerning whether [REDACTED] like ours under this Document are subject to the M&A Rules; and (ii) our FIEs were incorporated as foreign-invested enterprises without involving acquisition of the equity or asset of a PRC “domestic company,” especially a PRC domestic company owned by beneficial owners who are PRC companies or individuals, as such term is defined under the M&A Rules. However, our PRC Legal Adviser has further advised us that there remains some uncertainty as to how the M&A Rules will be interpreted or implemented and its opinions summarized above are subject to any new laws, rules and regulations or detailed implementations and interpretations in any form relating to the M&A Rules. We cannot assure you that relevant PRC government agencies, including the CSRC, would reach the same conclusion as we did, and hence we may face regulatory actions or other sanctions from the CSRC or other PRC regulatory agencies.

On February 17, 2023, the CSRC promulgated Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “Overseas Listing Trial Measures”) and relevant five guidelines, which will become effective on March 31, 2023.

According to the Overseas Listing Trial Measures, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provides that if the issuer both meets the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as indirect overseas offering by PRC domestic companies: (i) 50% or more of any of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (ii) the main parts of the issuer’s business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are PRC citizens or have their usual place(s) of residence located in mainland China. The determination of the indirect overseas offering by PRC domestic companies shall follow the principle of substance over form. Where an issuer submits an application for initial public offering to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted.

At a press conference held for these new regulations, officials from the CSRC clarified that the domestic companies that have already been listed overseas on or before the effective date of the Overseas Listing Trial Measures (i.e. March 31, 2023) shall be deemed as existing issuers, or the Existing Issuers. Existing Issuers are not required to complete the filing procedures immediately, and they shall be required to file with the CSRC when subsequent matters such as refinancing are involved. Furthermore, according to the officials from the CSRC, domestic companies that have obtained approval from overseas regulatory authorities or securities exchanges (for example, a contemplated offering and/or listing in Hong Kong has passed the hearing of the Stock Exchange) and do not need to re-obtain the approval from the relevant overseas regulatory authorities or securities exchanges for their indirect overseas offering and listing prior to the effective date of the Overseas Listing Trial Measures (i.e.

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March 31, 2023) but have not yet completed their indirect overseas issuance and listing, are granted a six-month transition period from March 31, 2023. Those who complete their overseas offering and listing within such six-month transition period are deemed as Existing Issuers and do not need to file with the CSRC. Within such six-month transition period, however, if such domestic companies need to reapply for offering and listing procedures to the overseas regulatory authorities or securities exchanges (such as requiring a new hearing of the Stock Exchange), or if they fail to complete their indirect overseas issuance and listing, such domestic companies shall complete the filing procedures with the CSRC.

Based on the foregoing and as advised by our PRC Legal Adviser, we may be deemed as a PRC domestic company and therefore subject to the Overseas Listing Trial Measures. If we fail to qualify as an Existing Issuer, we will be required to complete the filing procedures with the CSRC in connection with the [REDACTED] as required under the Overseas Listing Trial Measures.

As of the Latest Practicable Date, we have not received any inquiries, comments, instructions, guidance or other concerns from the CSRC or any other PRC authorities with respect to our [REDACTED] plan. However, given that the Overseas Listing Trial Measures were recently promulgated, there remain substantial uncertainties as to their interpretation, application, and enforcement and how they will affect our operations and our future financing. If it is determined that we are subject to any CSRC approval or filing requirements, we may fail to obtain such approval or meet such filing requirements in a timely manner or at all. Such failure may subject us to fines, penalties or other sanctions which may have a material adverse effect on our business and financial condition as well as our ability to complete the [REDACTED].

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.

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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 [REDACTED] 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, the mainland China and Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements Between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “**Arrangement**”), 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 the Hong Kong Special Administrative Region and the China. The New Arrangement discontinued the requirements for a choice of court agreement for bilateral recognition and enforcement. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People’s Court 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 [REDACTED] to effect service of process against our assets or management in China in order to seek recognition and enforcement of foreign judgments in China.

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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.

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.

SAFE has promulgated several regulations associated with offshore investment such as Circular of the State Administration of Foreign Exchange on the Administration of Foreign Exchange Involved in Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles Conducted by Domestic Residents in China via Special-Purpose Companies (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) or SAFE Circular 37, issued and effective on July 4, 2014, and the Notice of the State Administration of Foreign Exchange on Issuing the Provisions on the Foreign Exchange Administration of the Overseas Direct Investments (《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). Failure to comply with the various SAFE regulations might result in liability under PRC laws for evasion of applicable foreign exchange restriction, including (1) the requirement by the SAFE to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas and deemed to have been evasive, and (2) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive.

There remains uncertainty as to the interpretation and implementation of the latest SAFE rules at practice level. We are committed to complying 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 always be fully aware or informed of the identities of our beneficial owners who are PRC nationals or entities, and may not be able to compel them to comply with relevant SAFE rules and other regulations. We cannot assure you that all of our Shareholders or beneficial owners 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.

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We and our Shareholders face uncertainty relating to PRC laws and regulations relating to the indirect transfer of equity interests in PRC resident enterprises by a non-PRC resident enterprise.

On February 3, 2015, the State Taxation Administration of the PRC (STA) 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 Equity Transfers by 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 STA 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 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

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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 one implementing rule for Circular 698. In general, transfers of the Shares by Shareholders on the Stock Exchange or other public market would not be subject to the PRC tax liabilities and reporting obligations imposed under the Circular 7 if the transfers fall under the Public Market Safe Harbor. 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 the EIT Law, we may be classified as a “PRC resident enterprise” for PRC income tax purposes, and such classification could result in unfavorable tax consequences to us and our non-PRC shareholders.

Under 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. The Notice Regarding the Determination of Chinese-Controlled Offshore-Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies (《關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》) issued by STA on April 22, 2009, or Circular 82, regarding the standards used to classify resident enterprises clarified that dividends and other distributions 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

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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 STA issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial) (《境外註冊中資控股居民企業所得稅管理辦法(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 are, and the management team of some of our offshore shareholders may be, 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 STA may take the view that the determining criteria set forth in Circular 82 and Bulletin 45 reflect the general position on how the “de facto management body” test should be applied in determining the tax resident status of all offshore enterprises. Additional implementing regulations or guidance may be issued determining that 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 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 would be able to obtain in

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practice 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. Any such tax may reduce the returns on your investment in our Shares.

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 and the SAMR through the Enterprise Registration System (企業登記系統) and the National Enterprise Credit Information Publicity System (國家企業信用信息公示系統) and the SAFE.

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. 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 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. For example, 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 its non-affiliated company. On October 23, 2019, 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 non-investment foreign-invested enterprises are permitted to make domestic equity investments with their capital funds provided that such investments do not violate the Negative List and the

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target investment projects are genuine and in compliance with laws. On April 10, 2020, 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, 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 evidentiary materials concerning authenticity of each expenditure, provided that their capital use shall be authentic and in line with provisions, 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 exist substantial uncertainties with respect to its interpretation and implementation by government authorities and banks.

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 on or otherwise fund our PRC operations may be negatively affected, which could adversely affect our ability to fund and expand our business.

The M&A Rules and certain other PRC regulations establish complex procedures for some acquisitions of PRC companies by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.

The Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (《關於外國投資者併購境內企業的規定》), or the M&A Rules, and relevant regulations and rules concerning mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. The M&A Rules require that the MOFCOM shall be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have an impact on the national economic security; or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. The approval from MOFCOM shall be obtained in circumstances where overseas companies established or controlled by PRC enterprises or residents acquire affiliated domestic companies.

The Anti-Monopoly Law (《中華人民共和國反壟斷法》) promulgated by the Standing Committee of the National People's Congress, or NPC, which became effective in August 2008, requires that when a concentration of undertakings occurs and reaches statutory thresholds, the undertakings concerned shall file a prior notification with MOFCOM. Without the clearance from MOFCOM, no concentration of undertakings shall be implemented and

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effected. Mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the MOFCOM when the threshold under the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings, (《關於經營者集中申報標準的規定》) or the Prior Notification Rules, issued by the State Council in August 2008 is triggered. If such prior notification is not obtained, MOFCOM may order the concentration to cease its operations, dispose of shares or assets, transfer the business of the concentration within a time limit, take any other necessary measures to restore the situation as it was before the concentration, and may impose administrative fines. SAMR becomes the successive authority of MOFCOM with regard to the above matters, upon the government reorganization in March 2018.

In addition, the Implementing Rules Concerning Security Review on the Mergers and Acquisitions by Foreign Investors of Domestic Enterprises (《商務部實施外國投資者併購境內企業安全審查制度的規定》), issued by the MOFCOM in August 2011, specify that mergers and acquisitions by foreign investors relating to national security are subject to strict review by the MOFCOM, and prohibit any activities attempting to bypass such security review, including by structuring the transaction through a proxy or contractual control arrangement. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the abovementioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval from the MOFCOM or its local counterparts, may delay or inhibit our ability to complete such transactions.

We cannot preclude the possibility that the MOFCOM or other government agencies may publish explanations contrary to our understanding or broaden the scope of such security reviews in the future, in which case our future acquisitions in the PRC, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

Failure to comply with relevant regulations relating to social insurance and housing provident fund may subject us to penalty.

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), we are required to make contributions to the social insurance plans and the housing provident fund under the relevant PRC laws and regulations for our employees. For details relating to these relevant laws and regulations, please refer to the paragraph headed “Regulatory overview – Labor and social security” in this document.

As of the Latest Practicable date, we have engaged third-party human resource agency to pay social insurance premium and housing provident funds for four of our employees. Pursuant to the agreement entered into between such third-party human resources agency and us, the third-party human resources agency have the obligation to pay social insurance premium and housing provident funds for our relevant employees on behalf of us. As of the Latest

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Practicable Date, we had not received any administrative penalty or labor arbitration application from employees for its agency arrangement with third-party human resources agency. These four employees have confirmed in writing that they have accepted this arrangement and will not pursue any claims against us with the competent authorities. As advised by our PRC Legal Adviser, considering the facts stated above, the risk of us being subject to material penalties as a result of paying the social insurance premium or housing provident funds through third-party agency and thus have any material adverse effect on our financial condition or results of operations taken as a whole is relatively low. However, if the local governments determine the use of third-party agency to pay social insurance and housing provident funds to be non-compliant in the future or such human resource agency fail to pay the social insurance premium or housing provident funds for and on behalf of our employees as required by applicable PRC laws and regulations, we may be subject to additional contribution, late payment fee and/or penalties imposed by the relevant PRC authorities for failing to discharge our obligations in relation to payment of social insurance and housing provident funds as an employer or be ordered to rectify. This in turn may adversely affect our financial condition and results of operations.

We have enhanced our internal control measures requiring social insurance and housing provident fund contributions to be made in compliance with relevant PRC laws and regulations. In particular, we plan to regularly review and monitor the reporting and contributions of social insurance and housing provident fund and consult our PRC legal counsel on a regular basis to keep us abreast of relevant regulatory developments.

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. and certain other countries and regions. Establishing new collaboration partnerships 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 business partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Since mid-2018, political tension has increased between China and the U.S. 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

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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] (for itself and on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the market price of the Shares following the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to deal in, the Shares. In addition, each existing Shareholder, including our [REDACTED] Investors, has entered into [REDACTED] undertakings in favor of our Company and/or the Sole Sponsor and/or the [REDACTED] pursuant to which they are subject to [REDACTED] arrangements ending on the date which is six months from the [REDACTED], subject to certain exceptions. As a result, a [REDACTED] on the Hong Kong Stock Exchange does not guarantee that an active and liquid trading market for our Shares will develop, especially during the period when a significant portion of our Shares are subject to [REDACTED] undertakings, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the Shares will rise following the [REDACTED].

The price and [REDACTED] of our Shares may be volatile, which could lead to substantial losses to [REDACTED].

The price and [REDACTED] 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 [REDACTED] of our Shares. In addition to market and industry factors, the price and [REDACTED] 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 [REDACTED] 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.

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There will be a gap of several days between [REDACTED] and [REDACTED] 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 [REDACTED] 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.

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 [REDACTED] 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.

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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, among other things, conduct clinical trials in China and other jurisdictions on our drug candidates and to expand our sales and marketing staff in preparation for the approval and commercialization of our drug candidates. For details, see “Future Plans and 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].

Our single largest Shareholder has had and will continue to have substantial influence over the outcome of shareholder actions in our Company. The interests of our Shareholder may not be aligned with the interests of our other Shareholders.

Upon completion of the [REDACTED] and [REDACTED], the single largest Shareholder will hold [REDACTED]% of our total issued and outstanding Shares (assuming that all of the Preferred Shares have been converted into the Shares on a one-to-one basis and the [REDACTED] is not exercised). As a result, the single largest Shareholder, will have significant influence over our business, including decisions regarding mergers, consolidations, liquidations and the sale of all or substantially all of our assets, election of directors and other significant corporate actions.

It may take actions that are not in the best interest of us or our other Shareholders. This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could have the effect of depriving our other Shareholders of the opportunity to receive a premium for their shares as part of a sale of our Company and may reduce the price of the Shares. This concentrated control will limit your ability to influence corporate matters and could discourage others from pursuing any potential merger, takeover or other change of control transactions that other holders of our ordinary shares may view as beneficial.

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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 the section headed “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 our single largest Shareholder, 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. We believe that the sources of such information is appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. The information has not been independently verified by us, the Sole Sponsor, the [REDACTED] or any other party involved in the [REDACTED] and no representation is given as to its accuracy. The Directors and the Sole Sponsor have exercised reasonable care in selecting and identifying the named information sources, in compiling, extracting, and reproducing the information, and in ensuring that there is no material omission of the information.

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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 purchase our Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document.

WAIVERS AND EXEMPTIONS

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 a 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 a 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 Hong Kong, and the executive Directors of our Company ordinarily reside 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 Directors or appointment of additional executive Directors. Our Company does not have and does not contemplate in the foreseeable future that we will have a sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 of the Listing Rules.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from strict compliance with the requirements under Rule 8.12 of the Listing Rules. 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 Ms. Xie, one of our executive Directors, and Ms. TANG Wing Shan Winza (鄧穎珊) (“**Ms. Tang**”), one of our joint company secretaries, as authorized representatives of our Company (the “**Authorized Representatives**”) pursuant to Rule 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 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) each Director has provided his/her mobile phone number, office phone number, email address and fax number, if applicable, to the authorized representatives of our Company and the Stock Exchange;
- (d) 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;
- (e) we have appointed Huajin Corporate Finance (International) Limited as our Compliance Adviser upon [REDACTED] pursuant to Rule 3A.19 of the Listing Rules for a period commencing on the [REDACTED] and ending on the date on which 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 the Listing Rules. 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; and
- (f) we may also retain legal advisers to advise on on-going compliance requirements as well as other issues arising under the Listing Rules and other applicable laws and regulations of Hong Kong after [REDACTED].

WAIVER IN RESPECT OF JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules, the company secretary of an issuer must be an individual who, by virtue of his or her academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of the company secretary. Note 1 to Rule 3.28 of the Listing Rules sets out the following academic and professional qualifications considered to be acceptable by the Stock Exchange:

- (a) a member of The Hong Kong Chartered Governance Institute;
- (b) a solicitor or barrister as defined in the Legal Practitioners Ordinance (Chapter 159 of the Laws of Hong Kong); and
- (c) a certified public accountant as defined in the Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong).

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

- (a) length of employment with the issuer and other issuers and the roles he/she played;
- (b) familiarity with the Listing Rules and other relevant law and regulations including the SFO, Companies Ordinance, Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code;
- (c) relevant training taken and/or to be taken in addition to the minimum requirement under Rule 3.29 of the Listing Rules; and
- (d) professional qualifications in other jurisdictions.

We have principal business activities primarily outside Hong Kong. Our Company is established under the laws of the Cayman Islands and a significant part of our business operations are conducted in the PRC. All Directors and members of the senior management of our Company who are familiar with its activities and have extensive experience in board and corporate management matters presently do not possess any of the qualifications under Rules 3.28 and 8.17 of the Listing Rules, and may not be able to solely fulfill the requirements of the Listing Rules.

Our Company had appointed Mr. KE Chenyu (柯晨煜) (“**Mr. Ke**”) and Ms. Tang as our joint company secretaries. Ms. Tang is an associate member of both the Hong Kong Chartered Governance Institute and the Chartered Governance Institute, 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.

Mr. Ke joined our Group in August 2021 and is our head of legal, responsible for overseeing legal, regulatory and compliance matters of our Company. He has extensive experience in legal and compliance matters of our Company but presently does not possess any of the qualifications under Rules 3.28 and 8.17 of the Listing Rules. While Mr. Ke 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 Mr. Ke as our joint company secretary due to his thorough understanding of the internal administration and business operations of our Group.

Accordingly, while Mr. Ke 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] us, a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules such that Mr. Ke may be appointed as a joint company secretary of our Company.

The waiver [was granted] for a three-year period on the condition that Ms. Tang, as a joint company secretary of our Company, will work closely with, and provide assistance to, Mr. Ke in the discharge of his 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

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with the requirements of the Listing Rules and other applicable Hong Kong laws and regulations. For further information regarding the qualifications of Mr. Ke and Ms. Tang, see “Directors and Senior Management.”

Given Ms. Tang’s professional qualifications and experience, she will be able to explain to both Mr. Ke and our Company the relevant requirements under the Listing Rules. She will also assist Mr. Ke in organizing Board meetings and Shareholders’ meetings of our Company as well as other matters of our Company which are incidental to the duties of a company secretary. She is expected to work closely with Mr. Ke, and will maintain regular contact with Mr. Ke, the Directors and the senior management of our Company. Pursuant to the Guidance Letter HKEX-GL108-20, the waiver will be for a fixed period of time 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 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. This means that such waiver will be revoked immediately if Ms. Tang ceases to provide assistance to Mr. Ke as the joint company secretary for the three-year period after [REDACTED], and can also be revoked if there are material breaches of the Listing Rules by our Company. In addition, Mr. Ke will comply with the annual professional training requirement under Rule 3.29 of the Listing Rules and will enhance his knowledge of the Listing Rules during the three-year period from the [REDACTED]. The waiver [has been] granted on the condition that (i) Mr. Ke is assisted by a person who possesses the qualifications or experience as required under Rule 3.28 of the Listing Rules and is appointed as one of the joint company secretaries throughout the three-year period from the [REDACTED]; and (ii) it can be revoked if there are material breaches of the Listing Rules by our Company.

In the course of preparation of the [REDACTED], Mr. Ke 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 Mr. Ke has access to the relevant training and support that would enhance his understanding of the Listing Rules and the duties of a company secretary of an issuer [REDACTED] 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. Ke and Ms. Tang will seek and have access to advice from our Company’s Hong Kong legal and other professional advisors as and when required.

Our Company has appointed Huajin Corporate Finance (International) Limited as the Compliance Adviser upon our [REDACTED] pursuant to Rule 3A.19 of the Listing Rules, which will act as our Company’s additional channel of communication with the Stock Exchange, and provide professional guidance and advice to our Company and its joint company secretaries as to compliance with the Listing Rules and all other applicable laws and regulations. Prior to the end of the three-year period, the qualifications and experience of Mr. Ke and the need for on-going assistance of Ms. Tang will be further evaluated by our Company. We will liaise with the Stock Exchange to enable it to assess whether Mr. Ke, having benefited from the assistance of Ms. Tang for the preceding three years, will have acquired the skills necessary to carry out the duties of company secretary and the “relevant experience” within the meaning of Note 2 to Rule 3.28 of the Listing Rules so that a further waiver will not be necessary.

WAIVERS AND EXEMPTIONS

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

Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires all documents 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 the 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 listing document be included in the accountants’ report to this document.

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 listing under substantially the same management. Rule 18A.06 of the Listing Rules requires that a Biotech Company must comply with Rule 4.04 of the Listing Rules modified so that references to “three financial years” or “three years” in Rule 4.04 shall instead be references to “two financial years” or “two years”, as the case may be. Further, pursuant to Rule 8.06 of the Listing Rules, the latest financial period reported on by the reporting accountants for a new applicant must not have ended more than six months from the date of the listing document.

WAIVERS AND EXEMPTIONS

In compliance with the abovementioned requirements under the Listing Rules, the accountants' report of our Company set out in Appendix I is currently prepared to cover the two financial years ended December 31, 2021 and 2022. As such, the Sole Sponsor has 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 discovery and development 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) given that our Company is only required to disclose its financial results for each of the two financial years ended December 31, 2021 and 2022 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;
- (c) notwithstanding that the financial results set out in this document are only for the two financial years ended December 31, 2021 and 2022 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements; and
- (d) the accountants' report covering the two financial years ended December 31, 2021 and 2022 (as set out in Appendix I), 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 [REDACTED] public.

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 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 [REDACTED].

WAIVERS AND EXEMPTIONS

WAIVER AND EXEMPTION IN RELATION TO THE [REDACTED] SHARE OPTION SCHEME

Rule 17.02(1)(b) of the Listing Rules requires a listing applicant to, inter alia, disclose in the document full details of all outstanding options and their potential dilution effect on the shareholdings upon [REDACTED] 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 document must state the matters specified in Part I of the Third Schedule. 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 document.

Up to the Latest Practicable Date, our Company had granted Share Options under the [REDACTED] Share Option Scheme to 113 grantees to subscribe for an aggregate of 4,705,302 shares (or [REDACTED] Shares as adjusted after the [REDACTED]). As of the Latest Practicable Date, Share Options to subscribe for 459,950 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) had lapsed following the resignation of certain grantees (including Share Options granted to two former consultants whereby part of their Share Options had lapsed after they ceased to be our consultants), and Share Options corresponding to 833,475 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) had been exercised. As of the Latest Practicable Date, Share Options granted to 101 grantees to subscribe for 3,411,877 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) were outstanding (excluding lapsed and exercised Share Options), representing approximately [REDACTED]% of our Company's issued share capital immediately after completion of the [REDACTED], Conversion and [REDACTED] (assuming the [REDACTED] is not exercised), which included Share Options granted to three Directors with respect to 1,161,827 underlying shares (or [REDACTED] Shares as adjusted after the [REDACTED]), two other senior management members with respect to 850,000 underlying shares (or [REDACTED] Shares as adjusted after the [REDACTED]), three other employees who have been granted Share Options to subscribe for 120,000 ordinary shares of

WAIVERS AND EXEMPTIONS

the Company (or [REDACTED] Shares as adjusted after the [REDACTED]) or more with respect to 390,000 underlying shares (or [REDACTED] Shares as adjusted after the [REDACTED]), four existing and two former consultants with respect to 25,250 underlying shares (or [REDACTED] Shares as adjusted after the [REDACTED]), and 87 other grantees (including 83 employees and 4 former employees) (the “Other Grantees”) with respect to an aggregate of 984,800 underlying shares (or [REDACTED] Shares as adjusted after the [REDACTED]). For details, see “Statutory and General Information – D. [REDACTED] Share Option Scheme” in Appendix IV. Save and except for Share Options corresponding to 83,475 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) which had been granted to and exercised by a former Director, no Share Options were granted to other connected persons of the Company.

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

- (a) since the outstanding Share Options under the [REDACTED] Share Option Scheme were granted to a total of 101 grantees involved, strict compliance with the relevant disclosure requirements to disclose names, addresses, and entitlements on an individual basis in the document will require substantial number of pages of additional disclosure that does not provide any material information to the [REDACTED] public and would significantly increase the cost and timing for information compilation and document preparation;
- (b) key information of the Share Options granted under the [REDACTED] Share Option Scheme to the Directors, members of senior management, consultants, connected persons of our Company, other employees who have been granted Share Options to subscribe for 120,000 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) or more, has already been disclosed in “Statutory and General Information – D. [REDACTED] Share Option Scheme” in Appendix IV;
- (c) the key information of the [REDACTED] Share Option Scheme as disclosed in “Statutory and General Information – D. [REDACTED] Share Option Scheme” in Appendix IV is sufficient to provide potential [REDACTED] with information to make an informed assessment of the potential dilution effect and impact on earnings per share of the Share Options granted under the [REDACTED] Share Option Scheme in their [REDACTED] decision making process;
- (d) the disclosure of the personal details of each grantee, including the number of Share Options granted and address may require obtaining consent from all the grantees in order to comply with personal data privacy laws and principles and it would be unduly burdensome for our Company to obtain such consents;

WAIVERS AND EXEMPTIONS

- (e) given the nature of the business of our Company, it is extremely important for our Company to recruit and retain talents, and the success of our Company's long-term development plan will very much depend on the loyalty and contribution of the grantees, whereas the information relating to the Share Options granted to the grantees is highly sensitive and confidential, and may adversely affect our Company's cost and ability to recruit and retain talents;
- (f) with respect to the Other Grantees, such number of Shares (representing only approximately [REDACTED]% of the total issued share capital of our Company immediately following the completion of the [REDACTED], Conversion and [REDACTED], assuming the [REDACTED] is not exercised) 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; and
- (g) the lack of full compliance with such disclosure requirements will not prevent potential [REDACTED] from making an informed assessment of the activities, assets and liabilities, financial position, management and prospects of our Group and will not prejudice the interest of the [REDACTED] public.

The Stock Exchange [has granted] us a waiver from strict compliance with the disclosure requirements under Rule 17.02(1)(b) of the Listing Rules and paragraph 27 of Part A of Appendix 1A to the Listing Rules on the conditions that the following information will be clearly disclosed in this document:

- (a) on individual basis, full details of all the Share Options granted by our Company under the [REDACTED] Share Option Scheme to each of the Directors, members of the senior management, consultants, connected persons of our Company, and other employees who have been granted Share Options to subscribe for 120,000 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) or more, including all the particulars required under Rule 17.02(1)(b) of the Listing Rules, paragraph 27 of Appendix 1A to the Listing Rules and para 10 of Part I of the Third Schedule;
- (b) in respect of the Share Options granted by our Company to the grantees other than those referred to in sub-paragraph (a) above:
 - (i) the aggregate number of the 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;
- (c) the dilution effect and impact on earnings per Share upon full exercise of the outstanding Share Options granted under the [REDACTED] Share Option Scheme;

WAIVERS AND EXEMPTIONS

- (d) the aggregate number of Shares subject to the outstanding Share Options granted by our Company under the [REDACTED] Share Option Scheme and the percentage of our Company's issued share capital of which such number represents;
- (e) a summary of the [REDACTED] Share Option Scheme; and
- (f) the list of all the grantees (including the persons referred to in paragraph (ii) above), containing all details as required under Rule 17.02(1)(b), paragraph 27 of Appendix 1A to the Listing Rules and paragraph 10 of Part I of the Third Schedule be made available for public inspection in accordance with the paragraph headed "Appendix V – Documents Delivered to the Registrar of Companies and Available on Display– Document Available for Inspection".

The SFC [has agreed] to grant to our Company 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 all the Share Options granted under the [REDACTED] Share Option Scheme to each of (i) the Directors, (ii) members of senior management, (iii) consultants, (iv) connected persons of our Company, and (v) other employees who have been granted Share Options to subscribe for 120,000 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) or more, be disclosed in this document, such details include all the particulars required under paragraph 10 of Part I of the Third Schedule;
- (b) in respect of the Share Options granted by our Company to the grantees other than those referred to in sub-paragraph (a), the following details be disclosed in this document:
 - (i) the aggregate number of the 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;
- (c) a list of all the grantees (including the persons referred to in sub-paragraph (b) above) who have been granted Share Options to subscribe for Shares under the [REDACTED] Share Option Scheme, containing all details as required under paragraph 10 of Part I of the Third Schedule, be made available for public inspection in accordance with the paragraph headed "Appendix V – Documents Delivered to the Registrar of Companies and Available on Display – Document Available for Inspection"; and
- (d) the particulars of the exemption be disclosed in this document and that this document will be issued on or before [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]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
Executive Directors		
Dr. LU Chris Xiangyang	26 Rockville Ave Lexington, MA 02421 United States of America	American
Ms. XIE Ling (謝玲)	Room 214 No. 15 Sijing Road Huangpu District Shanghai, PRC	Chinese
Dr. GU Xiang Ju Justin	10-1901, Lane 388 Chuanhe Road Pudong New Area Shanghai, PRC	American
Non-executive Directors		
Dr. WANG David Guowei	34 Green LN Weston, MA 02493 United States of America	American
Ms. JI Dongmei (吉冬梅)	No. 61, Lane 55 Lianmin Road Qingpu District Shanghai, PRC	Chinese
Mr. SUN Yuan (孫淵)	1-3-301, No. 8, Zhuzong Xiangxie Yard 2, Bakeyang North Street Chaoyang District Beijing, PRC	Chinese
Independent Non-executive Directors		
Dr. YIN Xudong	3800 No. 60 Longdong Road Shanghai, PRC	American
Mr. CHAU Kwok Keung (鄒國強)	Flat B, 9/F, Block 2 Royal Peninsula, 8 Hung Lai Road Hung Hom, Kowloon Hong Kong	Chinese (Hong Kong)
Dr. LI Min	221 Settlers Row N Ponte Vedra Beach FL 32082-3941 United States of America	American

See “Directors and Senior Management” for further information with respect to our Directors.

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

Sole Sponsor

**China International Capital Corporation
Hong Kong Securities Limited**
29/F One International Finance Centre
1 Harbour View Street
Central
Hong Kong

[REDACTED]

Legal Advisers to our Company

As to Hong Kong law and United States law:

Davis Polk & Wardwell
10th Floor
The Hong Kong Club Building
3A Chater Road
Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

As to PRC law:

Jingtian & Gongcheng

34/F, Tower 3
China Central Place
77 Jianguo Road
Chaoyang District
Beijing, PRC

As to Cayman Islands law:

Harney Westwood & Riegels

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

**Legal Advisers to the Sole Sponsor
and the [REDACTED]**

As to Hong Kong law and United States law:

Cooley HK

35/F, Two Exchange Square
8 Connaught Place
Central, Hong Kong

As to PRC law:

Commerce & Finance Law Offices

12-14/F, China World Office 2
No. 1 Jianguomenwai Avenue
Chaoyang District
Beijing, PRC

Reporting Accountants and Auditor

KPMG

Certified Public Accountants
8th Floor, Prince's Building
10 Chater Road
Central, Hong Kong

DIRECTORS AND PARTIES INVOLVED IN THE [REDACTED]

Industry Consultant

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

2504

Wheelock Square

1717 Nanjing West Road

Shanghai 200040

PRC

[REDACTED]

CORPORATE INFORMATION

Registered Office	4th Floor Harbour Place 103 South Church Street P.O. Box 10240 Grand Cayman KY1-1002 Cayman Islands
Head Office and Principal Place of Business in the PRC	5th Floor, No. 987 Cailun Road Zhangjiang Hi-Tech Park Pudong New District Shanghai PRC
Principal Place of Business in Hong Kong	46F, Hopewell Centre 183 Queen's Road East Wan Chai Hong Kong
Company's Website	<u>www.laekna.com</u> <i>(The information contained in this website does not form part of this document)</i>
Joint Company Secretaries	Mr. KE Chenyu (柯晨煜) 5th Floor, No. 987 Cailun Road Zhangjiang Hi-Tech Park Pudong New District Shanghai PRC Ms. TANG Wing Shan Winza (鄧穎珊) <i>(associate member of both the Hong Kong Chartered Governance Institute and the Chartered Governance Institute)</i> 46F, Hopewell Centre 183 Queen's Road East Wan Chai, Hong Kong
Audit Committee	Mr. CHAU Kwok Keung (鄒國強) <i>(Chairperson)</i> Dr. WANG David Guowei Dr. LI Min

CORPORATE INFORMATION

Remuneration Committee

Dr. YIN Xudong (*Chairperson*)
Ms. XIE Ling (謝玲)
Mr. CHAU Kwok Keung (鄒國強)

**Nomination and Corporate
Governance Committee**

Dr. LU Chris Xiangyang (*Chairperson*)
Dr. YIN Xudong
Dr. LI Min

Authorized Representatives

Ms. XIE Ling (謝玲)
Room 214
No. 15 Sijing Road
Huangpu District
Shanghai, PRC

Ms. TANG Wing Shan Winza (鄧穎珊)
46F, Hopewell Centre
183 Queen’s Road East
Wan Chai, Hong Kong

Compliance Adviser

**Huajin Corporate Finance (International)
Limited**
Suite 1101, 11/F
Champion Tower
3 Garden Road
Central, Hong Kong

[REDACTED]

CORPORATE INFORMATION

Principal Banks

Bank of Ningbo Shanghai Zhangjiang

Branch

1/F, Northern Building
No. 350 Chunxiao Road
Pudong New District
Shanghai
PRC

China Merchants Bank Shanghai

Zhangjiang Branch

1/F, Building 1
German Center
No. 88 Keyuan Road
Pudong New District
Shanghai
PRC

Citibank N.A., Hong Kong Branch

3 Garden Road
Central, Hong Kong

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from the report prepared by Frost & Sullivan, which was commissioned by us, and from various official government publications and other publicly available publications. We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the [REDACTED]. The information from official government sources has not been independently verified by us, the Sole Sponsor, the [REDACTED], the [REDACTED], the Sole [REDACTED], the [REDACTED], 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.

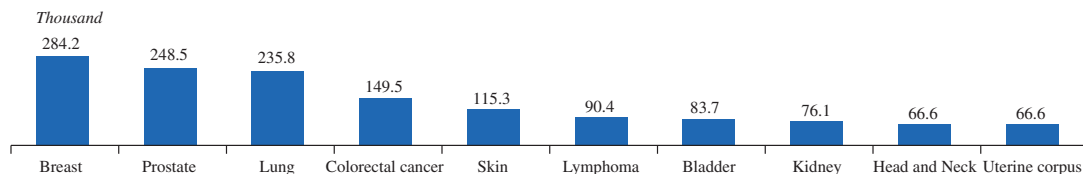
ONCOLOGY DRUG MARKET

Most Common Cancers by Incidence

Due to the differences in dietary structure, environment and other factors such as lifestyle, smoking habits, age, and vaccination programs, the most prevalent cancer types in China differ from those of the U.S. In China, lung cancer accounted for the highest incidence in 2021, while breast cancer accounted for the highest in the U.S. The number of gastric cancer and liver cancer patients ranked the second and fourth out of all cancer patients in China in 2021, respectively, whereas their incidence in the U.S. ranked much lower. The cancer types that are prevalent in China but have lower incidence in other more developed markets generally have much more limited treatment options, suggesting significant unmet medical needs and market opportunities to further tap in China.

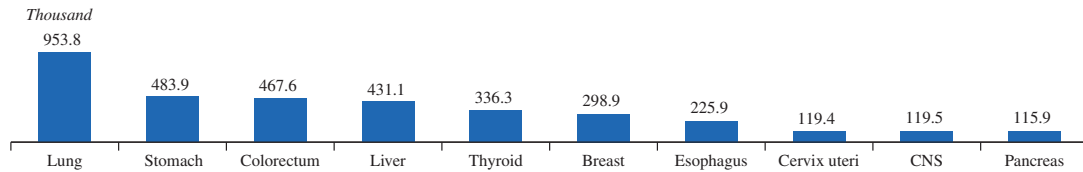
The following charts show the top 10 cancer types by incidence in the U.S. and China in 2021, respectively:

Top 10 Cancers by Incidence in the U.S., 2021



INDUSTRY OVERVIEW

Top 10 Cancers by Incidence in China, 2021

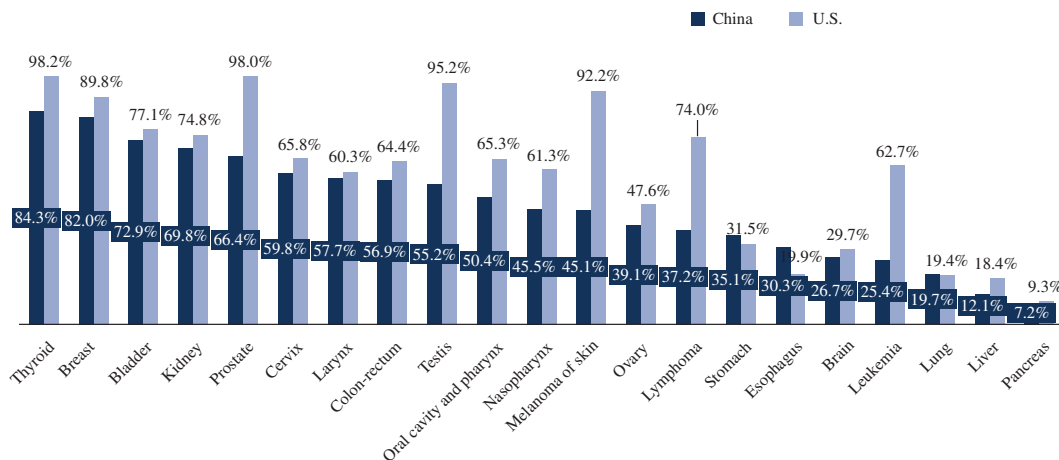


Source: IARC, ACS, NCCR, Globocan, Frost & Sullivan analysis

As illustrated below, China has much lower five-year survival rates on some of the most common cancers than those of in the U.S., which indicates a great market opportunity for cancer treatment in China.

The following chart sets forth the five-year survival rate of cancers in China and the U.S., respectively:

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








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

Cancer Treatment

Research and development on cancer treatment has seen major advancements over the past 20 years and is expected to sustain growth with continued innovation. There are currently several major therapy options to treat a variety of cancers, including surgery, radiotherapy, chemotherapy, targeted therapy, and immuno-oncology therapy according to Frost & Sullivan.

INDUSTRY OVERVIEW

With continued progress in the understanding of cancer biology and advancement of modern biotechnology, it is expected that more cutting-edge technologies will be devised and deployed for oncology drug development in the future, and an increasing number of innovative treatment options are expected to be brought to oncology patients in dire needs. The following diagram illustrates a paradigm shift from conventional cancer treatments to novel cancer treatments:

	Conventional Cancer Treatments			Novel Cancer Treatments	
					
	Surgery	Radiotherapy	Chemotherapy	Targeted Therapy	Immuno-oncology
Description	A procedure in which a surgeon removes cancer from a patient's body	High doses of radiation to kill cancer cells and shrink tumors	Use single or combinations of anti-cancer drugs to stop or slow tumor growth	Act on specific targets that are associated with cancer development	Harness the patient's own immune system to fight cancer
Features	Foundation of solid tumor treatment. More effective for early stage, while relatively limited for most late stage	Affects surrounding normal cells causing side effects such as fatigue, hair loss	Targets all fast growing cells, causing side effects such as hair loss, easy bruising/bleeding	Includes both small-molecule drugs and mAbs, less harmful to healthy cells	Includes cytokines, mAbs, checkpoint inhibitors, immune cell therapies
Examples	Liver resection	3D-CRT, IMRT, SBRT	Taxanes, fluorouracil, chlorambucil	AKT inhibitor	PD-1 inhibitor, CAR-T cell therapy

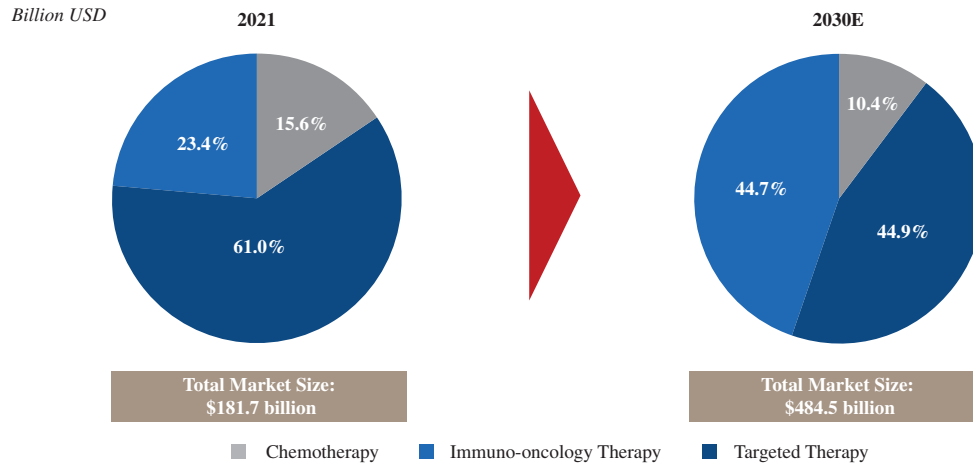
Source: Literature research, Frost & Sullivan analysis

Innovative Targeted and Immuno-Oncology Therapies

Compared with conventional cancer treatments, targeted therapy and immune-oncology therapy are expected to further propel the growth of the global oncology drug markets. Immuno-oncology therapy is designed to stimulate the patient's own immune system to generate or augment an anti-tumor immune response in order to control or eradicate cancer cells. Major types of immuno-oncology therapies include checkpoint inhibitors, cytokines and cellular immunotherapies. Targeted therapy accounted for the largest share of the global oncology drug market in 2021, representing 61% of the total market share based on revenue. The market size of each type of therapy is expected to grow in absolute amounts from 2021 to 2030, and targeted and immuno-oncology therapies together are expected to account for approximately 90% of the global oncology drug market by 2030, according to Frost & Sullivan.

INDUSTRY OVERVIEW

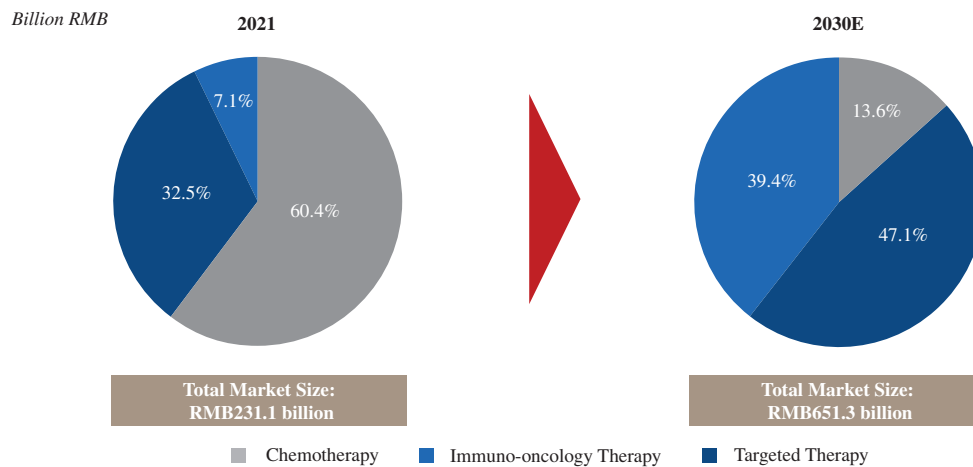
Breakdown of the Global Oncology Drug Market by Therapy, 2021 and 2030E



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

The following charts set forth the actual and expected total market sizes for chemotherapy, immuno-oncology therapy and targeted therapy in China’s oncology drug market during the years indicated, showing a much more considerable growth in China’s novel oncology drug market as compared to the global market:

Breakdown of the Oncology Drug Market by Therapy in China, 2021 and 2030E



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

INDUSTRY OVERVIEW

Increasing Trend of Combination Therapies

The emergence of combination therapies, a treatment modality that combines two or more therapeutic agents, represents an increasing trend in the treatment of oncology. As a result of targeting multiple key pathways in a synergistic or additive manner, the adoption of oncology drugs in combination therapies could have the potential to improve efficacy, treatment response rate and durability as compared to monotherapies.

Both pre-clinical and clinical studies in therapeutic combination have exhibited better efficacy, which in turn leads to more combination trials and the potential to penetrate the untapped market. Studies also show that the combination therapies of multiple small-molecule targeted oncology therapies significantly improve the overall survival rate of patients. Specifically, although the modalities of targeted therapy and immuno-oncology therapy differ in nature, in many cases, the combination of these therapies has generated synergic effects, typically with one therapeutic agent complementing the other, unleashing the anti-tumor immunity of patients and thereby leading to enhanced efficacy. Such combinations have been improved to result in better outcomes in clinical practice, demonstrating a promising strategy of cancer treatment.

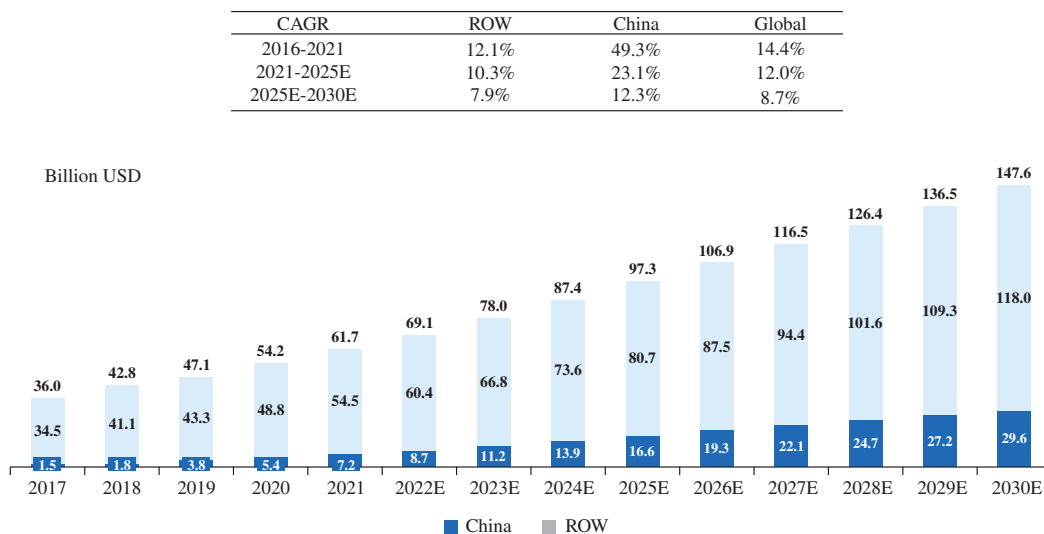
SMALL-MOLECULE TARGETED ONCOLOGY THERAPY

Overview

Targeted oncology drug therapies can be roughly classified into two categories: small molecules and biologics (e.g. antibodies, recombinant proteins). Compared with biologics, small-molecule drugs have advantages in aspects such as the pharmacokinetic (PK) properties, manufacturing costs, patient compliance, drug storage and transportation.

The following chart shows the historical market size breakdown of global and China small-molecule targeted oncology therapy market from 2017 to 2021, and the estimated market size in these markets from 2022 to 2030, as well as CAGRs during the periods indicated:

Global Small-Molecule Targeted Oncology Drug Therapy Market, 2017-2030E



Note: ROW refers to rest of the world excluding China

Source: Globocan, IARC, NCCR, Frost & Sullivan analysis

INDUSTRY OVERVIEW

Growth Drivers and Future Trends

The key growth drivers of the global and China small-molecule targeted oncology therapy market include the following:

- Safety and patient compliance. Safety is one of the major causes of failure of small molecule drug development at early clinical stage. Besides, some of the marketed drugs need specific administration regimen to limit the potential sides effects. For instance, despite its significant role in prostate cancer treatment, abiraterone needs to be co-administered with prednisone, and has specific risks of hypertension, fluid retention and hypokalemia. LAE001 may eliminate the need for long-term prednisone use under abiraterone acetate regimens for mHSPC as first-line treatment, thereby reducing the risk of potential cardiovascular toxicity and hepatotoxicity. Drugs with improved safety profile and fewer side effects would have better patient compliance and often represents growth opportunities once marketed.
- Advancement of biology and translational science. With the development of molecular biology, proteomics, and translational science, more drug targets and innovative mechanism of actions are unveiled. Small molecule drugs, which can penetrate cell membrane and cell sub-compartments, are able to access a much larger number of drug targets. The discovery of new target and protein structure would provide more information regarding drug interactions, thus leading to more efficient identification of lead compounds. With the development of small-molecule discovery technology, for instance, bioinformatics data mining, it is expected that the discovery process would become more efficient and make more candidates to enter the development timeline, thus driving the market growth.
- Combination therapies. The emergence of combination therapies represents an increasing trend in cancer treatment. Small-molecule drugs offer complementary mechanisms to potentially combine with other small-molecule drugs and biologics, to enhance efficacy profile and expand clinical adoptions. As a result of targeting multiple key pathways in a synergistic or additive manner, the adoption of oncology drugs in combination therapies could have the potential to improve efficacy, treatment response rate and durability as compared to monotherapies, and have the potential to penetrate untapped markets. Studies also show that the combination of multiple small-molecule targeted oncology therapies significantly improve the overall survival rate of patients, which also increases the patient pool. For example, studies have shown that combinatory use of new generation anti-androgen agents tend to provide better survival benefit to mHSPC patients compared with using single anti-androgen agent for treatment. Additionally, an increasing number of biotech companies are exploring the combination potentials of their drug candidates, which would further enrich the treatment options for patients. This also includes LAE002 and other drug candidates which are being developed in a variety of combination therapies. The increasing availability of combination therapies will further enrich the varieties of combinations and expand the oncology drug market globally.

INDUSTRY OVERVIEW

Barriers to Research and Development

The entry barriers of global and China small-molecule targeted oncology therapy market include the following:

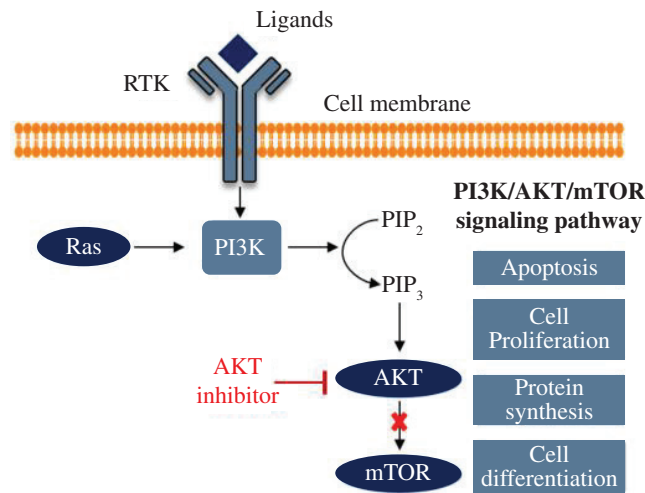
- Target selection capability. The selection of targets requires a detailed understanding of molecular mechanisms and strong research capability, which represents a technical barrier for small-molecule targeted oncology therapy.
- Clinical development capability. Antitumor drugs have different requirements compared to non-oncology drugs in terms of clinical trial design, selection of clinical endpoints, patient enrollment criteria, patient recruitment process, and patient follow-up. The adverse events also need to be carefully monitored and resolved. Therefore, a clinical trial team with professional strength and rich experience is required, representing another entry barrier to the small-molecule targeted oncology therapy market.

AKT INHIBITORS

Overview

The serine/threonine kinase AKT is a key component of the PI3K intracellular pathway that plays a pivotal role in regulating cell proliferation, survival, and metabolism. Three AKT isoforms (namely AKT1, AKT2, and AKT3) are encoded by different genes with high sequence homology and display a conserved protein structure. While AKT1 and AKT2 present a ubiquitous distribution, AKT3 is prevalently expressed in neural cells. Enhanced activation of all the isoforms can be related to tumor growth and progression in certain types of cancer, including in breast, ovarian, pancreatic, and prostate cancers. In cancer cells, AKT1 is involved in proliferation and growth, promoting tumor initiation and suppressing apoptosis, whereas AKT2 regulates cytoskeleton dynamics, favoring tumor invasiveness and metastasis. The role of AKT3 hyperactivation in cancer is still controversial, although a possible stimulation of cell proliferation has been hypothesized. Activation of AKT can be inhibited by two different direct classes (allosteric or ATP-competitive) of AKT inhibitors. The allosteric AKT inhibitors lock AKT in an auto-inhibited conformation and interfere with PH-domain mediated-membrane recruitment, thus preventing AKT kinase activation and AKT phosphorylation. The ATP-competitive AKT inhibitor attenuates AKT activity by preventing ATP from binding to kinases.

INDUSTRY OVERVIEW



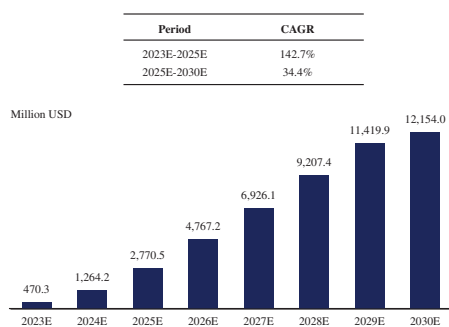
Notes: RTK: receptor protein tyrosine kinase; mTOR: mammalian target of rapamycin; PIP₂: phosphatidylinositol(4,5) biphosphate; PIP₃: phosphatidylinositol-3,4,5-triphosphate

Source: Frost & Sullivan analysis

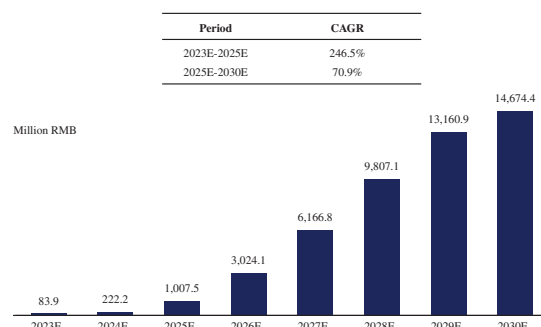
Market Size

The following chart shows the forecasted market size of the global and China AKT inhibitor drug market from 2023 to 2030, as well as CAGRs for the periods indicated:

Forecasted Global AKT Targeting Drug Market Size, 2023E-2030E



Forecasted China AKT Targeting Drug Market Size, 2023E-2030E



Source: Expert interview, Frost & Sullivan analysis

Notes: It is expected that the market size of AKT inhibitors will see significant growth as:

- (i) AKT inhibitors are expanding their indications for more solid tumors such as TNBC, mCPRC and PROC, which will further contribute to the growth of the AKT inhibitor drug market. The incidences of those indications are expected to experience significant growth in the next decade. The AKT inhibitor drug market is expected to expand significantly in correspondence to the growth of the market of AKT inhibitors' key indications;

INDUSTRY OVERVIEW

- (ii) *Currently, there are a number of companies developing AKT inhibitors. A number of AKT inhibitors are expected to be approved and commercialized in China in the next decade with additional indications. Multiple candidates are being developed for different indications, and the indications for future commercial approval will be diversified, thus contributing to market expansion and growth. Multiple competitors will conduct various clinical trials, and the evidence-based data out of such trials will further facilitate academic development, which in turn will lay the foundation for future market growth; and*
- (iii) *AKT inhibitors may be included in NRDL. NRDL inclusion and marketing promotion by companies for AKT inhibitors will further contribute to the growth of AKT inhibitors.*

AKT Overexpression in Various Tumor Types

AKT activation has been shown to correlate with advanced disease and/or poor prognosis in some tumor types. For example, one study examining the role of AKT kinase signaling networks in cancers reported that approximately 40% of breast and ovarian cancers and more than 50% of prostate carcinomas exhibited increased AKT1 kinase activity; and nearly 80% of tumors with activated AKT1 were high grade and stage III/IV carcinomas (Song M. et al., AKT as a Therapeutic Target for Cancer. *Cancer Res.* 2019; 79(6):1019-1031). Among other studies, activation of the AKT2 kinase was observed in around 40% of ovarian cancers. Moreover, elevated AKT3 activity has been reported in estrogen receptor-deficient breast cancer and androgen-insensitive prostate cancer cell lines, suggesting that AKT3 may contribute to the aggressiveness of steroid hormone-insensitive carcinomas.

AKT Phosphorylation in Inducing Drug Resistance

AKT is one of the most commonly dysregulated pathways in all of the cancers. Dysregulation of AKT-dependent pathways is associated with the development and maintenance of a range of solid tumors. AKT/NF- κ B and AKT/mTOR are the two main mutated pathways, where mutations lead to inhibition of apoptosis, stimulation of cell growth, and modulation of cellular metabolism such as overexpression of drug efflux pumps. These mechanisms are related to the development of drug resistance in cancer treatment. Therefore, targeting AKT represents a potential strategy to overcome drug resistance.

Studies have shown that the phosphorylated AKT (pAKT) level is correlated with higher rates of chemo-resistance. For instance, cisplatin-resistant ovarian cancer cell line exhibited higher AKT expression levels than its cisplatin sensitive isotype. The cell lines expressing higher levels of pAKT were more resistant to paclitaxel. AKT inhibition has been shown to overcome oncology drug resistance in a number of pre-clinical scenarios. For example, AKT inhibition can increase chemo-sensitivity in TNBC in pre-clinical settings, eventually overcoming chemo-resistance in this disease subset.

AKT Combination Therapies

Cancer cells may become resistant to previously effective treatments, including chemotherapy and targeted therapy. Drug resistance is one of the major/primary causes of cancer recurrence and death in many cancer patients and has become a major factor limiting their survival and quality of life. For patients with cancer that has progressed to an advanced stage, treatment options may become limited with poor outcome. Thus, there is a significant unmet need for therapies to overcome drug resistance.

INDUSTRY OVERVIEW

Solid tumors are heterogeneous neoplasms composed of different types of cancer cells, with heterogeneousness in their molecular signatures; this is referred to as intra-tumor heterogeneity. There is a strong pre-clinical rationale for the combination therapies of AKT inhibitors with other molecules to treat the drug-resistant cancer, including acquired resistance to other anticancer agents and adaptive resistance to chemotherapy and targeted therapy. AKT activation is reported to correlate with drug resistance.

AKT combination therapies have demonstrated clinical benefits. For instance, for the treatment of metastatic castration-resistant prostate cancer (mCRPC), a Phase II trial sponsored by AstraZeneca demonstrated significantly longer median overall survival (31.2 months in treatment group vs. 20.3 months in the placebo group) in the AKT inhibitor combined with chemotherapy treatment group compared to chemotherapy control group. In a Phase II randomized controlled trial, combination therapy of an AKT inhibitor capivasertib with fulvestrant significantly prolonged progression-free survival in patients with aromatase inhibitor-resistant HR+/HER2- locally advanced or metastatic breast cancer (10.3 months in capivasertib group vs. 4.8 months in the placebo group). AKT inhibitors are also being evaluated in combination with fulvestrant in multiple targeted therapies, including PD-1/PD-L1, CDK4/6, poly (ADP-ribose) polymerase (PARP) inhibitors, anti-hormone and other therapies.

Competitive Landscape

Currently, there is no AKT inhibitor approved for global commercialization, according to Frost & Sullivan. There are seven AKT inhibitor candidates under clinical development for the treatment of cancer globally.

Pipeline Globally				
INN/Drug Code	Company	Phase*	First Post Date**	Indication***
Capivasertib	AstraZeneca	III	2019/6/25	Prostate Cancer (III, HSPC), locally advanced or metastatic breast cancer (III), triple negative breast neoplasms (III), Non-Hodgkin Lymphoma (II), endometrial cancer (II), meningioma (II)
LAE002 (Afuresertib)	Laekna	II (Registrational)	2020/5/5	PROC (II), mCRPC(II), Locally advanced or metastatic HR+/HER2-breast cancer (Ib/III), PD-1/PD-L1 inhibitor resistant solid tumor (I/II)
Ipatasertib	Roche	II	2020/07/13	NSCLC (II), gastric cancer (II), ovarian cancer (II, R/R epithelial OC), glioblastoma multiforme (I/II), endometrial cancer (I/II)
TAS-117	Taiho Oncology	II	2021/2/25	Advanced or metastatic solid tumors (excluding primary brain tumors) harboring germline PTEN inactivating mutations
M2698	EMD Serono	I	2013/10/29	Solid tumors
TAS0612	Taiho Oncology	I	2020/10/14	Advanced or metastatic solid tumors
WGI-0301	HaichangBiotech	I	2022/3/07	Advanced Solid Tumors

INDUSTRY OVERVIEW

Notes:

- * Phase refers to the drug’s most advanced phase stage of all ongoing studies.
- ** First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced. Information as of March 6, 2023.
- *** The chart shows cancer indications only.

Source: *ClinicalTrials.gov, Frost & Sullivan analysis*

Currently, there are three AKT inhibitor candidates under clinical development in China, according to Frost & Sullivan.

Pipeline in China				
INN/Drug Code	Company	Phase*	First Post Date**	Indication***
Capivasertib	AstraZeneca	III	2020/10/9	Metastatic CSPC (III), Metastatic CRPC (III), TNBC (III), HR+/HER2-Locally Advanced or Metastatic Breast Cancer (III)
LAE002 (Afuresertib)	Laekna	II (Registrational)	2020/11/19	PROC (including fallopian tube carcinoma and primary peritoneal carcinoma) (II), TNBC (I/II), HR+/HER2- Locally Advanced or Metastatic Breast Cancer (Ib/III), PD-1/P1-L1 resistant solid tumor (I/II)
NTQ1062	Chia Tai Tianqing	I	2021-08-18	Advanced solid tumor

Notes:

- * Phase refers to the drug’s most advanced phase of all ongoing clinical trials.
- ** First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced. Information as of March 6, 2023.
- *** The chart shows cancer indications only.

Source: *CDE, Frost & Sullivan analysis*

Therapeutic Areas of Interest

Ovarian Cancer

Ovarian cancer is a group of diseases that originates in the ovaries, or in the related areas of the fallopian tubes and the peritoneum. In the early stages, there may be few or even no symptoms. If symptoms occur, they can resemble those of other conditions, such as premenstrual syndrome, irritable bowel syndrome, or a temporary bladder problem. However, in ovarian cancer, the symptoms will persist and worsen.

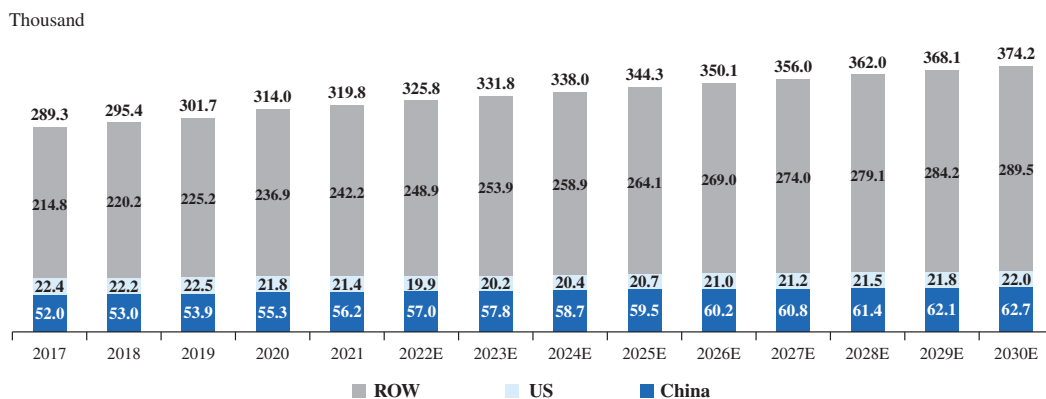
INDUSTRY OVERVIEW

Ovarian cancer risk factors include age, nulliparity or first pregnancy after age of 35 years old, postmenopausal hormone therapy, and pelvic inflammatory disease. There is an association with women who develop early-onset ovarian cancer (about 15% of ovarian cancer patients) with family history of ovarian cancer and BRCA1/2 mutations, and with Lynch syndrome. About 70% of ovarian cancer patients present with advanced disease. No regular screenings are available.

The following chart shows the historical incidence breakdown of global ovarian cancer from 2017 to 2021, and the estimated incidence from 2022 to 2030, as well as CAGRs during the periods indicated:

Incidence Breakdown of Global Ovarian Cancer, 2017-2030E

CAGR	ROW	US	China	Global
2017-2021	3.1%	-1.2%	1.9%	2.5%
2021-2025E	2.2%	-0.8%	1.5%	1.9%
2025E-2030E	1.9%	1.2%	1.0%	1.7%



Note: ROW refers to rest of the world excluding China and US

Source: Globocan, IARC, NCCR, Frost & Sullivan analysis

Platinum Resistant Ovarian Cancer (PROC)

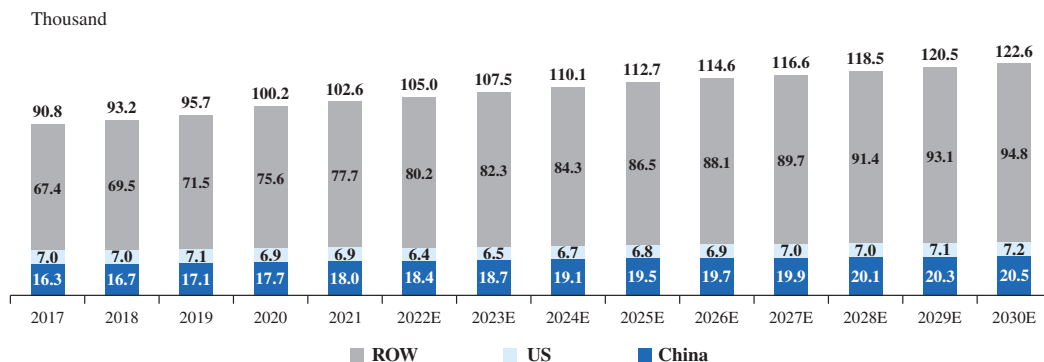
PROC is broadly defined as primary ovarian cancer recurrence within six months of completing platinum-based chemotherapy, either in the primary or recurrent setting. Although there is significant heterogeneity, PROC is generally associated with poor outcomes and low response rates to standard chemotherapy.

INDUSTRY OVERVIEW

The following chart shows the historical incidence breakdown of global PROC from 2017 to 2021, and the estimated incidence from 2022 to 2030, as well as CAGRs during the periods indicated:

Incidence Breakdown of Global PROC, 2017-2030E

CAGR	ROW	US	China	Global
2017-2021	3.6%	-0.6%	2.5%	3.1%
2021-2025E	2.7%	-0.3%	2.0%	2.4%
2025E-2030E	1.9%	1.2%	1.0%	1.7%



Note: ROW refers to rest of the world excluding China and US

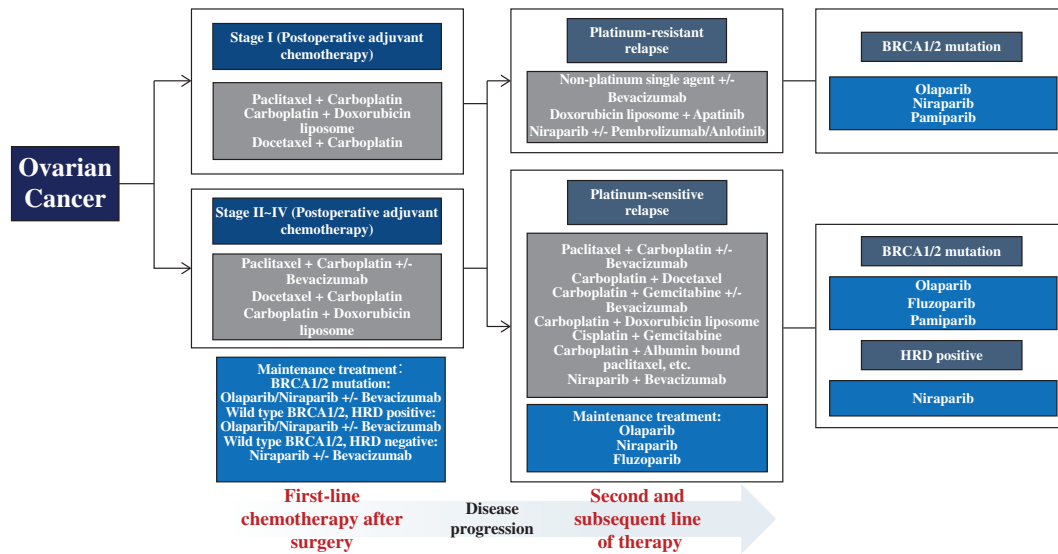
Source: Globocan, IARC, NCCR, Frost & Sullivan analysis

Treatment Paradigm and Unmet Medical Needs

The current standard of care (SOC) of ovarian cancer in China mainly consists of debulking surgery and platinum-based chemotherapy +/- bevacizumab or PARP inhibitor. The American National Comprehensive Cancer Network Guideline (“**NCCN Guideline**”) recommends platinum-based chemotherapy with or without bevacizumab as a first-line treatment for a recurrence of platinum-sensitive ovarian cancer. PARP inhibitor is also recommended for patients with platinum-sensitive ovarian cancer. However, once the ovarian cancer becomes platinum-resistant or refractory, only limited, less-effective options, such as the sequential use of single-agent nonplatinum cytotoxic therapy, are available. The immunotherapies and targeted therapies, including bevacizumab and PARP inhibitors, are only useful in certain subtypes of ovarian cancer patients. Although platinum-based chemotherapy +/- bevacizumab or PARP inhibitor as an initial treatment is effective, ovarian cancer in more than 80% of the patients will recur, and the patients will eventually become resistant to platinum-based therapy (Pignata S. et al., Treatment of Recurrent Ovarian Cancer, Annals of Oncology, 2017, Volume 28, Supplement 8, viii51-viii56; Garzon S. et al., Secondary and Tertiary Ovarian Cancer Recurrence: What is the Best Management? Gland Surgery, 2020, 9(4): 1118–V1129; Keener A., Innovative Therapies to Tackle Platinum-Resistant Ovarian Cancer, Nature, 2021, 600, S45-S47). The five-year survival rate of ovarian cancer is less than 40%. However, PROC has a poor prognosis compared to PSOC that its overall survival is only 12-14 months under the current SOC. There are limited treatment options, such as non-platinum-based chemotherapy, for relapsed ovarian cancer patients. Moreover, the interval between recurrences decreases and the rate of tumor relapse jumps with the increase in the number of recurrences.

INDUSTRY OVERVIEW

The below table sets forth maintenance and treatment options for ovarian cancer under the clinical guidelines in China:



Source: *Guideline for Diagnosis and Treatment of Ovarian Cancer (2022)*, *Guidelines for Clinical Application of PARP Inhibitors in Ovarian Cancer (2022)*, *Frost & Sullivan analysis*

NCCN Guideline with respect to the standard of care and treatment guidelines for ovarian cancer in the U.S. is largely consistent with the standard of care and treatment guidelines recognized in China described above. However, the current PROC treatment paradigm is facing challenges.

As the first-line treatment for ovarian cancer after surgery, platinum-based chemotherapy in combination with paclitaxel, has been successful in initially shrinking and killing the remaining tumors left in most patients. However, it is observed that about 10-15% of patients do not respond to platinum-based chemotherapy. In addition, more than 80% of tumors that have initially responded relapse and eventually develop resistance to platinum-based therapy. The cause of platinum resistance is not fully clear given that there can be many mechanisms by which tumor cells acquire platinum resistance, including enhanced DNA repair, improved cell survival, increased drug efflux processes, or production of proteins that protect the genome from the effects of platinum, and cancer cells may develop as a result of any combination of these mechanisms.

In the U.S. and China, a combination of non-platinum monotherapy and bevacizumab (a vascular endothelial growth factor inhibitor) is recommended as the first and second lines of therapy for patients with PROC according to guidelines. However, 66% to 84% of treated patients may develop primary resistance and almost all patients who initially responded may develop acquired resistance to bevacizumab. In addition, PARP inhibitors are recommended for patients with BRCA1/2 mutations. However, studies have shown that ovarian cancer patients carrying BRCA mutations represent less than 30% of the ovarian cancer patients. While the time interval of recurrence becomes shorter after each relapse, effective treatment options for subsequent lines of treatments are limited. Those with BRCA1/2 mutations have a high probability of failing PARP inhibitors of about 70%. The rest of the 70% patients without

INDUSTRY OVERVIEW

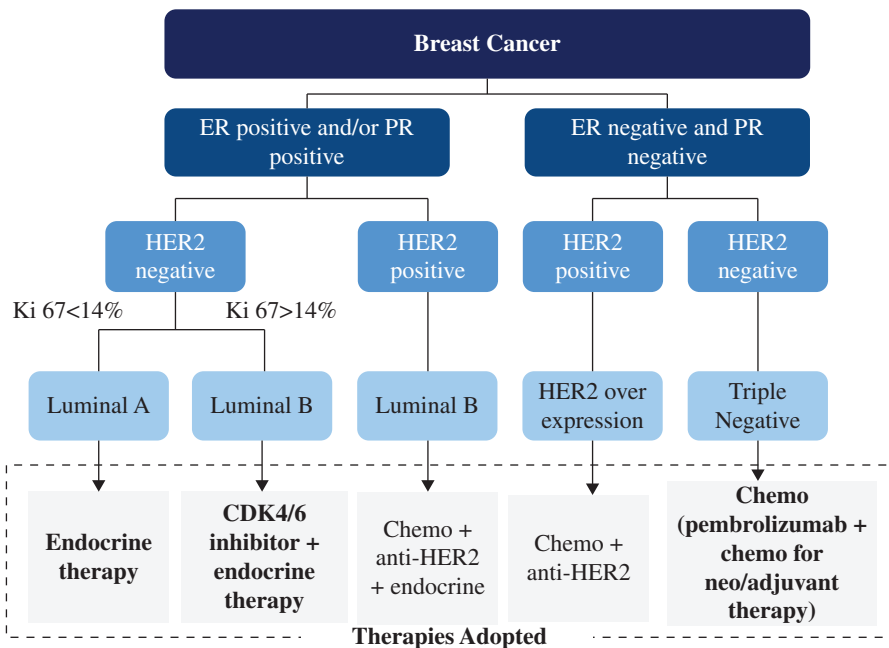
BRCA mutations and the 30% ovarian cancer patients with BRAC mutations who failed PARP inhibitor treatment have limited treatment options, such as non-platinum-based chemotherapies, and usually have poor outcome. In 2022, three approved PARP inhibitors, including niraparib, olaparib and rucaparib (not approved in China yet), voluntarily withdraw their FDA’s approvals for late-line ovarian cancer treatment because of safety concerns. The FDA also restricted the use of niraparib to the second-line maintenance treatment for BRCA mutation cancer patients. Because of PARP inhibitors’ safety issues and limited clinical benefits there exists great unmet medical needs for late line ovarian cancer treatment.

Breast Cancer

Overview

Breast cancer was one of the most common types of cancer in women globally in 2021 and occurs most frequently in women aged 50 and over. Factors that may increase the risk of developing breast cancer include: genetic predisposition (BRCA1 or BRCA2 mutations), estrogen and progesterone exposure, oral contraceptives or birth control drugs, atypical hyperplasia of the breast, lobular carcinoma *in situ*, lifestyle factors (such as weight, food, alcohol or physical activity), breast density (dense breast tissue) and family history of breast cancer.

Breast cancer can be classified into four genotypes based on the expression level of hormone receptor (HR) and epidermal growth factor receptor-2 (HER2), and HR includes estrogen receptor (ER) and progesterone receptor (PR). The below table sets forth the genotypes of the breast cancer and the therapy adopted:



Source: NCCN Breast Cancer Guideline (2021 V8), Frost & Sullivan analysis

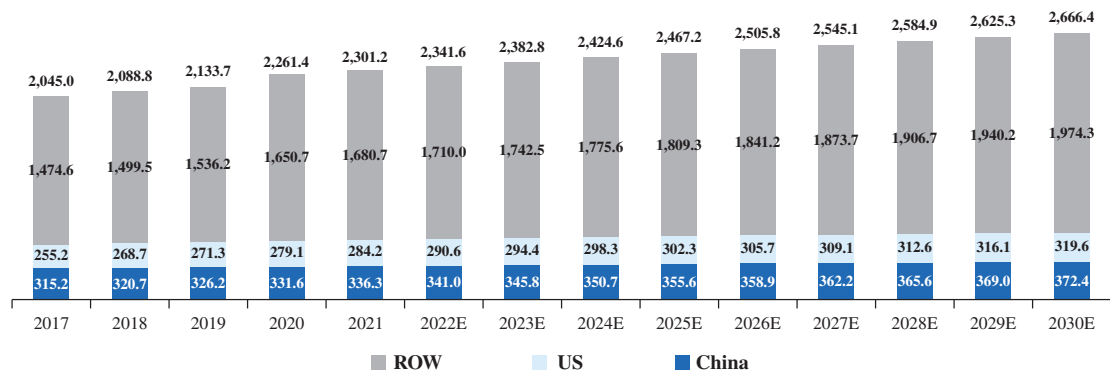
INDUSTRY OVERVIEW

The following chart shows the historical incidence breakdown of the breast cancer from 2017 to 2021, and the estimated incidence from 2022 to 2030, as well as CAGRs during the periods indicated. The incidence of TNBC, HR+/HER2- breast cancer, HR+/HER2+ breast cancer and HR-/HER2+ breast cancer account for 15%, 60%, 10% and 15% of breast cancers in China, respectively.

Incidence Breakdown of Global Breast Cancer, 2017-2030E

CAGR	ROW	US	China	Global
2017-2021	3.3%	2.7%	1.6%	3.0%
2021-2025E	1.9%	1.6%	1.4%	1.8%
2025E-2030E	1.8%	1.1%	0.9%	1.6%

Thousand



Note: ROW refers to rest of the world excluding China and US

Source: Globocan, IARC, NCCR, Frost & Sullivan analysis

HR+/HER2- Metastatic Breast Cancer (HR+/HER2- mBC)

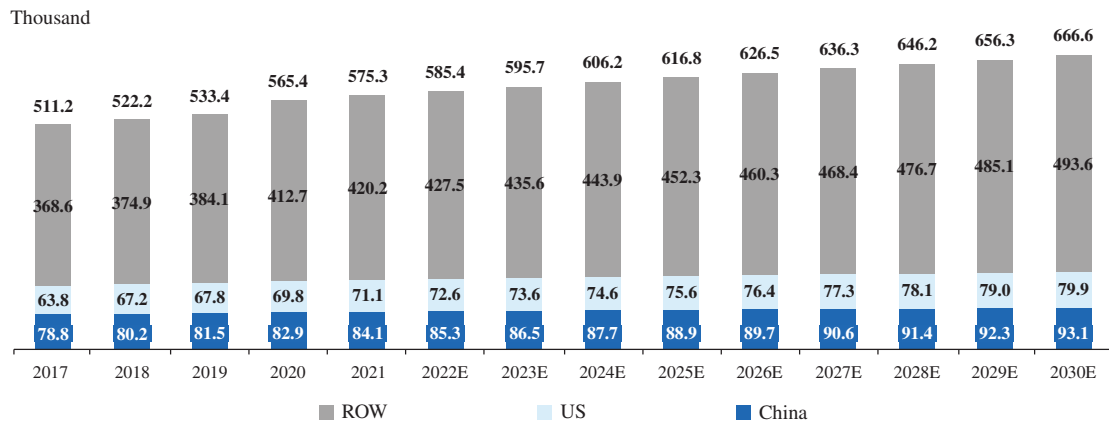
The status of the HR and HER2 in a breast cancer defines the four most common types of breast cancer. HR and HER2 can be either present, or positive (HR+, HER2+), or absent, or negative (HR-, HER2-), in the tumor. HR+/HER2- is the most common subtype among the four.

INDUSTRY OVERVIEW

The following chart shows the historical incidence breakdown of global HR+/HER2-mBC from 2017 to 2021, and the estimated incidence from 2022 to 2030, as well as CAGRs during the periods indicated:

Incidence Breakdown of Global HR+/HER2- mBC, 2017-2030E

CAGR	ROW	US	China	Global
2017-2021	3.3%	2.7%	1.6%	3.0%
2021-2025E	1.9%	1.6%	1.4%	1.8%
2025E-2030E	1.8%	1.1%	0.9%	1.6%



Note: ROW refers to rest of the world excluding China and US

Source: Globocan, IARC, NCCR, Frost & Sullivan analysis

Triple Negative Breast Cancer (TNBC)

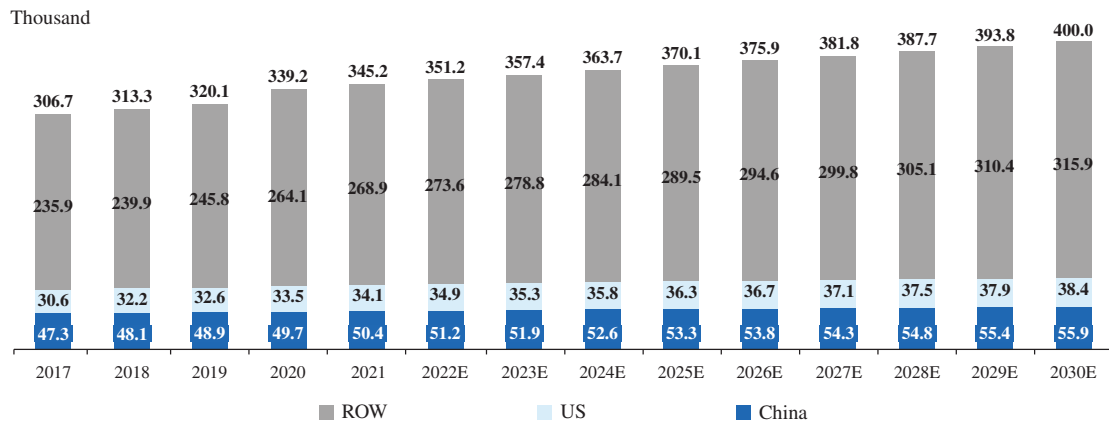
TNBC is a type of breast cancer that does not have any of the receptors that are commonly identified in breast cancer, including ER, PR, and HER2. TNBC is characterized by a shorter overall survival rate and an early peak in distant recurrences three years after diagnosis. In 2020, TNBC accounted for approximately 15% and 15% of the total breast cancer population globally and in China, respectively.

INDUSTRY OVERVIEW

The following chart shows the historical incidence breakdown of global TNBC from 2017 to 2021, and the estimated incidence from 2022 to 2030, as well as CAGRs during the periods indicated:

Incidence Breakdown of Global TNBC, 2017-2030E

CAGR	ROW	US	China	Global
2017-2021	3.3%	2.7%	1.6%	3.0%
2021-2025E	1.9%	1.6%	1.4%	1.8%
2025E-2030E	1.8%	1.1%	0.9%	1.6%



Note: ROW refers to rest of the world excluding China and US

Source: Globocan, IARC, NCCR, Frost & Sullivan analysis

Treatment Paradigm and Unmet Medical Needs

In the U.S., according to the NCCN Guideline on HR+/HER2- breast cancer, the anti-cancer therapy of resectable breast cancer is surgery plus systemic therapies as listed in the following table. Once the disease progresses, the locally advanced or metastatic breast cancer will be treated by multiple endocrine therapy, CDK4/6 inhibitors and targeted therapy as listed in the following table. NCCN Guideline recommends sacituzumab govitecan-hziy (an antibody-drug conjugate composed of an antibody targeting the human trophoblast cell surface antigen 2 coupled to SN-38, a topoisomerase I inhibitor) after patients failed the prior line of therapy of chemotherapy plus pembrolizumab (an anti-PD-1 antibody), in a systemic treatment of recurrent or stage IV TNBC.

INDUSTRY OVERVIEW

The below table sets forth the treatment paradigm of HR+/HER2- mBC and TNBC in the U.S.:

Indication	Treatment			
ER ⁺ and/or PR ⁺ ; HER2	Visceral crisis	<ul style="list-style-type: none"> Initial systemic therapy (<i>Chemotherapy</i>¹) 		
	No visceral crisis	Prior endocrine therapy within 1y	Premenopausal	<ul style="list-style-type: none"> Ovarian ablation or suppression + Systemic therapy² Continue Endocrine therapy
		Postmenopausal	<ul style="list-style-type: none"> Systemic therapy² Continue Endocrine therapy 	
	No prior endocrine therapy within 1y	Premenopausal	<ul style="list-style-type: none"> Ovarian ablation or suppression + Systemic therapy Selective ER modulators⁴ Continue Endocrine therapy 	
Postmenopausal		<ul style="list-style-type: none"> Systemic therapy² Continue Endocrine therapy 		
ER ⁻ and PR ⁻ , HER2 ⁻ (Triple Negative)	<ul style="list-style-type: none"> Chemotherapy¹ + PD-1 (pembrolizumab) as neo/adjuvant therapy Chemotherapy + pembrolizumab/sacituzumab/govitecan for advanced TNBC PARP inhibitors for BRCA mutation TNBC 			

Notes:

- Chemotherapy (Preferred Regimens + Other Recommended Regimens) = Anthracyclines, taxanes, anthracyclines, anti-metabolites, microtubule inhibitors, platinum, cyclophosphamide, docetaxel, albumin-bound paclitaxel, epirubicin, ixabepilone;
- Systemic therapy (Preferred Regimens - First-Line) = Aromatase inhibitor + CDK4/6 inhibitor, Selective ER down-regulator ± non-steroidal aromatase inhibitor, Fulvestrant + CDK4/6 inhibitor, Non-steroidal aromatase inhibitor, Selective estrogen receptors modulator, Steroidal aromatase inactivator.

Source: NCCN 2020, Frost & Sullivan analysis

According to Chinese Society of Clinical Oncology Guideline (“CSCO Guideline”), the below table sets forth the treatment paradigm of HR+/HER2- mBC and TNBC in China:

Indication	Treatment			
HER2 ⁻	After First Line Treatment	Sensitive to taxane therapy	<ul style="list-style-type: none"> Paclitaxel-albumin/docetaxel/paclitaxel TX GT TP X N G Etoposide Paclitaxel-albumin+ PD-1 inhibitor T+Bevacizumab LD Paclitaxel Liposome Olaparib Chemo+ PD-1 inhibitor 	
	Systemic therapies	After the treatment failure of taxane	<ul style="list-style-type: none"> Alibrin/X/N/G NP GP NX UTD1+X Sacituzumab govitecan-hziy/Paclitaxel-albumin/Etoposide Bevacizumab +X Paclitaxel-albumin + Chemotherapeutic drug LD Paclitaxel Liposome Olaparib Chemo+ PD-1 inhibitor 	
ER ⁺ and/or PR ⁺	Without prior endocrine therapy	<ul style="list-style-type: none"> AI+Abemaciclib/Palbociclib AI F F+CDK4/6 inhibitor TAM 		
	After the treatment failure of TAM	<ul style="list-style-type: none"> AI+Abemaciclib/Palbociclib/Chidamide AI F F+CDK4/6 inhibitor 		
	After the treatment failure of NSAI	<ul style="list-style-type: none"> F+Abemaciclib/Palbociclib/Dalpicililb SAI+Chidamide/CDK4/6 inhibitor/F/Everolimus F/SAI TAM/toremifene Progestogen 		
	After the treatment failure of SAI	<ul style="list-style-type: none"> F+Abemaciclib/Dalpicililb/Palbociclib F/NSAI NSAI+CDK4/6 inhibitor TAM/toremifene Progestogen 		
	After the treatment failure of CDK4/6 i	<ul style="list-style-type: none"> Chidamide+Endocrine therapy Another CDK4/6 inhibitor+ Endocrine therapy Toremifene Progestogen 		

Notes: H=trastuzumab; L=lapatinib; P=pertuzumab; T=docetaxel; paclitaxel and albumin-bound paclitaxel; X=capecitabine; N=navelbine; Cb=carboplatin; G=gemcitabine; LD=liposomal doxorubicin; F=fulvestrant; AI=Aromatase inhibitor; TAM=tamoxifen.

Source: CSCO 2022, Frost & Sullivan analysis

INDUSTRY OVERVIEW

According to Frost & Sullivan, the current HR+/HER2- mBC treatment is facing multiple major challenges, including:

- Low penetration of endocrine therapy. Different from the recommendations of the CSCO guidelines, the proportion of Chinese HR+/HER2- mBC patients currently receiving first-line chemotherapy is high, while the penetration rate of the recommended endocrine therapy is low. Due to the influence of family income level and regional medical insurance reimbursement level, HR+/HER2- mBC patients have differences in endocrine therapy affordability, and there are still unmet clinical needs.
- Endocrine + CDK4/6 therapy resistance in HR+/HER2- mBC. The endocrine/anti-estrogen therapies in combination with CDK4/6 inhibitors has emerged as the first- and second-line treatment for patients with HR+/HER2- mBC. However, most patients will develop drug resistance over time.

According to Frost & Sullivan, the current TNBC treatment is facing multiple major challenges, including:

- Lack of therapies for treatment. Because TNBC is ER negative, PR negative and HER2 negative, hormonal therapy and HER2 receptor target therapy cannot be effective for TNBC patients.
- Limitations of current therapies. Currently, TNBC is primarily treated with systemic therapies (chemotherapies), PD-1 (pembrolizumab plus chemotherapies) as neo/adjuvant therapy or first line therapy and antibody-drug conjugate therapies as the second-line therapy for TNBC have been approved by FDA recently. However, current treatments for patients with immunotherapy- and/or chemotherapy-resistant TNBC are limited in clinical practice and have relatively poor prognosis, high risk of recurrence, and no significant survival benefit, indicating huge unmet medical needs for the treatment of TNBC.

ANTI-CYP17A1 ANDROGEN DRUG

Overview

Androgens are closely related to the growth of the prostate and the occurrence of prostate cancer. Therefore, endocrine therapy has become an effective treatment for prostate cancer. Endocrine therapy includes androgen deprivation therapy (ADT) with estrogen therapy, gonadotropin-releasing hormone analog therapy, gonadotropin-releasing hormone antagonist therapy, and androgen suppressive. Androgen suppressive therapy can be used on top of ADT for the treatment of early-stage prostate cancer or combined with surgery for adjuvant therapy.

INDUSTRY OVERVIEW

Androgen suppressive therapy is one of the major methods of clinical treatment of prostate cancer, which involves intervention of the androgen signaling pathway. The main categories of androgen suppressive drugs are anti-CYP17A1 drugs and AR inhibitors. Anti-CYP17A1 drugs inhibit the synthesis of androgen, the best known drug of which is abiraterone. AR inhibitor represented by enzalutamide inhibits binding of androgen and receptor.

Competitive Landscape and Market Size

Currently, there are seven anti-androgen drugs approved for commercialization globally (ex-China) and there are seven anti-androgen drugs approved in China.

Marketed Anti-androgen Drug in the US and China								
Approved drug	Flutamide	Bicalutamide	Nilutamide	Abiraterone	Enzalutamide	Apalutamide	Darolutamide	Rezvilutamide
Commercial name	Fugerel	Casodex	Nilandron	Zytiga	Xtandi	Erleada	Nubeqa	艾瑞恩
Mechanism	AR inhibitor	AR inhibitor	AR inhibitor	CYP17A1 inhibitor	AR inhibitor	AR inhibitor	AR inhibitor	AR inhibitor
Company	Ferring	Astra Zeneca	Concordia	Janssen Biotech	Astellas	Janssen Biotech	Bayer	Hengrui Medicine
US approval time	1989*	1995	1996	2011	2012	2018	2019	Not approved
2020 global revenue (million US dollar)	NA	388.3	NA	2,767.6	5,134.3	760.0	317.0	NA
2022 US market price (US dollar)	NA	115.0 (50mg)	285.8 (150mg)	94.8 (250mg)	113.8 (40mg)	117.8 (60mg)	106.7 (300mg)	NA
2022 US monthly treatment cost (thousand US dollar)	NA	3.5 (PFS:NA)	3.5 (PFS:21.1)	11.4 (PFS:NA)	13.6 (mCRPC PFS:19.5 nmCRPC PFS:36.6 mCSPC PFS:NA)	14.1 (mCSPC PFS:NA nmCRPC PFS:40.5)	12.8 (PFS:40.4)	NA
FDA approved indications	B2-C stage prostate cancer, D2 stage metastasis prostate cancer		Metastatic prostate cancer	mCRPC, CSPC	CRPC, mCSPC	mCSPC, nmCRPC	nmCRPC	NA
China approval time	2003	1999	Not approved	2015	2019	2019	2021	2022
NMPA approved indications	Prostate cancer	Late stage Prostate cancer	NA	mCRPC, mCSPC	mCRPC, nmCRPC	nmCRPC, mCSPC	nmCRPC	mCSPC
China NRDL inclusion	Category B	Category B	NA	Category B	Category B	Category B	Category B	Category B
China generic drug approval status	Y	Y	NA	Y	Y	N	N	N
2020 China revenue (million RMB)	20.5	776.6	NA	1,614.3	141.5	38.9	NA	NA
2021 China market price (RMB)	NA	31.0 (50mg)	NA	108.5 (250mg)	69.6 (40mg)	332.5 (60mg)	196.7 (300mg)	NA
2021 China generic drug market price (RMB)	3.8 (250mg)	25.0 (50mg)	NA	30.0 (250mg)	48.2 (40mg)	NA	NA	NA
2021 China monthly treatment cost (thousand RMB)	NA	0.9 (PFS:NA)	NA	13.0 (PFS:NA)	8.4 (mCRPC PFS:19.5 nmCRPC PFS:36.6)	39.9 (mCSPC PFS:NA nmCRPC PFS:40.5)	23.6 (PFS:40.4)	NA
2021 China generic drug monthly treatment cost (thousand RMB)	0.3 (PFS:NA)	0.8 (PFS:NA)	NA	3.6 (PFS:NA)	5.8 (mCRPC PFS:19.5 nmCRPC PFS:36.6)	NA	NA	NA

Notes:

- There were over 15 generic competitors of the approved anti-androgen drugs as of March 6, 2023. If the generic name of a drug is listed in the NRDL, both the original drug and the generics under such generic name will be included in the NRDL and available for reimbursement. Once a drug is included in the NRDL, it will be subject to volume-based purchasing in China.
- The revenue refers to the overall sales under the generic name.
- The chart does not include androgen deprivation therapy (ADT) drugs. Flutamide original drug has been withdrawn from China and the US market.
- Information as of March 6, 2023.

Source: NMPA, FDA, Frost & Sullivan analysis.

INDUSTRY OVERVIEW

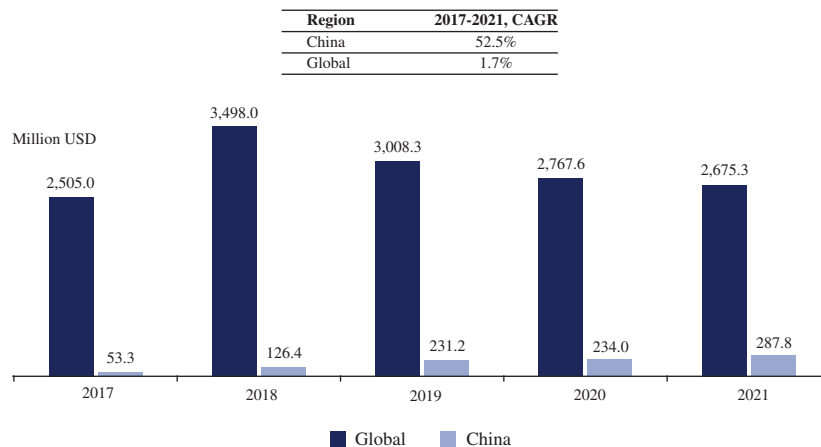
Currently, there is only one CYP17A1 inhibitor approved for commercialization globally including China, namely abiraterone, according to Frost & Sullivan.

Marketed Anti-CYP17A1 Drug in the US and China	
Approved drug	Abiraterone
Commercial name	Zytiga
Mechanism	CYP17A1 inhibitor
Company	Janssen Biotech
US approval time	2011
2020 global revenue (million US dollar)	2,767.6
2022 US market price (US dollar)	94.8 (250 mg)
2022 US monthly treatment cost (thousand US dollar)	11.4 (PFS: NA)
FDA approved indications	mCRPC, mHSPC
China approval time	2015
NMPA approved indications	mCRPC, mHSPC
China NRDL inclusion	Category B
2020 China revenue (million RMB)	1,614.3
2021 China market price (RMB)	108.5 (250 mg)
2021 China monthly treatment cost (thousand RMB)	13.0 (PFS:NA)

Source: NMPA, FDA, Frost & Sullivan analysis

The market size of anti-CYP17A1 drug from 2017 to 2021 is thus equivalent to the historical sale of abiraterone. The following chart shows the historical market size (sale) of the global and China anti-CYP17A1 drug market from 2017 to 2021, as well as CAGRs for the periods indicated:

Historical sale of Abiraterone globally and in China, 2017-2021



Notes: Global revenues for abiraterone declined in 2019, 2020 and 2021 due to (i) patent expiration and generic entry in 2018, (ii) entry of new AR antagonists in 2019, including dalotamide and apalutamide, and (iii) an increased proportion of AR antagonists, particularly enzalutamide.

Source: Annual reports published by the relevant market players, Expert interview, Frost & Sullivan analysis

INDUSTRY OVERVIEW

There are 11 anti-androgen drugs in clinical trials globally and LAE001 is the only CYP17A1 and CYP11B2 dual inhibitor candidate under development. In China, there are five anti-androgen drugs in clinical trials and LAE001 is also the only CYP17A1 and CYP11B2 dual inhibitor candidate in clinical trial stage.

Pipeline global					
Drug name	Target	Company	Indication	Phase	First posted date
SHR3680	AR inhibitor	Hengrui Medicine	HSPC, mCRPC, advanced breast cancer	III	2018-05-09
HC-1119	AR inhibitor	Hinova Pharmaceuticals	mCRPC	III	2019-02-22
Seviteronel/VT-464	Dual CYP17A1 and AR inhibitor	Innocrin Pharmaceuticals	CRPC, HR+ breast cancer, TNBC	II	2013-12-17
Proxalutamide/GT0918	AR inhibitor	Kintor Pharma	mCRPC	II	2019-04-02
TRC253	AR inhibitor	Tracon	mCRPC	I/II	2016-12-09
ODM-208	CYP11A1	Orion Corporation/Merck	mCRPC	I/II	2018-02-19
LAE001	Dual CYP17A1 and CYP11B2 inhibitor	Laekna	mHSPC*	II	2019-02-18
ODM-209	CYP11A1	Orion Corporation	Metastatic/advanced prostate cancer, metastatic/advanced breast cancer	I/II	2019-03-18
EPI-7386	AR inhibitor	ESSA Pharmaceuticals	mCRPC	I/II	2021-10-13
TAS3681	AR inhibitor	Taiho Oncology	mCRPC	I	2015-10-02
ONC1-0013B	AR inhibitor	Avionco LLC	mCRPC	I	2017-03-03

Notes: Only includes oncology drugs. The chart does not include androgen deprivation therapy (ADT) drugs or PROTAC. First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced. Information as of March 6, 2023.

* We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC. As part of our clinical development strategy for LAE001 in prostate cancer and based on the clinical data from trials on mCRPC, we plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S. and apply the NDA for mHSPC.

Pipeline in China					
Drug name	Mechanism/Target	Company	Indication	Phase	First posted date
Proxalutamide	AR inhibitor	Kintor Pharma	mCRPC	III	2018-07-02
HC-1119	AR inhibitor	Hinova Pharmaceuticals	mCRPC	III	2019-03-01
ISIS560131/AZD5312	AR inhibitor	Pyramid Laboratories	AR-V7 positive mCRPC	II	2021-04-29
LAE001	Dual CYP17A1 and CYP11B2 inhibitor	Laekna	mHSPC*	II	2019-04-25
TQB3720	AR inhibitor	Chia Tai-Tianqing Pharmaceutical	mCRPC	I	2021-01-26

Notes: Only includes oncology drugs. First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced. The chart does not include ADT drugs or PROTAC. Information as of March 6, 2023.

* We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC. As part of our clinical development strategy for LAE001 in prostate cancer and based on the clinical data from trials on mCRPC, we plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S. and apply the NDA for mHSPC.

Source: ClinicalTrials.gov, CDE, Frost & Sullivan analysis

INDUSTRY OVERVIEW

Growth Drivers and Further Trends

The anti-CYP17A1 androgen drug market is largely driven by the following key growth drivers:

- Increasing patient pool and clinical adoptions. With the growing aging population and increasing prostate cancer screening rate, the patient pool (including mHSPC and mCRPC) will continue to expand. Globally, the mHSPC prevalence has increased from 1.6 million in 2017 to 1.9 million in 2021, and is expected to continue to grow and reach 2.4 million in 2030. As for mCRPC, it is expected that the global prevalence will reach 2.1 million in 2030, representing great clinical needs. Abiraterone is currently listed as the Class I recommendation in the CSCO guideline for mCRPC. This is primarily attributed to its better safety profile than that of other chemotherapy drugs and proven efficacy in androgen inhibition. With the growing patient pool and buildup of clinical knowledge, it is estimated that the China anti-CYP17A1 drug market will continue to grow.
- Drug candidates with less side effects are under development. Despite its important role in prostate cancer treatment, abiraterone needs to be co-administered with prednisone for both mHSPC and mCRPC treatment, and has specific risks of hypertension, fluid retention and hypokalemia. To overcome the issue, drugs with improved safety profile and fewer side effects are being developed to drive the market growth.
- Novel therapy or combination therapies. For mCRPC patients, there are only limited treatment options other than chemotherapy, including abiraterone and enzalutamide. With disease progression, almost all patients will become resistant to currently available treatment. Therefore, novel therapies are being developed to overcome the issue. For example, studies have shown that combinatory use of new generation anti-androgen agents tend to provide better survival benefit to mHSPC patients compared with using single anti-androgen agent for treatment. Furthermore, combination of anti-CYP17A1 drugs with other treatment represents a future trend and will further drive the anti-CYP17A1 market growth.

Therapeutic Areas of Interest

Prostate Cancer

Prostate cancer begins when healthy cells in the prostate change and grow out of control, eventually developing into a tumor. The risk factors that may lead to prostate cancer include: mutations in the BRCA1 and/or BRCA2 genes, other genetic changes (HPC1, HPC2, HPCX, CAPB, ATM and FANCA), family history and eating habits. The overall five-year survival rate in the U.S. for prostate cancer was 97.5%, as compared to 69.2% in China.

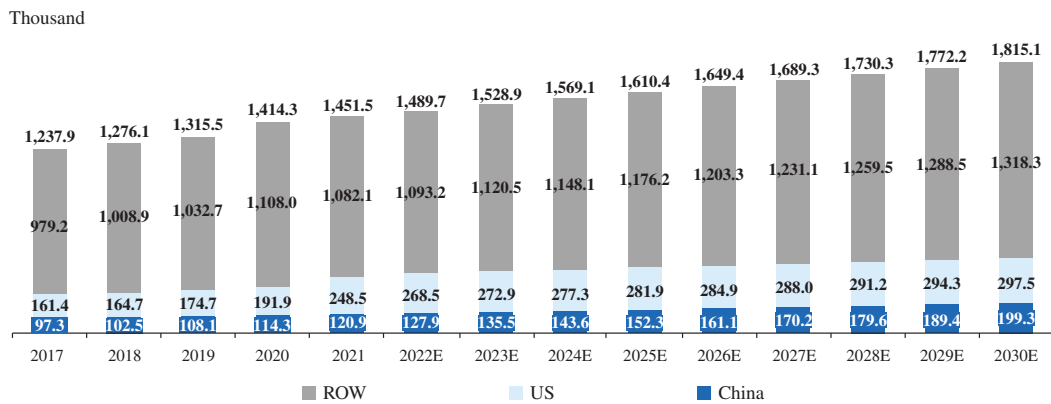
INDUSTRY OVERVIEW

Localized prostate cancer is the stage the tumor cells have not spread beyond the prostate. As the disease progresses and treatment is administered, prostate cancer may develop into two stages: (i) become metastatic but remain sensitive to ADT treatment (mHSPC); and (ii) remain in the localized stage but are resistant to ADT treatment (nmCRPC). Approximately 45% of patients with localized prostate cancer will progress to mHSPC. As treatment continues, almost all mHSPC patients will become resistant to ADT therapy, which is known as mCRPC.

The following chart shows the historical incidence breakdown of global prostate cancer from 2017 to 2021, and the estimated incidence from 2022 to 2030, as well as CAGRs during the periods indicated:

Incidence Breakdown of Global Prostate Cancer, 2017-2030E

CAGR	ROW	US	China	Global
2017-2021	2.5%	11.4%	5.6%	4.1%
2021-2025E	2.1%	3.2%	5.9%	2.6%
2025E-2030E	2.3%	1.1%	5.5%	2.4%



Note: ROW refers to rest of the world excluding China and US

Source: Globocan, IARC, NCCR, Frost & Sullivan analysis

Metastatic Hormone-Sensitive Prostate Cancer (mHSPC)

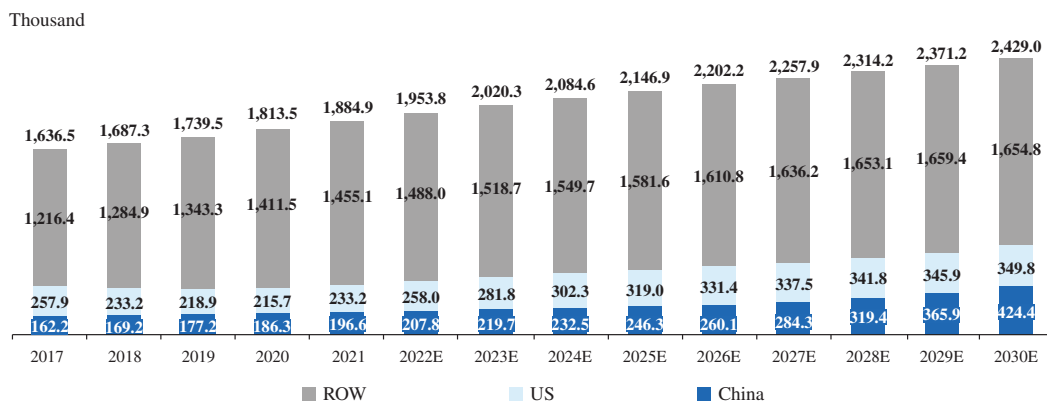
Hormone-sensitive prostate cancer (HSPC) is the stage of prostate cancer where the patients effectively respond to hormone therapies, typically androgen deprivation therapy (ADT). mHSPC is a prostate cancer that has spread to other parts of the body.

INDUSTRY OVERVIEW

The following chart shows the historical prevalence breakdown of global mHSPC from 2017 to 2021, and the estimated prevalence from 2022 to 2030, as well as CAGRs during the periods indicated:

Prevalence Breakdown of Global mHSPC, 2017-2030E

CAGR	ROW	US	China	Global
2017-2021	4.6%	-2.5%	4.9%	3.6%
2021-2025E	2.1%	8.1%	5.8%	3.3%
2025E-2030E	0.9%	1.9%	11.5%	2.5%



Note: ROW refers to rest of the world excluding China and US

Source: Globocan, IARC, NCCR, Frost & Sullivan analysis

Metastatic Castration-Resistant Prostate Cancer (mCRPC)

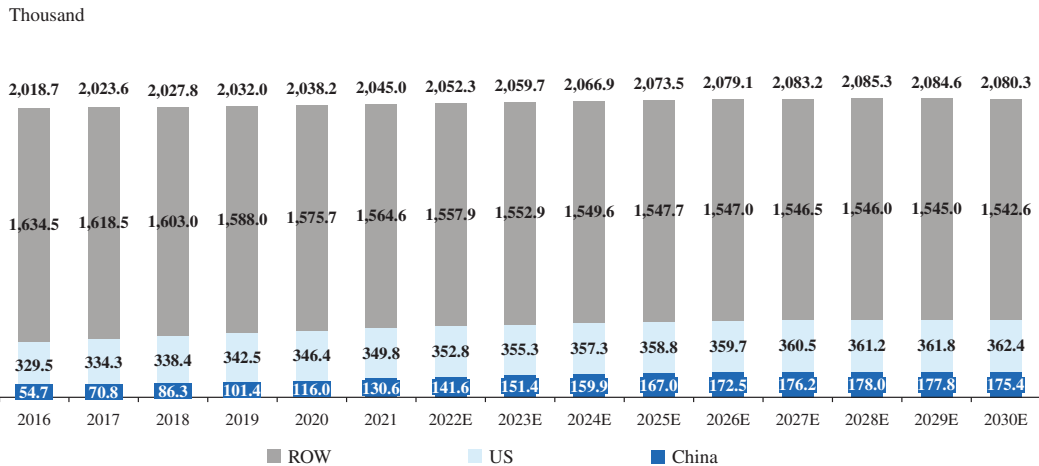
Castration-resistant prostate cancer (CRPC) is a prostate cancer that progresses clinically, radiographically or biochemically, despite castrate levels of serum testosterone (<50 ng/dL) in a patient. Patients with prostate cancer that have relapsed after local therapy or that have distant metastasis usually respond to ADT. However, despite receiving ADT, most of these patients eventually experience disease progression and develop CRPC within a median of 18 to 24 months from receiving ADT. A substantial majority of CRPC will be developed into mCRPC.

INDUSTRY OVERVIEW

The following chart shows the historical prevalence breakdown of global mCRPC from 2016 to 2021, and the estimated prevalence from 2022 to 2030, as well as CAGRs during the periods indicated:

Prevalence Breakdown of Global mCRPC, 2016-2030E

CAGR	ROW	US	China	Global
2016-2020	-0.9%	1.3%	20.7%	0.2%
2020-2025E	-0.4%	0.7%	7.6%	0.3%
2025E-2030E	-0.1%	0.2%	1.0%	0.1%



Note: ROW refers to rest of the world excluding China and US

Source: Globocan, IARC, NCCR, Frost & Sullivan analysis

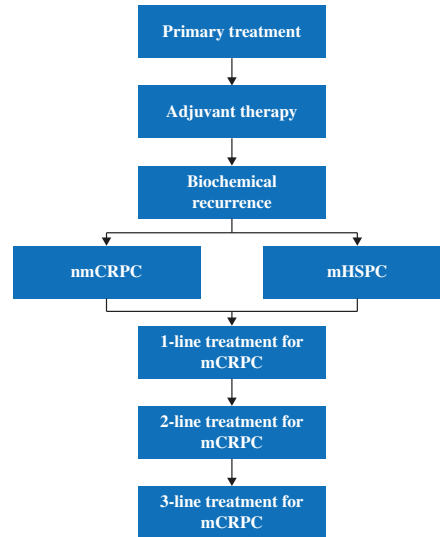
Treatment Paradigm and Unmet Medical Needs

The treatment of prostate cancer can be categorized into primary treatment, adjuvant therapy, mHSPC treatment, non-mCRPC and mCRPC treatment based on the disease stages. Since the 1940s, endocrine therapy and chemotherapy have been the optimized option for first-line therapies of prostate cancer. According to the latest NCCN Guideline for the treatment of prostate cancer, several combination therapies, which are all endocrine-based therapies, are also recommended for the treatment of the early stage of prostate cancer.

INDUSTRY OVERVIEW

The following chart sets forth the treatment process for prostate cancer in the national and international guidelines.

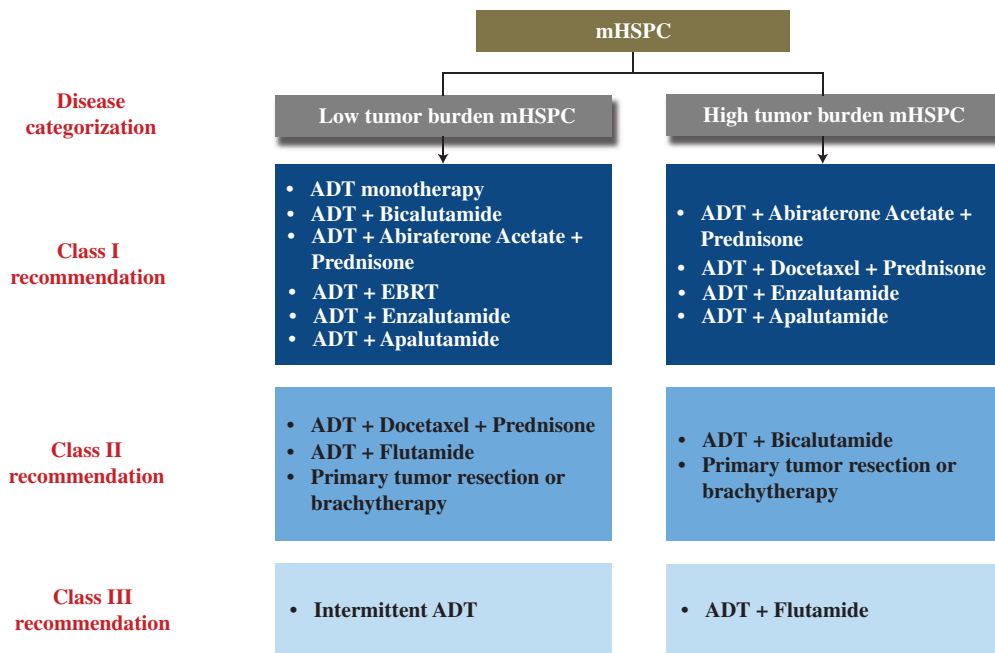
Treatment Process for Prostate Cancer



Notes: nmCRPC: nonmetastatic castration-resistant prostate cancer.

Source: NCCN Guideline, CSCO 2020, Frost & Sullivan analysis

The following chart sets forth the recommended mHSPC treatment in the national and international guidelines:



Source: NCCN Guideline, CSCO 2020, Frost & Sullivan analysis

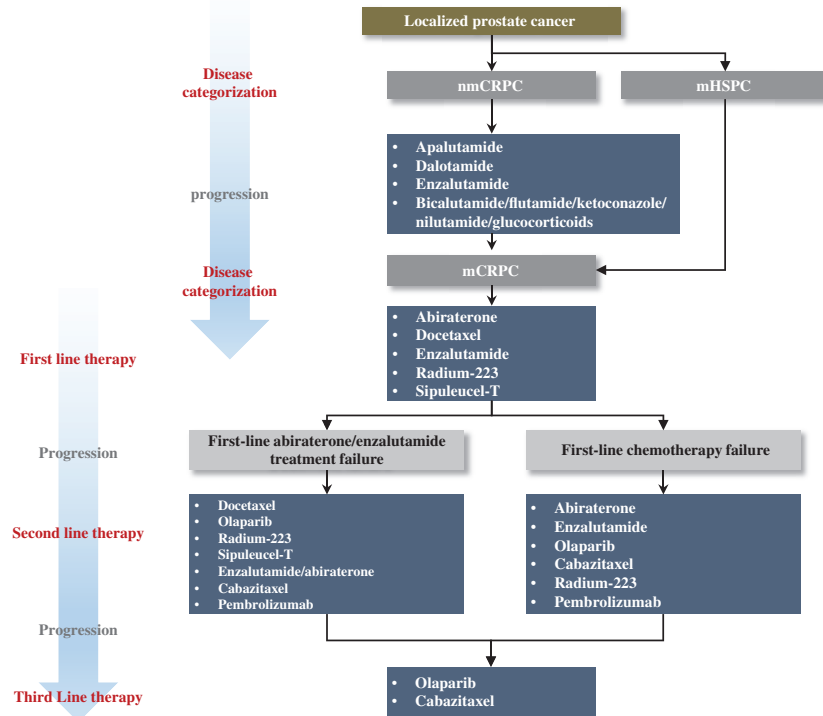
INDUSTRY OVERVIEW

The following chart sets forth the recommended CRPC treatment according to the international guideline, the NCCN Guideline:

Recommended Treatment for CRPC							
Stage	Non-metastatic CRPC	Metastatic CRPC					
Index	Asymptomatic	Asymptomatic or minimally symptomatic	Symptomatic				
			No prior docetaxel chemotherapy		Prior docetaxel chemotherapy		
			Good performance	Poor performance	Good performance	Poor performance	
2 nd Generation AR Antagonists		Androgen Biosynthesis Inhibitor Abiraterone + Prednisone	Androgen Biosynthesis Inhibitor Abiraterone + Prednisone		Androgen Biosynthesis Inhibitor Abiraterone + Prednisone		
Apalutamide		2 nd Generation AR Antagonists Enzalutamide		Clinicians should not offer Sipuleucel-T to patients.			
		Chemotherapy Docetaxel + Prednisone	2 nd Generation AR Antagonists Enzalutamide		Chemotherapy Cabazitaxel + Prednisone		Clinicians should offer palliative care to the patients, and should not offer systemic chemotherapy or immunotherapy. Preventative treatment, like supplemental calcium, vitamin D should be offered.
Enzalutamide		Immunotherapy Sipuleucel-T	Chemotherapy Docetaxel + Prednisone		2 nd Generation AR Antagonists Enzalutamide		

Source: Castration-Resistant Prostate Cancer: America Urological Association Guideline, Frost & Sullivan analysis

The following chart sets forth the recommended CRPC treatment in the national guideline, the CSCO Guideline:



Source: CSCO 2020, Frost & Sullivan analysis

INDUSTRY OVERVIEW

According to Frost & Sullivan, the current prostate cancer treatment paradigm is facing multiple major challenges, including:

- Lack of early diagnosis in China. Most prostate cancer patients are diagnosed at an advanced stage, mainly due to the lack of awareness and limited diagnostic techniques for regular prostate examinations in China. Only approximately 30% of new prostate cancer cases are diagnosed at an early stage in China, while more than 70% new prostate cancer patients are diagnosed at an early stage in the U.S.
- Unsatisfied prognosis. Radical treatment is not suitable for patients with locally advanced or metastatic prostate cancer, so the prognosis for these patients is usually relatively poor compared to the patients who were diagnosed in local stages. ADT is a primary treatment for metastatic prostate cancer. However, CRPC patients have developed resistance to ADT and have limited treatment options. The median survival duration for CRPC patients is less than two years due to the rapid progress of disease and lack of effective treatment.
- Limited treatment for drug-resistant mCRPC patients. Currently, there are limited treatment options for CRPC, mainly including chemotherapy, abiraterone and enzalutamide. However, these patients will most likely develop drug resistance within two years. For most drug-resistant mCRPC patients, there are limited effective treatments when they become resistant to first to third lines of SOCs, such as abiraterone, A/AR inhibitors and chemotherapies. However, the prognosis is poor in these drug-resistant mCRPC patients.

LIVER FIBROSIS DRUG

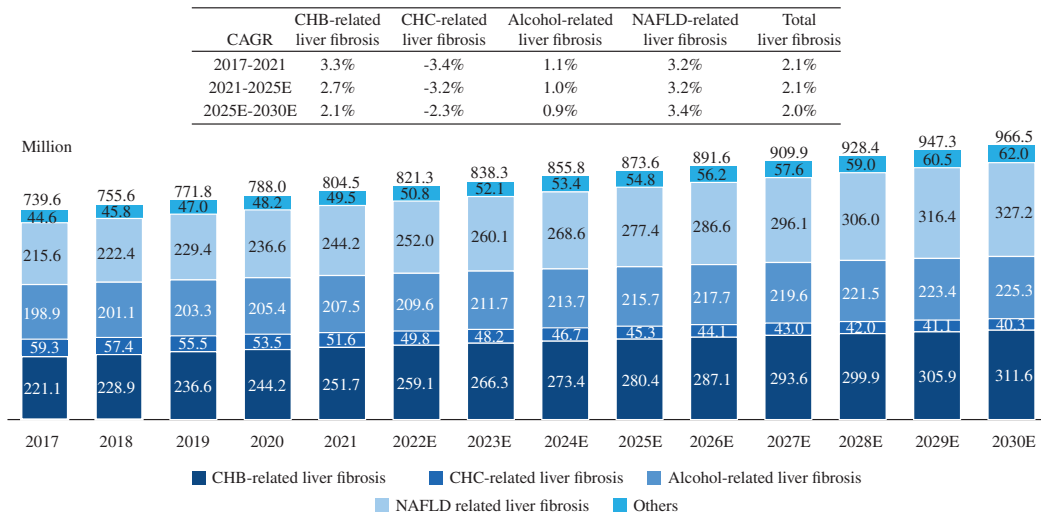
Liver Fibrosis

Liver fibrosis is a pathological change in most chronic liver diseases, such as chronic hepatitis B (CHB), chronic hepatitis C (CHC), alcoholic liver disease (ALD), non-alcoholic fatty liver disease (NAFLD) and others. Liver fibrosis is a reversible over-repair reaction of liver tissue injury and is an important process in the progression from chronic liver disease to cirrhosis. In the course of fibrosis progression, the extracellular matrix (ECM) such as collagen, glycoprotein and proteoglycan, in liver tissue develops diffuse hyperplasia and deposition, while normal liver parenchymal cells undergo necrosis and apoptosis. As this process continues, the scar tissue formed by ECM gradually replaces normal liver parenchyma cells, leading to abnormal changes in liver tissue structure, which eventually leads to cirrhosis and liver cancer, furthering to liver failure. Liver fibrosis can be caused by not only chronic liver diseases, but also etiologies such as genetic and metabolic diseases.

INDUSTRY OVERVIEW

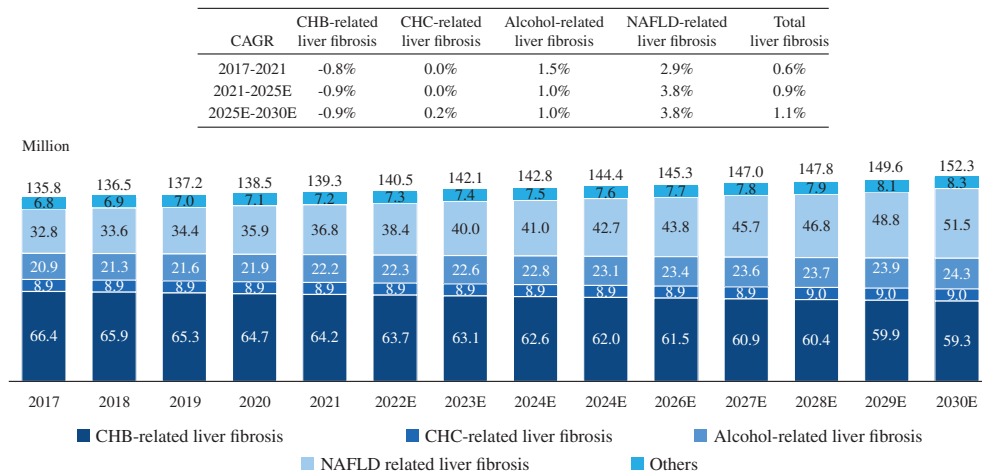
The following chart shows the historical prevalence breakdown of liver fibrosis globally and in China from 2017 to 2021, and the estimated prevalence from 2022 to 2030, as well as CAGRs during the periods indicated:

Prevalence of Liver Fibrosis Globally, 2017-2030E



Source: Frost & Sullivan Analysis

Prevalence of Liver Fibrosis in China, 2017-2030E



Source: Frost & Sullivan Analysis

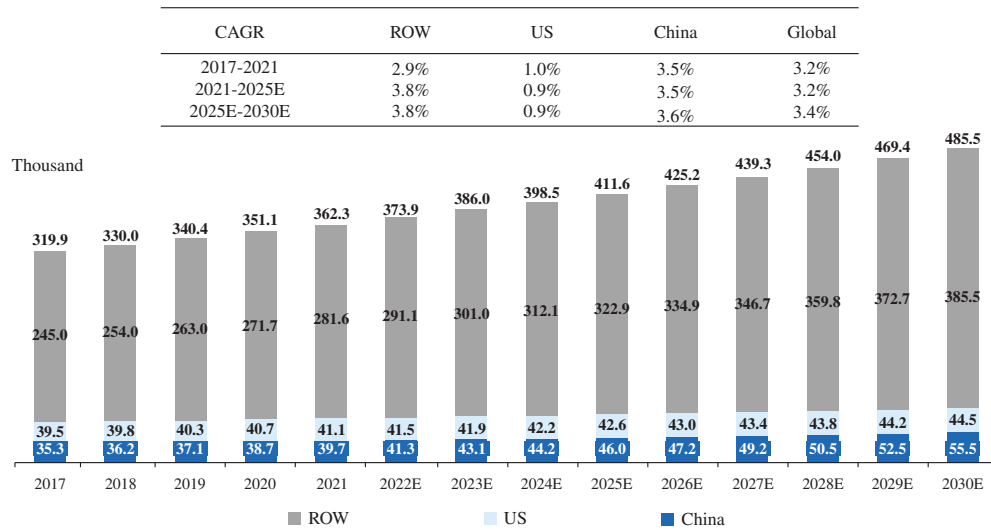
INDUSTRY OVERVIEW

Non-Alcoholic Steatohepatitis (NASH)

NASH is an advanced form of non-alcoholic fatty liver disease (NAFLD). NAFLD is caused by build-up of fat in the liver. When this build-up causes inflammation and damage, it is known as NASH, which can lead to scarring of the liver. Scarring of the liver is a potentially life-threatening condition called cirrhosis. There are often no outward signs or symptoms associated with NASH. The most common symptoms are fatigue and pain in the upper right abdomen. NASH is most common in patients who are overweight or obese.

The following chart shows the historical prevalence breakdown of global NASH from 2017 to 2021, and the estimated prevalence from 2022 to 2030, as well as CAGRs during the periods indicated:

Prevalence Breakdown of Global NASH, 2017-2030E



Note: ROW refers to rest of the world excluding China and US

Source: Globocan, IARC, NCCR, Frost & Sullivan analysis

Treatment Paradigm and Unmet Medical Needs

Liver Fibrosis

Currently, there are no effective specific therapies for liver fibrosis treatment, according to Frost & Sullivan. Both China and U.S. guidelines focus on prevention of the disease progression, and control liver damage and inflammation by etiological treatment.

INDUSTRY OVERVIEW

Treatment Paradigm of Liver Fibrosis

Category	Underlying Cause	Mechanism of Action
Causal Treatment	CHB and CHC	Antiviral therapies are recommended to treat CHB and CHC. Currently, there are two classes of agents licensed for CHB treatment: standard or pegylated interferon alpha (IFN or Peg-IFN) and nucleoside/nucleotide analogues (NAs). Long-term treatment with NAs is the treatment option most often used in the majority of CHB patients. Entecavir and tenofovir, the most potent NAs with high barrier to resistance, are recommended as first-line monotherapy by all major treatment guidelines and can lead to long-lasting virological suppression, resulting in histological improvement or reversal of advanced fibrosis and reduction in disease progression and liver-related complications. According to the Chinese Medical Association Guidelines for the Prevention and Treatment of Hepatitis C, 2019, the use of sofosbuvir/velpatasvir or glecaprevir/pibrentasvir combination tablets in a pan-gene therapy regimen can effectively eliminate hepatitis C virus in most patients. In addition, sofosbuvir combined with dasabuvir and sofosbuvir/velpatasvir/vosilaprevir combination tablets are also effective in treating hepatitis C.
	NAFLD	Both the U.S. and China guidelines recommend lifestyle intervention as the most recommended therapies for NAFLD. The management of NAFLD should consist of treating liver disease as well as the associated metabolic comorbidities such as obesity, hyperlipidemia. The U.S. guideline states that thiazolidinediones, GLP-1 analogues and vitamin E can be used only on a case-by-case manner after careful evaluation.
	Alcohol Associated Liver Disease	Alcohol cessation therapy is recommended. For relapse prevention, medication also includes those to reduce the level of addiction, including naltrexone, acamprosate and gabapentin.
Anti-fibrosis Treatment	N/A	At early stage of the disease, liver fibrosis is an important process of liver damage repair and has disease defensive effect. Therefore, causal treatment and anti-inflammation therapy are recommended. With fibrosis progression to later stage and cirrhosis, anti-fibrosis treatment are recommended. Currently, there are no approved drugs specifically targeting liver fibrosis. Liver protective drug, anti-inflammatory drug, and antioxidants are currently recommended to improve the fibrosis condition in the China CMA guideline, including glucocorticoids, glycyrrhizic acid, silymarin, etc.

Source: Literature Review, Frost & Sullivan analysis

NASH

In both the U.S. and China, treatment of NASH is currently limited to lifestyle change and specific treatment of comorbidities, and no evidence-based pharmacological therapy is approved, according to Frost & Sullivan. The NASH treatment is moving towards a multi-mechanistic strategy of combination therapy, given the complexity in pathophysiology and heterogeneity nature of the disease.

U.S. Guidance of NASH:

Category	Classification	Target	Mechanism of Action
Behavior Intervention	Lifestyle Intervention	N/A	Lifestyle modification consisting of diet, exercise, and weight loss has been advocated to treat patients with NAFLD/NASH.
Drug Intervention	Thiazolidinediones/ Pioglitazone	(PPAR)- γ	Peroxisome proliferator-activated receptor gamma (PPAR)- γ , nuclear transcription factor, have broad effects on glucose and lipid metabolism, as well as vascular proliferation and inflammation.
	Vitamin E	N/A	Oxidative stress is considered a key mechanism of hepatocellular injury and disease progression in subjects with NASH. Vitamin E is an antioxidant and has been investigated as a treatment for NASH.
Surgical Intervention	Bariatric Surgery	N/A	Weight loss is effective in improving all disease features of NAFLD, including fibrosis. Bariatric surgery improves or eliminates comorbid disease in most patients and improves long-term survival of NASH.

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China Guidance of NASH:

Category	Classification	Target	Mechanism of Action
Behavior Intervention	Lifestyle Intervention	N/A	In order to achieve weight loss and reduce BMI value, diet and adequate exercises has been used to treat patients with NAFLD/NASH.
Drug Intervention	Metformin + Liraglutide/ Pioglitazone	GLP-1/ (PPAR)- γ	For patients with metabolic syndrome (MetS), such as diabetes, hypertension and obesity, metformin and other precision drugs are recommended to regulate the metabolism of patients, thereby improve NAFLD indices and delay the progression of NAFLD/NASH.
	Hepatoprotective drugs	N/A	A category of drugs improve liver function, promote regeneration of damaged liver cells, and enhance liver detoxification functions.
Surgical Intervention	Bariatric surgery	N/A	For patients with severe (BMI>40 kg/m ²) or moderate obesity (35 kg/m ² ≤BMI≤39.9 kg/m ²), bariatric surgery are recommended to efficiently reduce the weight of patients.

Note: MetS = Metabolic Syndrome

Source: Frost & Sullivan analysis

Competitive Landscape

Liver Fibrosis

Currently, no specific anti-liver fibrosis drug candidates have been approved worldwide. There are a number of active anti-liver fibrosis drug candidates in Phase II or later clinical stage globally. In China, there are five anti-liver fibrosis drug candidates in clinical stage as shown in the table below.

Drug	Target	Company	Indication	Status	First Posted Date
Hydronidone	TGF β	BJContinent Pharmaceuticals Limited	Chronic hepatitis B liver fibrosis	Phase III	2021-10-14
BI456906	GCGR, GLP1R	Boehringer Ingelheim	NASH and liver fibrosis	Phase II	2021-09-01
Fluorofenidone	TGF β	Hainan Haiyao	Liver fibrosis	Phase II	2021-10-18
TB001	GLP-1R/GCGR agonist	Turier Biotech	Liver fibrosis	Phase I	2021-12-16
GST-HG151	MAP3K5	Fujian Cosunter	NASH with liver fibrosis	Phase I	2022-03-03

Notes:

* First posted date denotes the date when the trial is first publicly announced.

Not including liver cirrhosis indication. Information as of March 6, 2023

Source: ClinicalTrials.gov, CDE, Frost & Sullivan analysis

INDUSTRY OVERVIEW

NASH

Currently, there are no approved drug candidates for commercialization in terms of NASH treatment globally, according to Frost & Sullivan. There are a number of drug candidates under development globally for NASH. The table below summarizes all the later clinical-stage (Phase III and NDA) drugs for NASH treatment globally:

Global Pipelines for NASH Treatment				
Pipeline	Target	Company	Status	First Posted Date*
Obeticholic Acid	FXR	Intercept Pharmaceuticals	NDA	2022/12/23
Resmetirom (MGL-3196)	THRβ	Madrigal Pharmaceuticals, Inc.	Phase III	2019/4/3
Semaglutide	GLP1R	Novo Nordisk	Phase III	2021/3/30
IVA337	PPAR	Inventiva Pharma	Phase III	2021/4/19
Aramchol	SCD	Galmed Pharmaceuticals	Phase III	2019/09/26
MSDC-0602K	NA	Cirius Therapeutics, Inc.	Phase III	2019/05/31

Notes: Excluding clinical trials only conducted in China. Only including pipelines in Phase III and later. Information as of March 6, 2023.

* First posted date denotes the date when the trial is first publicly announced.

Source: ClinicalTrials.gov, FDA, Frost & Sullivan analysis

There are a number of drug candidates under development in China for NASH. The table below summarizes all the later clinical-stage (Phase II or later) drugs for NASH treatment in China:

Pipelines for NASH Treatment in China ¹					
Drug	Target	Company	Indication	Status	First Post Date*
Semaglutide	GLP1R	Novo Nordisk	NASH	III	2021/07/27
Cotadutide	GCCR, GLP1R	Astra Zeneca	NASH	II/III	2022-10-31
TVB-2640	FASN	3-V Biosciences/Ascleptis	NASH	II	2020/4/30
Tropifexor	FXR	Norvatis	NASH	II	2020/12/17
PF-06865571 /+ PF-05221304	DGAT2	Pfizer	NASH	II	2021/03/15
HEC96719	FXR	HEC Pharma	NASH	II	2021/07/27
BI 456906	GLP-1	Boehringer Ingelheim	NASH and liver fibrosis	II	2021/09/01
Chiglitazar Sodium	PPAR	Chipscreen	Insulin Resistance NASH with High Triglycerides	II	2021/12/07
ASC41	THRB	Ascleptis Pharma Inc.	NASH	II	2022/06/21
ZSP1601	PDE	Zhongsheng Pharma	NASH	II	2022/12/30

Notes: The table only includes pipelines in Phase II and later clinical stage, as well as approved drugs. Information as of March 6, 2023.

* First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced.

Source: CDE, Frost & Sullivan analysis

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HEREDITARY HEMORRHAGIC TELANGIECTASIA AND PROTEUS SYNDROME

Hereditary Hemorrhagic Telangiectasia

Hereditary hemorrhagic telangiectasia (HHT) is a disorder in which some blood vessels do not develop properly. A person with HHT may form blood vessels without the capillaries (tiny blood vessels that pass blood from arteries to veins) that are usually present between arteries and veins.

Although there are no clear guidelines for the treatment of HHT, there are a number of treatments for the symptoms of HHT according to the “Second International Guidelines for the Diagnosis and Management of Hereditary Hemorrhagic Distal Capillary Dilatation”. Antiestrogens such as tamoxifen and raloxifene, drugs that stop blood vessel growth such as bevacizumab, and drugs that slow down the breakdown of blood clots such as tranexamic acid have all been used to control symptoms such as blood vessel growth and excessive bleeding caused by HHT.

Currently, there are no HHT drugs approved globally and no HHT drugs under clinical stage in China. The following table sets forth the competitive landscape of HHT drugs in clinical trials globally.

Global Pipelines for HHT Treatment				
Pipeline	Target	Company	Status	First Posted Date*
Tranexamic acid	PLG	Baxter Healthcare	Phase III	2009/12/15
Nintedanib	PDGFR/FGFR/VEGFR	Boehringer Ingelheim	Phase II	2021/7/26
VAD044	–	Vaderis Therapeutics	Phase I	2022/6/6

Notes: Information as of March 6, 2023.

* First posted date denotes the date when the trial is first publicly announced.

Source: *Clinical Trials, Frost & Sullivan Analysis*

Proteus Syndrome

Proteus syndrome is a rare condition characterized by overgrowth of the bones, skin, and other tissues. Organs and tissues affected by the disease grow out of proportion to the rest of the body. The overgrowth is usually asymmetric, which means it affects the right and left sides of the body differently. Newborns with Proteus syndrome have few or no signs of the condition. Overgrowth becomes apparent between the ages of six and 18 months and gets more severe with age. The cause of the disorder is a mosaic variant in a gene called AKT1.

As an extremely rare disease, there are no guidelines for the treatment of Proteus syndrome. Treatment of this disease is limited to supportive care and surgical intervention. Genetic mosaicism, such as the activated AKT1 mutation, has been suggested as an important cause of Proteus syndrome.

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Currently, there are no approved drugs for the treatment of Proteus syndrome globally. There are no Proteus syndrome drugs under development that reaching clinical stage in China. The following table sets forth the competitive landscape of Proteus syndrome drugs in clinical trials globally.

Global Pipelines for Proteus Syndrome Treatment				
Pipeline	Target	Company	Status	First Posted Date*
MK-7075 /Miransertib	AKT1	Merck	Phase II	2021/7/28

Notes: Information as of March 6, 2023.

* First posted date denotes the date when the trial is first publicly announced.

Source: ClinicalTrials, Frost & Sullivan Analysis

REPORT COMMISSIONED BY FROST & SULLIVAN

In connection with the [REDACTED], we commissioned Frost & Sullivan, an Independent Third Party, to prepare a report on global and China’s oncology and liver fibrosis drug markets. Except as otherwise noted, all data and forecasts in this section come from the Frost & Sullivan report. We have agreed to pay a total of US\$76,500 in fees for the preparation of the Frost & Sullivan report. Frost & Sullivan is a market research and consulting company that provides market research on a variety of industries including healthcare. In preparing the report, Frost & Sullivan collected and reviewed publicly available data such as government-derived information, annual reports and industry association statistics, as well as market data collected by conducting interviews with key industry experts and leading industry participants. Frost & Sullivan has exercised due care in collecting and reviewing the information so collected.

REGULATORY OVERVIEW

PRC LAWS AND REGULATIONS

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the principal PRC laws, regulations and rules that are relevant to our business and operations.

Regulations on Company Establishment and Foreign Investment

The PRC Company Law (《中華人民共和國公司法》), which was promulgated by the Standing Committee of the National People’s Congress (the “NPC”) and further amended in December 1999, August 2004, October 2005, December 2013 and October 2018, applies to the establishment, operation and management of both PRC domestic companies and foreign-invested enterprises. According to the PRC Company Law, where there are otherwise provisions in the laws relating to foreign investment, such provisions shall prevail.

The Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “FIL”), which was promulgated by the NPC 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 organizations (“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 FIL further adopts the management system of pre-establishment national treatment and negative list for foreign investment. The “pre-establishment national treatment” refers to granting to foreign investors and their investments, in the stage of investment access, the treatment no less favorable than that granted to domestic investors and their investments; the “negative list” refers to special administrative measures for access of foreign investment in specific fields as stipulated by the State. The FIL granted national treatment to foreign investments outside the negative list. The negative list will be released by or upon approval of the State Council.

In December 2019, the State Council promulgated the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) (the “Implementation Rules”) which came into effect in January 2020. The Implementation Rules further clarified that the state shall encourage and promote foreign investment, protect the lawful rights and interests in foreign investments, regulate foreign investment administration, continue to optimize foreign investment environment, and advances a higher-level opening.

Investment activities in the PRC by foreign investors were principally governed by the Special Administrative Measures (Negative List) for Access of Foreign Investment (2021 version) (《外商投資准入特別管理措施(負面清單)(2021年版)》) (the “Negative List”), and the Catalogue of Industries for Encouraging Foreign Investment (《鼓勵外商投資產業目錄(2020年版)》) (the “Encouraging List”) promulgated by the MOFCOM and the NDRC in

REGULATORY OVERVIEW

December 2020. The Negative List, which came into effect on January 1, 2022, sets out special administrative measures (restricted or prohibited) in respect of the access of foreign investments in a centralized manner, and the Encouraging List, which came into effect on January 27, 2021, sets out the encouraged industries for foreign investment. The Negative Lists cover 11 industries, and any field not falling in the Negative Lists shall be administered under the principle of equal treatment for domestic and foreign investment. Our business as currently conducted does not fall within the confines of the Negative Lists and is not subject to special administrative measures.

The Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》) was released by the MOFCOM and the State Administration for Market Regulation (the “SAMR”) on December 30, 2019, and became effective on January 1, 2020. Foreign investors directly or indirectly conducting investment activities within the territory of China shall submit the investment information through submission of initial reports, change reports, deregistration reports, annual reports etc. to the competent commerce authorities in accordance with The Measures on Reporting of Foreign Investment Information. When submitting an annual report, a foreign-invested enterprise shall submit the basic information on the enterprise, the information on the investors and their actual controlling party, the enterprise’s operation and asset and liabilities information etc, and where the foreign investment admission special administrative measures are involved, the foreign investment enterprise shall also submit the relevant industry licensing information.

Laws and Regulations on Pharmaceutical Product Development, Approval and Registration

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 National Medical Products Administration (the “NMPA”), the National Health Commission (the “NHC”) and the SAMR. The NMPA’s predecessor, the State Drug Administration, or the SDA, was replaced by the State Food and Drug Administration, the SFDA, which was later reorganized into the China Food and Drug Administration, or the CFDA, as part of the institutional reforms implemented by the State Council. The responsibilities of the National Health and Family Planning Commission (the “NHFPC”) and certain other governmental authorities are consolidated into the NHC, and the CFDA had been replaced by the NMPA 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 18, 2018. The NMPA is a regulatory authority responsible for registration and supervision of pharmaceutical products, cosmetics and medical equipment under the supervision of the SAMR.

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The NMPA has set up the Center for Drug Evaluation (the “CDE”) conducting the technical evaluation of each drug and biologic application to assess safety and efficacy 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 CFDA on March 17, 2017 and effective as of 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.

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, 2018 and 2019, and the Implementing Measures of the PRC Drug Administration Law (《中華人民共和國藥品管理法實施條例》) 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, 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.

Nonclinical Research

The NMPA promulgated the Administrative Measures for Good Laboratories Practice of Nonclinical Laboratory (2017) (《藥物非臨床研究質量管理規範》(2017)) 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. 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 organizational administration, its research personnel, its equipment and facilities and its operation and management of nonclinical pharmaceutical projects. If all the requirements are met, a Certification of Good Laboratory Practice will be issued by the NMPA and the result will be published on the NMPA’s website.

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Conduction of Clinical Trials

In addition, according to the Administration of Quality of Drug Clinical Practice (《藥物臨床試驗質量管理規範》) issued by the NMPA on April 23, 2020 and effective as of July 1, 2020, which replaced the Administration of Quality of Drug Clinical Practice 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-center clinical trial conducted in the PRC, after ethical review by the leader unit of the clinical trial, other member units should recognize the review results of the leader unit and should not conduct repeated reviews.

All clinical trials conducted in China for new drug registration purposes must be approved and conducted at pharmaceutical clinical trial institutions filed according to the Regulations on the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》) promulgated by NMPA and NHC on November 29, 2019, and took effect from December 1, 2019.

Clinical Trials Approval and Registration

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.

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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.

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 enrollment 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.

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 bio-equivalence 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.

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According to the Circular on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs, where the application for clinical trial of a 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.

According to the Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》) issued by the CDE On November 19, 2021, the fundamental purpose of the drug market is to address the needs of patients, and drug research and development should be based on patient needs and clinical value.

Approval or Filing relating to Chinese Human Genetic Resources

On July 2, 2015, the MOST 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 organization of China shall apply for approval of the China Human Genetic Resources Management Office through the online system. On October 26, 2017, the MOST 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 PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council on May 28, 2019 and implemented on July 1, 2019, further stipulates that using Chinese human genetic resources to carry out international scientific research cooperation shall meet certain conditions and subject to approval by the administrative department of MOST. It also provides that any providing or opening for use of Chinese human genetic resources information to foreign organizations, individuals or institutions established or actually controlled by foreign organizations and individuals shall make filing to the MOST and shall submit information backup.

On March 21, 2022, the MOST promulgated the Implementation Rules of the Administration of Human Genetic Resources (Draft for Comments) (《人類遺傳資源管理條例實施細則(徵求意見稿)》) to further clarify the requirements for administrative licensing, record-filing and security review in respect of the collection, preservation, use, and outbound supply of Chinese human genetic resources, and detail the issues concerning relevant supervision, inspection and administrative penalties.

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According to the Bio-security Law of the PRC (《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, where information on Chinese human genetic resources is to be provided or opened for use to foreign organizations, individuals or institutions established or actually controlled thereby foreign organizations and individuals, a report shall be filed in advance to the administrative department of the MOST and the information backup shall be submitted. It also provides that approvals are required to conduct international scientific research cooperation using Chinese biological resources. Furthermore, failure to comply with the requirement under the Bio-security Law of the PRC will result in the penalties, including fines, suspension of related activities and confiscation of related human genetic resources and gains generated from conducting these activities.

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》), (“the Multi-Center Clinical Trial Guidelines”), promulgated by the NMPA on January 30, 2015 and effective from March 1, 2015, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicants plan to implement the international multi-center clinical trials in the PRC, the applicants shall comply with relevant laws and regulations, such as the PRC Drug Administration Law, the Implementing Regulations of the PRC Drug Administration Law and the Administrative Measures for Drug Registration, execute the Good Clinical Practice (the “GCP”), make reference to universal international principles such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), 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 Multi-Center Clinical Trial Guidelines and other related laws and regulations.

According to the Opinions on Deepening the Reform of the Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices, clinical trial data obtained in an 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.

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 trace-ability of overseas clinical trial data; (2) the process of generating overseas clinical trial data shall comply with the relevant requirements of the ICH-GCP; (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

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that the clinical trial design and statistical analysis of the data are scientific and reasonable, for the drugs with simultaneous R&D at home and abroad and forthcoming clinical trials in China, the applicants may, prior to implementing registrational clinical trials, contact the CDE to ensure the compliance of registrational 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.

Drug Application, Registration and Marketing Authorization

According to the Administrative Measures for Drug Registration, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes, and preparation for acceptance of verification and inspection for drug registration, the applicant may apply to the NMPA for approval of 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.

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. 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. Pursuant to the Administrative Measures for Drug Registration, drug marketing registration applications shall be subject to three categories, namely traditional Chinese drugs, chemical drugs and biological products. Among them, the registration applications of chemical drugs shall be categorized by innovative chemical drugs, improved new chemical drugs, generic chemical drugs, etc.

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.

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

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already approved any other IND of the same drug, may proceed along with 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.

PRC Medical Insurance Coverage and Reimbursement Regulations

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 enroll 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 enlarging 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.

Medical Insurance Catalog

Program participants are eligible for full or partial reimbursement of the cost of medicines included in the medical insurance catalog. 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 catalog 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 pharmacopeia of the PRC, (2) satisfy the standards promulgated by the NMPA, and (3) be approved by the NMPA for imported pharmaceutical products.

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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 Ministry of Human Resources and Social Security, 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.

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.

Intellectual Property Rights

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, and most recently amended on October 17, 2020, 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, last amended on January 9, 2010, and effective from February 1, 2010 and the Interim Measures on the Handling of Examination Operations in relation to the Implementation of the Amended Patent Law (《關於施行修改後專利法的相關審查業務處理暫行辦法》) issued by the China National Intellectual Property Administration on May 24, 2021, invention patents are valid for twenty years, utility model patents are valid for 10 years and design patents filed no later than May 31, 2021 are valid for 10 years while design patents filed on or after June 1, 2021 are valid for 15 years, from the date of application.

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 on 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

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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 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 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 canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In the 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 the PRC internet domain names. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

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Regulations on Environmental Protection and Fire Prevention

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 Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》) (the “Construction Environmental Protection Rule”), 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 environmental impact assessment of its construction projects and prepare environmental impact reports and environmental impact statements on construction projects. If a construction entity has the technical capability of environmental impact assessment, it may carry out the above activities itself.

Inspection and Acceptance of Environmental Protection Facilities

The Construction Environmental Protection Rule also requires that upon completion of construction for which an environmental impact report or environmental impact statement is formulated, the constructor shall conduct an acceptance inspection of the environmental protection facilities pursuant to the standards and procedures stipulated by the environmental protection administrative authorities of the State Council, formulate the acceptance inspection report, and announce the acceptance inspection report pursuant to the law except for circumstances where there is a need to keep confidentiality pursuant to the provisions of the State. Where the environmental protection facilities have not undergone acceptance inspection or do not pass acceptance inspection, the construction project shall not be put into production or use.

Environmental Impact Assessment

According to the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), promulgated by the SCNPC on October 28, 2002 and amended on July 2, 2016 and December 29, 2018 respectively, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

Fire Protection Design Approval and Filing

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 and latest amended on April 29, 2021. According to the Fire Prevention Law and other relevant laws and regulations of the PRC, the Emergency

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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 the People's Government are 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 (as the case may be). According to the Interim Provisions on the Administration of Fire Protection Design Review and Final Inspection of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》), issued by the Ministry of Housing and Urban-Rural Development on April 1, 2020 and effective on June 1, 2020, special construction projects as defined under such Interim Provisions shall conduct fire protection design review and fire protection final inspection, construction projects other than such special construction projects shall fill protection design and acceptance of the project with competent authority.

Regulations on Construction and Leased Properties in the PRC

Approval or Record-filing for Projects

Pursuant to the Regulations on the Administration of Enterprise Investment Projects by Verification and Approval and Record-filing (《企業投資項目核准和備案管理條例》) promulgated by the State Council on November 30, 2016 and effective on February 1, 2017, fixed asset investment projects related to national security, layout of major production capacity across the country, strategic resources development and major public interests, etc. shall be subject to administration by verification and approval. Projects other than those prescribed above shall be subject to administration by record-filing.

Commodity House Leasing Filing

The Administrative Measures for Commodity House Leasing (《商品房屋租賃管理辦法》) was deliberated and adopted by the Ministry of Housing and Urban-Rural Development on December 1, 2010 and came into effect on February 1, 2011, within a prescribed time limit, the parties of such lease agreement shall conduct the house leasing filing with the competent authority. Any entity that fails to conduct such house leasing filing will be ordered to correct within the time limit and if such order of correction is ignored, such entity will be fined between RMB1,000 and RMB10,000.

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

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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 the State Administration of Exchange Control 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 (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 and amended on December 30, 2019, 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.

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本金結匯管理方式的通知》) promulgated by the SAFE on March 30, 2015, effective from June 1, 2015 and as amended on December 30, 2019, and the Circular on the Reform and Standardization 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.

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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.

Labor and Social Security

According to the PRC Labor 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 Labor 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, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages cannot be lower than the local minimum wage. The employers must establish a system for labor safety and sanitation, strictly abide by State rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor 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.

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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 utilize 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 26, 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 must hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall make detailed explanations of sources of capital and utilization arrangements, and provide board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

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 organizations 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.

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Enterprise Income Tax

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》), or the EIT Law, promulgated by the NPC 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 EIT Law (《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 does 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 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 issued on December 31, 2019 by the STA, 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 STA, 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 STA 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.

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Data Security, Cyber Security and Data Privacy Protection

Pursuant to the PRC Civil Code (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and effective from January 1, 2021, the personal information of a natural person shall be protected by the law. An information processor shall not disclose or tamper with any personal information collected or stored thereby; and without the consent of the natural person, no personal information shall be illegally provided to any other person.

The Data Security Law of the PRC (《中華人民共和國數據安全法》), which was promulgated by the SCNPC on June 10, 2021 and took effect on September 1, 2021, provides that entities and individuals carrying out data activities shall establish a data classification and grading protection system and important data catalogs to enhance the protection of important data. Processors of important data shall specify the person responsible for data security and management agencies to implement data security protection responsibilities. Relevant authorities will establish the measures for the cross-border transfer of important data. If any company violates the Data Security Law of the PRC to provide important data outside China, such company may be punished by administration sanctions, including penalties, fines, and/or suspension of relevant business or revocation of the business license. In addition, the Data Security Law of the PRC provides a national security review procedure for those data activities which affect or may affect national security and imposes export restrictions on certain data and information.

The MCR was promulgated by the CAC and other twelve PRC regulatory authorities on December 28, 2021 and became effective on February 15, 2022. The Article 2 of the MCR provides that where a critical information infrastructure operator (the “**CIIO**”) purchases network products and services, and an online platform operator carries out data processing activities, which affect or may affect national security, cybersecurity review shall be conducted. Article 7 of the MCR further provides that the online platform operators holding personal information of more than one million users shall file for cybersecurity review with the Cybersecurity Review Office if it is seeking a listing abroad. As of the Latest Practicable Date, (i) we had not been determined or identified as a CIIO by any governmental authorities; and (ii) the Directors believe that we are not online platform operators who carry out data processing activities that affect or may affect national security or possess personal information of more than one million users. Our PRC Legal Adviser is of the view that as long as there is no material change to the Group’s current business, we have no obligation to proactively apply for cybersecurity review.

On November 14, 2021, the CAC promulgated the Draft Cyber Data Security Regulation, which proposes to provide more detailed guidelines on the current rules on various aspects of data processing, including the processors’ announcement of data processing rules, obtaining consents and separate consents, security of important data and cross-border transfer of data, and further obligations of platform operators. Pursuant to Article 2 and Article 73 of the Draft Cyber Data Security Regulation, the Draft Cyber Data Security Regulation applies to data processing activities by utilizing internet as well as cyber data security supervision and management activities within the PRC. “Cyber data” refers to any information that is

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electronically recorded, whereas “data processing activities” refer to activities such as data collection, storage, usage, processing, transmission, provision, disclosure and deletion. In general, any company engages in data processing activities through internet within the PRC will be subject to the Draft Cyber Data Security Regulation. In addition, Article 13 of the Draft Cyber Data Security Regulation stipulates that data processors shall apply for cybersecurity review when carrying out activities including (i) seeking to be listed in Hong Kong that affects or may affect national security; and (ii) seeking to be listed abroad that processing the personal information of more than one million user.

Regulations relating to Overseas Securities Offering and Listing

On 17 February 2023, the CSRC promulgated Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “Overseas Listing Trial Measures”) and relevant five guidelines, which will become effective on 31 March 2023. The Overseas Listing Trial Measures will comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities and will regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities by adopting a filing-based regulatory regime.

Pursuant to the Overseas Listing Trial Measures, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfil the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provides that an overseas offering and listing is explicitly prohibited, if any of the following: (i) such securities offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (ii) the intended overseas securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law; (iii) the domestic company intending to make the securities offering and listing, or its controlling shareholder(s) and the actual controller, have committed relevant crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (iv) the domestic company intending to make the securities offering and listing is currently under investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (v) there are material ownership disputes over equity held by the domestic company’s controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller.

The Overseas Listing Trial Measures also provides that if the issuer meets both the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as indirect overseas offering by PRC domestic companies: (i) 50% or more of any of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (ii) the main parts of the issuer’s business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are PRC

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citizens or have their usual place(s) of residence located in mainland China. The determination of the indirect overseas offering and listing of PRC domestic companies shall follow the principle of substance over form. Where an issuer submits an application for initial public offering to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted.

On the same day, the CSRC also held a press conference for the release of the Trial Measures and issued the Notice on Administration for the Filing of Overseas Offering and Listing by Domestic Companies, which, among others, clarifies that (1) on or prior to the effective date of the Overseas Listing Trial Measures, domestic companies that have already submitted valid applications for overseas securities offering and listing but have not obtained approval from overseas regulatory authorities or stock exchanges may reasonably arrange the timing for submitting their filing applications with the CSRC, and must complete the filing before the completion of their overseas securities offering and listing; (2) a six-month transition period will be granted to domestic companies which, prior to the effective date of the Overseas Listing Trial Measures, have already obtained and do not need to re-obtain the approval from overseas regulatory authorities or stock exchanges (such as the completion of hearing in the market of Hong Kong or the completion of registration in the market of the United States), but have not completed the indirect overseas listing; if domestic companies fail to complete the overseas listing within such six-month transition period, they shall file with the CSRC according to the requirements.

U.S. LAWS AND REGULATIONS

This section summarizes the principal laws and regulations in the U.S. that are relevant to our business.

U.S. Government Regulation of Drug and Biological Products

In the U.S., the FDA regulates drugs under the FDCA, its implementing regulations and biologics under the FDCA and the Public Health Service Act (the “PHSA”) and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

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Once a product candidate is identified for development, it enters pre-clinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Pre-clinical testing is conducted in accordance with FDA’s Good Laboratory Practice regulations. A sponsor of IND must submit the results of the pre-clinical testing, manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board (“IRB”), must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB’s requirements or if the product has been associated with unexpected serious harm to subjects.

Clinical trials generally are conducted in three sequential phases, known as Phase I, Phase II and Phase III, and may overlap.

- Phase I clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect, tolerability and safety of the product candidate.
- Phase II clinical trials involve studies on disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase III clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor’s initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

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Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions.

U.S. Review and Approval Processes

The results of product development, pre-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA or BLA. Unless deferred or waived, NDAs or BLAs, or supplements must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The submission of an NDA or a BLA is subject to the payment of a substantial user fee and an annual prescription drug product program fee.

Within 60 days of its receipt, the FDA reviews the NDA/BLA to ensure that it is sufficiently complete for substantive review before it accepts the NDA/BLA for filing. After accepting the NDA/BLA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product's manufacturing is GMP-compliant to assure the product's identity, strength, quality and purity. Before approving the NDA/BLA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA/BLA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and considers such recommendations when making decisions.

The FDA may refuse to approve the NDA/BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response letter describing all of the specific deficiencies that the FDA identified in the NDA/BLA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may either resubmit the NDA/BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

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The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase IV clinical trials, to further assess a product’s safety and effectiveness after NDA/BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In the U.S., products composed of components that would normally be regulated by different centers at the FDA are known as combination products. Typically, the FDA’s Office of Combination Products assigns a combination product to a specific Agency Center as the lead reviewer. The FDA determines which Center will lead a product’s review based upon the product’s primary mode of action. Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application. However, the FDA sometimes will require separate marketing applications for individual constituent parts of the combination product, which may require additional time, effort, and information. Even when a single marketing application is required for a combination product, the relevant Centers may participate in the review. An applicant will also need to discuss with the Agency how to apply certain premarket requirements and post-marketing regulatory requirements, including conduct of clinical trials, adverse event reporting and good manufacturing practices, to their combination product.

Expedited Development and Review Programs

Accelerated Approval

Under FDA’s accelerated approval regulations, the FDA may approve a drug or biologic candidate for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trial to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

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Breakthrough Designation

Another program available for sponsors is the breakthrough therapy designation. A drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of IND, and the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA shall act to expedite the development and review of the product’s marketing application, including by meeting with the sponsor throughout the product’s development, providing timely advice to the sponsor to ensure that the development program to gather pre-clinical and clinical data is as efficient as practicable.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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Founded in 2016, we are a science-driven, clinical-stage biotechnology company. Our Group was founded by Dr. Lu, our Chairman, executive Director and Chief Executive Officer, who has extensive entrepreneurial and managerial experience in the pharmaceutical industry across the PRC and the United States. For details of Dr. Lu’s biography, see “Directors and Senior Management”.

BUSINESS DEVELOPMENT MILESTONES

The following sets forth key business development milestones of our Group:

Year	Milestone
2016	In July, our Company was incorporated in the Cayman Islands
2017	In June, we acquired global licenses of LAE001 from Novartis
2018	In January, we completed onshore Series Seed financing in an aggregate amount of RMB40.368 million
	In May, we completed Series A financing in an aggregate amount of US\$12.5 million
	In May, we acquired global licenses of LAE002 and LAE003 from Novartis
2019	In January, we received IND approval for Phase I clinical trial of LAE001 for mCRPC sponsored by us from NMPA in China
	In May, we received IND approval for Phase I LAE002, prednisone and LAE001 combination MRCT study in patients with mCRPC from FDA in the United States
	In November, we received IND approval for registrational Phase II MRCT study of LAE002 plus paclitaxel versus paclitaxel in patients with PROC from FDA in the United States
2020	In February, we completed Series B financing in an aggregate amount of US\$27.5 million
	In February, we acquired global license of LAE005 from Novartis
	In August, we received IND approval for registrational Phase II MRCT study of LAE002 plus paclitaxel versus paclitaxel in patients with PROC from NMPA in China
	In December, we received IND approval for Phase I/II clinical trial of LAE002 combined with LAE005 and nab-paclitaxel for TNBC from NMPA in China

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Milestone
2021	<p>In February, we completed Phase I LAE002, prednisone and LAE001 combination study in patients with mCRPC in the United States</p> <p>In March, we completed Series C financing in an aggregate amount of US\$61 million</p> <p>In May, we declared the first internally discovered pre-clinical candidate, ActRIIA antibody for immunotherapy of cancers and advanced it to IND-enabling studies</p> <p>In June, we initiated the Phase II LAE002, prednisone and LAE001 combination study in patients with mCRPC in the United States</p> <p>In June, we received IND approval for Phase Ib/III study of LAE002 plus fulvestrant in patients with locally advanced or metastatic HR+/HER2- breast cancer from FDA in the United States</p> <p>In July, we entered into a collaboration agreement with Innovent to develop a combination therapy of LAE002 with sintilimab, targeting patients with solid tumors with prior PD-1/PD-L1 treatments</p> <p>In August, we received IND approval for Phase Ib/III study of LAE002 plus fulvestrant in patients with locally advanced or metastatic HR+/HER2- breast cancer from NMPA in China</p> <p>In September, we completed Phase I clinical trial of LAE001 for mCRPC in China, and entered Phase II stage</p>
2022	<p>In January, we received IND approval for Phase I/II combination therapy of LAE002 with sintilimab, targeting patients with solid tumors with prior PD-1/PD-L1 treatments from NMPA in China</p> <p>In March, we received IND approval for Phase II LAE002, prednisone and LAE001 combination study in patients with mCRPC in South Korea</p> <p>In April, we completed Series D financing in an aggregate amount of US\$61 million</p> <p>In September, we initiated the Phase II LAE002, prednisone and LAE001 combination study in patients with mCRPC in South Korea</p>

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR SUBSIDIARIES

The principal business activities and the dates of incorporation of our subsidiaries are shown below:

Name of subsidiary	Place of incorporation/ establishment	Date of incorporation/ establishment	Principal business activities
Laekna Limited	Hong Kong	August 26, 2016	Research and development of drug candidates
Laekna Therapeutics Shanghai Co., Ltd. (來凱醫藥科技(上海)有限公司)	PRC	December 28, 2016	Research and development of drug candidates
Laekna Pharmaceutical Shanghai Co., Ltd. (來凱製藥(上海)有限公司)	PRC	December 8, 2020	Pharmaceutical
Laekna LLC	Delaware, the United States	January 3, 2020	Research and development of drug candidates

MAJOR ACQUISITIONS, DISPOSALS AND MERGERS

We have not conducted any acquisitions, disposals or mergers since our inception that we consider to be material to us.

ESTABLISHMENT, MAJOR SHAREHOLDING CHANGES AND DEVELOPMENT OF OUR GROUP

1. Incorporation of our Company

On July 29, 2016, 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, one subscriber share was allotted and issued at par value to our initial subscriber, Offshore Incorporations (Cayman) Limited, which was subsequently transferred at par value to Dr. Lu. On the same day, 49,999 ordinary shares were allotted and issued at nominal value to Dr. Lu.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

2. Incorporation of Laekna HK

On August 26, 2016, Laekna HK was incorporated in Hong Kong as a limited liability company wholly-owned by our Company. On the date of incorporation of Laekna HK, an aggregate of 1,000 ordinary shares of Laekna HK were allotted and issued to our Company.

3. Establishment of Laekna Therapeutics

On December 28, 2016, Laekna Therapeutics, our principal operating entity in the PRC, was established as a limited liability company with an initial registered capital of RMB25 million, 80% (i.e. RMB20 million) and 20% (i.e. RMB5 million) of which was contributed by Laekna HK and Mr. Lin, respectively.

4. Series Seed financing in Laekna Therapeutics in 2018

Pursuant to an investment agreement dated December 13, 2017 entered into between our Company, Tibet Longmaide Venture Capital Fund (Limited Partnership) (西藏龍脈得股權投資中心(有限合夥)) (“**Tibet Longmaide**”), Laekna Therapeutics, Mr. Lin, Laekna HK and Dr. Lu, Tibet Longmaide and Mr. Lin agreed to subscribe for RMB4.5455 million and RMB909,100 registered capital of Laekna Therapeutics at a consideration of RMB33.64 million and RMB6.728 million, respectively. Such capital injection was completed on January 4, 2018. Upon completion of the capital injection, the equity interest of Laekna Therapeutics was owned as to 71.7954%, 13.2791% and 14.9255% by Laekna HK, Mr. Lin and Tibet Longmaide, respectively.

5. Consolidation of shareholding in Laekna Therapeutics and subscription of Series Seed Preferred Shares

On January 31, 2019 and July 19, 2019, Laekna HK entered into equity transfer agreements with Mr. Lin and Tibet Longmaide, respectively, pursuant to which Laekna HK agreed to purchase all the equity interests of Laekna Therapeutics held by Mr. Lin and Tibet Longmaide at a consideration of RMB11.728 million and RMB33.64 million, which was determined based on the initial investment amount made by them, respectively. Upon completion of the equity transfers, Laekna Therapeutics became a wholly-owned subsidiary of Laekna HK.

On January 31, 2019, Mr. Lin agreed to subscribe for a warrant of the Company which entitled him to purchase 1,166,525 ordinary shares and 338,273 Series Seed Preferred Shares at a total consideration of RMB11.728 million, which was determined based on the initial investment amount made by Mr. Lin in Laekna Therapeutics and was equivalent to the consideration Mr. Lin received from Laekna HK pursuant to the abovementioned equity transfer. The consideration of the warrant was fully settled on December 8, 2020. Such warrants have been fully exercised by Mr. Lin on March 31, 2022 and our Company has issued 1,166,525 ordinary shares and 338,273 Series Seed Preferred Shares to Rococean Technology Holdings Limited, a company owned as to 94.74% by Mr. Lin, on March 31, 2022.

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Pursuant to an investment agreement dated June 18, 2019 entered into between our Company, Laekna HK and Shanghai Haoyao Information Technology Partnership (Limited Partnership) (上海灝藥信息科技合夥企業(有限合夥)) (“**Shanghai Haoyao**”), Shanghai Haoyao agreed to subscribe for 1,691,367 Series Seed Preferred Shares at a total consideration of RMB33.64 million (or its equivalent in US\$), which was determined based on the initial investment amount made by Tibet Longmaide in Laekna Therapeutics and was equivalent to the consideration Tibet Longmaide received from Laekna HK in the abovementioned equity transfer pursuant to the equity transfer agreement dated July 19, 2019. The consideration was fully settled on November 7, 2019 and 1,691,367 Series Seed Preferred Shares were issued to Shanghai Haoyao in full on November 8, 2019.

Shanghai Haoyao is the entity designated by Tibet Longmaide to subscribe for the shares in our Company. At all material times and as of the Latest Practicable Date, Tibet Longmaide held a majority of the economic interest as a limited partner of Shanghai Haoyao.

6. Incorporation of Laekna LLC

On January 3, 2020, Laekna LLC was incorporated in Delaware, the United States and is wholly-owned by our Company.

7. Establishment of Laekna Pharmaceutical

On December 8, 2020, Laekna Pharmaceutical was established as a limited liability company with an initial registered capital of RMB1 million contributed by Laekna Therapeutics.

8. Share transfer of our Company in 2021

On September 1, 2021, Dr. Lu transferred 39,613 ordinary shares to HongRun Limited, a company beneficially owned in equal share by Qingsheng Zhu and James Lijing He, each a private investor and an Independent Third Party, at a total consideration of US\$500,000 which was fully settled on September 28, 2021. The consideration was determined based on arm’s length negotiations taking into account the operating activities of the Company and its prospects in the research and development of drug candidates at the time of investment.

9. Issue of Shares to ESOP Trusts

Our Company adopted the [REDACTED] Share Option Scheme on April 11, 2018 (which was subsequently amended on October 30, 2019, April 20, 2021 and March 31, 2022). On [●], [2,150,153] and [1,011,724] ordinary shares were issued to Laekna Wonderland Limited and Laekna Halley Limited, respectively, both of which were owned and managed by Futu Trustee Limited, the trustee of Laekna Wonderland Trust and Laekna Halley Trust. Laekna Wonderland

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Trust and Laekna Halley Trust are trusts set up by the Company to facilitate the administration of the [REDACTED] Share Option Scheme. Pursuant to the trust deed dated [●], Futu Trustee Limited (the trustee of the ESOP Trusts) will exercise their voting rights in accordance with the instructions of Ms. Xie.

Between January 2018 and April 2022, we conducted five rounds of [REDACTED] Investments. See the paragraph sub-section “– [REDACTED] Investments” in this section below for shareholding changes resulting from the [REDACTED] Investments.

[REDACTED] INVESTMENTS

1. Series Seed financing in Laekna Therapeutics

For details of the Series Seed financing in Laekna Therapeutics, please refer to the sub-section headed “Establishment, Major Shareholding Changes and Development of our Group – 4. Series Seed financing in Laekna Therapeutics in 2018” in this section. For details of the Series Seed Preferred Shares subsequently issued, please refer to the sub-section headed “Establishment, Major Shareholding Changes and Development of our Group – 5. Consolidation of shareholding in Laekna Therapeutics and subscription of Series Seed Preferred Shares” in this section.

2. Series A financing in 2018

Pursuant to a series A preferred share purchase agreement dated April 3, 2018 entered into among our Company, Laekna HK, Laekna Therapeutics, Dr. Lu and OrbiMed Asia Partners III, L.P., OrbiMed Asia Partners III, L.P. agreed to subscribe for an aggregate of 3,986,840 Series A Preferred Shares at a total consideration of US\$12.5 million, which was settled in full on May 17, 2018. The amounts of consideration were determined based on arm’s length negotiations taking into account the operative activities of the Company and its prospects in the research and development of drug candidates at the time of investment.

3. Series B financing in 2020

Pursuant to a series B preferred share purchase agreement dated April 2, 2019 entered into among our Company, Laekna HK, Laekna Therapeutics, Dr. Lu, OrbiMed Asia Partners III, L.P. and GP Healthcare Capital, Inc., GP Healthcare Capital, Inc. (or its designated affiliate) and OrbiMed Asia Partners III, L.P. agreed to subscribe for an aggregate of 3,303,988 and 1,238,996 Series B Preferred Shares at a total consideration of US\$20 million and US\$7.5 million, respectively, which was settled in full on February 21, 2020. The amounts of consideration were determined based on arm’s length negotiations taking into account our business prospects and the research and development of our drug candidates at the time of investment.

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4. Series C financing in 2021

On October 13, 2020, our Company entered into a series C preferred share purchase agreement with certain investors. An aggregate of 6,858,071 Series C Preferred Shares were subscribed by the Series C Preferred Shareholders at a total consideration of US\$61 million, which was settled in full on March 30, 2021. The amounts of consideration were determined based on arm’s length negotiations taking into account our business prospects and the research and development of our drug candidates at the time of investment. See “– 6. Capitalization of our Company” in this section below for details of subscription by the Series C Preferred Shareholders.

5. Series D financing in 2022

On September 16, 2021, our Company entered into a series D preferred share purchase agreement with certain investors. An aggregate of 3,866,186 Series D Preferred Shares were subscribed by the Series D Preferred Shareholders at a total consideration of US\$61 million, which was settled in full on April 28, 2022. The amounts of consideration were determined based on arm’s length negotiations taking into account our business prospects and the research and development of our drug candidates at the time of investment. See “– 6. Capitalization of our Company” in this section below for details of subscription by the Series D Preferred Shareholders.

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6. Capitalization of our Company

The below table summarizes the capitalization of our Company as at the Latest Practicable Date (assuming [3,411,877] ordinary shares have been issued to the ESOP Trusts) and immediately upon completion of the [REDACTED], assuming the [REDACTED] is not exercised.

Shareholders	Ordinary shares	Series Seed	Series A	Series B	Series C	Series D	As of the Latest Practicable Date ⁽¹⁾		Aggregate number of shares	Aggregate ownership percentage (%)	Aggregate number of Shares	Aggregate ownership percentage (%)	Immediately upon completion of the [REDACTED] ⁽²⁾
							Aggregate number of shares	Aggregate ownership percentage (%)					
Dr. Lu ⁽³⁾	4,960,387	-	-	-	-	-	-	4,960,387	[15.20]	[REDACTED]	[REDACTED]	[REDACTED]	
OrbiMed Asia Partners III, L.P.	-	-	3,986,840	1,238,996	562,137	-	-	5,787,973	[17.73]	[REDACTED]	[REDACTED]	[REDACTED]	
ESOP Trusts ⁽⁴⁾	[3,411,877]	-	-	-	-	-	-	[3,411,877]	[10.45]	[REDACTED]	[REDACTED]	[REDACTED]	
GP Healthcare Capital, Inc.	-	-	-	3,303,988	-	-	-	3,303,988	[10.12]	[REDACTED]	[REDACTED]	[REDACTED]	
Future Industry Investment Fund II	-	-	-	-	-	1,901,403	-	1,901,403	[5.83]	[REDACTED]	[REDACTED]	[REDACTED]	
Shanghai Haoyao Information Technology Partnership	-	-	-	-	-	-	-	-	-	-	-	-	
(Limited Partnership)	-	1,691,367	-	-	-	-	-	1,691,367	[5.18]	[REDACTED]	[REDACTED]	[REDACTED]	
Rocoean Technology Holdings Limited ⁽⁵⁾	1,250,000	338,273	-	-	-	-	-	1,588,273	[4.87]	[REDACTED]	[REDACTED]	[REDACTED]	
HTYL Investment Holdings Limited	-	-	-	-	1,124,274	-	-	1,124,274	[3.44]	[REDACTED]	[REDACTED]	[REDACTED]	
Novartis Pharma AG	941,637	-	-	-	-	-	-	941,637	[2.89]	[REDACTED]	[REDACTED]	[REDACTED]	
CMBI Private Equity Series B SPC	-	-	-	-	-	-	-	-	-	-	-	-	
on behalf of and for the account of	-	-	-	-	-	-	-	-	-	-	-	-	
Health Innovation Fund I SP	-	-	-	-	786,992	-	-	786,992	[2.41]	[REDACTED]	[REDACTED]	[REDACTED]	
Shenzhen Capital Group Company, Ltd.	-	-	-	-	786,991	-	-	786,991	[2.41]	[REDACTED]	[REDACTED]	[REDACTED]	

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Shareholders	Ordinary shares	Series Seed	As of the Latest Practicable Date ⁽¹⁾				Aggregate number of shares	Aggregate ownership percentage (%)	Aggregate number of Shares	Aggregate ownership percentage (%)	Immediately upon completion of the [REDACTED] ⁽²⁾
			Series A	Series B	Series C	Series D					
CDIB Yida Healthcare Private Equity (Kunshan) Enterprise (Limited Partnership)	-	-	-	786,992	-	786,992	[2.41]	[REDACTED]	[REDACTED]	[REDACTED]	
Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership)	-	-	-	786,992	-	786,992	[2.41]	[REDACTED]	[REDACTED]	[REDACTED]	
Limbell Technology Holdings Limited ⁽⁶⁾	750,000	-	-	-	-	750,000	[2.30]	[REDACTED]	[REDACTED]	[REDACTED]	
Worldstar Global Holdings Limited	-	-	-	-	633,801	633,801	[1.94]	[REDACTED]	[REDACTED]	[REDACTED]	
Beijing Longmaide Venture Capital Fund (Limited Partnership)	-	-	-	562,137	-	562,137	[1.72]	[REDACTED]	[REDACTED]	[REDACTED]	
Ningbo Yanchuang Borong Venture Capital Partnership (Limited Partnership)	-	-	-	-	348,591	348,591	[1.07]	[REDACTED]	[REDACTED]	[REDACTED]	
Sushang United PE Investment Fund (Limited Partnership)	-	-	-	337,282	-	337,282	[1.03]	[REDACTED]	[REDACTED]	[REDACTED]	
Jiangsu Yanyuan Oriental Venture Capital Investment Partnership (LP)	-	-	-	320,418	-	320,418	[0.98]	[REDACTED]	[REDACTED]	[REDACTED]	
Ningbo Yanchuang Yaoshang Yangming Venture Capital Investment Partnership (LP)	-	-	-	320,418	-	320,418	[0.98]	[REDACTED]	[REDACTED]	[REDACTED]	

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shareholders	As of the Latest Practicable Date ⁽¹⁾							Aggregate number of shares	Aggregate ownership percentage (%)	Immediately upon completion of the [REDACTED] ⁽²⁾
	Ordinary shares	Series Seed	Series A	Series B	Series C	Series D	Aggregate number of shares			
Chengdu Infinity Kechuang Jingrong Venture Capital Partnership (Limited Partnership)	-	-	-	-	-	278,873	278,873	[REDACTED]	[REDACTED]	[REDACTED]
Shenzhen Leaguer Infinity Innovation Investment Fund (Limited Partnership)	-	-	-	-	-	253,520	253,520	[REDACTED]	[REDACTED]	[REDACTED]
Ningbo Yanyuan Innovation Venture Capital Investment Partnership (LP)	-	-	-	-	241,719	-	241,719	[REDACTED]	[REDACTED]	[REDACTED]
Ningbo Rongshun Yanyuan Venture Capital Investment Partnership (LP)	-	-	-	-	241,719	-	241,719	[REDACTED]	[REDACTED]	[REDACTED]
Ningbo Yanchuang Xiangshang Venture Capital Partnership (Limited Partnership)	-	-	-	-	-	190,140	190,140	[REDACTED]	[REDACTED]	[REDACTED]
Yanchuang Biotech Investment L.P.	-	-	-	-	-	158,450	158,450	[REDACTED]	[REDACTED]	[REDACTED]
Infinity-HB Ventures Fund LP	-	-	-	-	-	101,408	101,408	[REDACTED]	[REDACTED]	[REDACTED]
HongRun Limited	39,613	-	-	-	-	-	39,613	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED] taking part in the [REDACTED]	-	-	-	-	-	-	-	[REDACTED]	[REDACTED]	[REDACTED]
Total	[11,353,514]	2,029,640	3,986,840	4,542,984	6,858,071	3,866,186	[32,637,235]	100.00	[REDACTED]	100.00

HISTORY, DEVELOPMENT 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].
2. Calculated after taking into account the [REDACTED] and the Shares to be issued pursuant to the [REDACTED].
3. Includes Shares held by Dr. Lu beneficially and Shares held by the Family Trust, which is in turn wholly-owned by The Bryn Mawr Trust Company of Delaware as trustee of the Family Trust, which Dr. Lu is the settlor.
4. Includes Shares held by Laekna Wonderland Trust and Laekna Halley Trust. Pursuant to the trust deed dated [●], Futu Trustee Limited (the trustee of the ESOP Trusts) will exercise their voting rights attached to the Shares held by the ESOP Trusts in accordance with the instructions of Ms. Xie, our executive Director.
5. Rococean Technology Holdings Limited is a limited liability company incorporated in the BVI and is owned as to 94.74% by Mr. Lin. Mr. Lin is a supervisor of both Laekna Pharmaceutical and Laekna Therapeutics. As a supervisor, Mr. Lin is responsible for overseeing and supervising the business of Laekna Pharmaceutical and Laekna Therapeutics and the performance of the directors and members of senior management and performing other supervisory duties. Mr. Lin is not involved in the daily operation of Laekna Pharmaceutical and Laekna Therapeutics.

The rest of the shareholding interests of Rococean Technology Holdings Limited is held by Mr. Lin Dianhai (林殿海), father of Mr. Lin and a former Director. Mr. Lin Dianhai was appointed as a Director in May 2018 and resigned as a Director with effect in May 2022 due to personal reasons. He had no executive role within the Group and was not involved in the daily operation of the Group. Mr. Lin Dianhai is experienced in equity investments and has invested in different biopharmaceutical and healthcare companies. His investment portfolio includes, among others, Changchun High-Tech Industries (Group) Inc. (長春高新技術產業(集團)股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 000661), Guangzhou Sianxin Biotechnology Co., Ltd. (廣州思安信生物技術有限公司) and Suzhou Chunhai Biopharmaceutical Co., Ltd. (蘇州春海生物醫藥有限公司). As a Director, Mr. Lin Dianhai was involved in the Company's strategic planning and oversight, and responsible for evaluating and monitoring the performance of the management team of the Company. Mr. Lin Dianhai also provided valuable contributions and strategic and general advices to the business management and development of the Company. The Company granted Mr. Lin Dianhai 83,475 Share Options under the [REDACTED] Share Option Scheme in March 2021. Such Share Options were exercised in full in April 2022 whereby 83,475 shares (or [REDACTED]) as adjusted after the [REDACTED]) were issued and allotted to his shareholding vehicle, Rococean Technology Holdings Limited. Mr. Lin Dianhai has confirmed that he had no disagreement with the Group and no claim or right of action against the Group arising out or in connection with loss of office as a Director or any remuneration or reimbursement. To the best of the Directors' knowledge and belief, there is (i) no incident that may have negative implications on Mr. Lin Dianhai's suitability to act as a Director; and (ii) no other matter relating to his resignation as a Director that needs to be brought to the attention of the Stock Exchange.
6. Linbell Technology Holdings Limited is a limited liability company incorporated in the BVI and is wholly-owned by Ms. Xie, our executive Director.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

7. Principal terms of the [REDACTED] Investments

The below table summarizes the principal terms of the [REDACTED] Investments:

	Series Seed	Series A	Series B	Series C	Series D
Date of the agreement	December 13, 2017	April 3, 2018	April 2, 2019	October 13, 2020	September 16, 2021
Date on which the investment was fully settled	January 4, 2018	May 17, 2018	February 21, 2020	March 30, 2021	April 28, 2022
Funds raised by our Group	RMB40.368 million	US\$12.5 million	US\$27.5 million	US\$61 million	US\$61 million
Cost per Preferred Share paid or converted	RMB1.99	US\$0.31	US\$0.61	US\$0.89	US\$1.58
Post-money valuation of the Company (approximation) (US\$)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED] ⁽⁴⁾⁽⁵⁾
Basis of determination of the consideration	The consideration of each round of [REDACTED] Investments was determined based on arm’s length negotiation between the respective [REDACTED] Investors and our Group after taking into account the timing of the [REDACTED] Investments and the status of our business operations and clinical trials.				
(Discount)/premium to the [REDACTED] (approximation) ⁽¹⁾	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Lock-up	Lock-up undertakings [have been given] by the [REDACTED] Investors in favor of the Sole Sponsor, the [REDACTED] and the Company, pursuant to which the Shares held by each of the [REDACTED] Investors will be subject to lock-up for a period of six months commencing from the [REDACTED]. See “[REDACTED] – [REDACTED] arrangements – [REDACTED] – Undertakings pursuant to the [REDACTED] – Undertakings by existing Shareholders.”				
Use of [REDACTED] and whether they have been fully utilized	We utilized the [REDACTED] to finance our research and development activities and fund our daily operations. As of the Latest Practicable Date, approximately [REDACTED] of the net [REDACTED] from the [REDACTED] Investments had been utilized by our Group.				
Strategic benefits of the [REDACTED] Investments brought to our Group	Our Group would benefit from the additional capital injected by the [REDACTED] Investors in our Group, their business resources, knowledge and experience, potential business opportunities and benefits that may be provided by them, and their investments demonstrate their commitment and confidence in the business performance and operations, strengths and long-term prospects of our Group.				

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Notes:

1. 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].
2. The valuation of our Company increased to US\$[REDACTED] in Series B financing primarily due to our research and development progress in the drug candidates, as we acquired global licenses of LAE002 and LAE003 from Novartis in May 2018 and we received IND approval for Phase I/II clinical trial of LAE001 for mCRPC from NMPA in China in January 2019.
3. The valuation of our Company increased to US\$[REDACTED] in Series C financing primarily due to the research and development progress we achieved in our drug candidates. In particular, we received IND approval for Phase I LAE002, prednisone and LAE001 combination MRCT study in patients with mCRPC, and registrational Phase II MRCT study of LAE002 plus paclitaxel versus paclitaxel in patients with PROC from FDA in the United States in May 2019 and November 2019, respectively. We also acquired global license of LAE005 from Novartis in February 2020, and received IND approval for registrational Phase II MRCT study of LAE002 plus paclitaxel versus paclitaxel in patients with PROC from NMPA in China in August 2020.
4. The valuation of our Company increased to US\$[REDACTED] in Series D financing primarily due to the research and development progress we achieved in our drug candidates. In particular, we received IND approval for Phase I/II clinical trial of LAE002 combined with LAE005 and nab-paclitaxel for TNBC from NMPA in China in December 2020; we completed Phase I LAE002, prednisone and LAE001 combination study in patients with mCRPC in the United States and entered Phase II stage in February 2021; we declared the first internally discovered pre-clinical candidate, ActRIIA antibody for immunotherapy of cancers and advanced it to IND-enabling studies in May 2021; and we received IND approval for Phase Ib/III study of LAE002 plus fulvestrant in patients with locally advanced or metastatic HR+/HER2- breast cancer from FDA in the United States in June 2021. Further, we entered into a collaboration agreement with Innovent to develop a combination therapy of LAE002 with sintilimab in July 2021, and we received IND approval for Phase Ib/III study of LAE002 plus fulvestrant in patients with locally advanced or metastatic HR+/HER2- breast cancer from NMPA in China in August 2021.
5. The proposed valuation of our Company at completion of the [REDACTED] further increased from US\$[REDACTED] in Series D financing primarily due to the research and development progress we achieved in our drug candidates and the business milestones we achieved after Series D financing. In particular, we completed Phase I clinical trial of LAE001 for mCRPC in China, and entered Phase II stage in September 2021; we received IND approval for Phase I/II combination therapy of LAE002 with sintilimab, targeting patients with solid tumors with prior PD-1/PD-L1 treatments from NMPA in China in January 2022, and had dosed the first subject in patients in June 2022; we received IND approval for Phase II LAE002, prednisone and LAE001 combination study in patients with mCRPC in South Korea in March 2022, and initiated this study in September 2022; and we had dosed the first subject in the Phase Ib/III study of LAE002 plus fulvestrant in patients with locally advanced or metastatic HR+/HER2- breast cancer in both China and the United States in May 2022.

8. Special rights of the [REDACTED] Investors

Pursuant to the Series D Shareholders Agreement, and the then memorandum and articles of association of our Company, the [REDACTED] Investors have, among other rights, (i) information rights; (ii) pre-emptive rights; (iii) right of first refusal and right of co-sale; and (iv) redemption rights.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

All special rights granted to the [REDACTED] Investors will be terminated on the consummation of the [REDACTED], except for the redemption right, which has been suspended immediately prior to the first submission of the [REDACTED] application form to the Stock Exchange for the purpose of the [REDACTED], and will only be exercisable upon the earliest of (i) the withdrawal of the [REDACTED] application by the Company, (ii) the rejection of the [REDACTED] application by the Stock Exchange, or (iii) the Company failing to complete the [REDACTED] within nine months after the first submission of the [REDACTED] application by the Company to the Stock Exchange.

9. Information about the [REDACTED] Investors

Our [REDACTED] Investors include certain Sophisticated Investors who made meaningful investments in the Company, including OrbiMed Asia Partners III, L.P., GP Healthcare Capital, Inc. and Shenzhen Capital Group Company, Ltd.. Set out below is a description of our [REDACTED] Investors.

OrbiMed Asia Partners III, L.P.

OrbiMed Asia Partners III, L.P. is a Sophisticated Investor. OrbiMed Asia Partners III, L.P. is an exempted limited partnership registered under the laws of the Cayman Islands. The general partner of OrbiMed Asia Partners III, L.P. is OrbiMed Asia GP III, L.P., with OrbiMed Advisors III Limited acting as its general partner. The shareholders of OrbiMed Advisors III Limited are comprised of Alexander M. Cooper, Carl L. Gordon, Geoffrey C. Hsu, William Carter Neild, Sunny Sharma, David Guowei Wang (one of our non-executive Directors), Sam Block III, Sven H. Borho, Anna Bitton, Douglas W. Coon, C. Scotland Stevens, and David P. Bonita. OrbiMed Asia Partners III, L.P. invests in the healthcare sector with investments ranging from early stage private companies to large multinational corporations globally.

OrbiMed Asia Partners III, L.P. has 101 limited partners. None of the limited partners has voting power or management control over the Company’s business by virtue of their partnership interests in OrbiMed Asia Partners III, L.P.. None of the limited partners holds more than 20% of the partnership interest of OrbiMed Asia Partners III, L.P. The largest two limited partners are non-PRC sophisticated investors, and hold 15.4% and 10.9% of the partnership, respectively. None of the other limited partners holds more than 10% of the partnership interest of OrbiMed Asia Partners III, L.P.. It manages approximately US\$551 million of limited partnership capital commitments.

GP Healthcare Capital, Inc. and Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership)

GP Healthcare Capital, Inc. is a Sophisticated Investor. It is an exempted company incorporated in the Cayman Islands in April 2017 and dedicated in investment in medical and healthcare sector. Its sole shareholder is Shanghai GP Healthcare Equity Investment Enterprise (Limited Partnership) (上海金浦醫療健康股權投資合夥企業(有限合夥)), whose general partner is GP Healthcare Capital Co., Ltd. (上海金浦醫療健康股權投資基

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

金管理有限公司), a limited liability company established in the PRC with no ultimate controller. The portfolio companies of GP Healthcare Capital, Inc. include Eureka Therapeutics, Inc., NuProbe Global, iRepertoire, Inc. and Genomicare Holdings (Cayman) Co. Ltd.

Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership) (上海金浦健康三期股權投資基金合夥企業(有限合夥)) is a limited liability partnership established in the PRC in October 2020 and its general partner is GP Healthcare Capital Co., Ltd.. Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership) has 15 limited partners, among whom each of Shandong New Growth Drivers Investment Management Co., Ltd. (山東省新動能投資管理有限公司) (an investment holding platform wholly-owned by Ministry of Finance of Shandong Province (山東省財政廳)) and Zhongtai Venture Capital (Shanghai) Co., Ltd. (中泰創業投資(上海)有限公司) (an investment holding platform wholly-owned by Zhongtai Securities Company Limited (中泰證券股份有限公司), a company listed on the Shanghai Stock Exchange (Stock code: 600918)) holds 15.9745% of the partnership interest and none of the other limited partners holds more than 10% of the partnership interest of Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership). Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership) has over RMB626 million of assets under management, and its portfolio companies include different biotechnology and pharmaceutical companies, such as Shanghai Orange Medical Technology Co., Ltd. (上海極橙醫療科技有限公司), Zhejiang Hengyu Biological Technology Co., Ltd. (浙江恒馭生物科技有限公司), Shanghai Handu Pharmaceutical Technology Co., Ltd. (上海漢都醫藥科技有限公司), Zhejiang R&L Medical Devices Co., Ltd. (浙江歸領醫療器械有限公司), Hangzhou Cellgene Biotech Co., Ltd. (杭州賽基生物科技有限公司), and TransThera Sciences (Nanjing), Inc. (藥捷安康(南京)科技股份有限公司).

Future Industry Investment Fund II

Future Industry Investment Fund II (先進製造產業投資基金二期(有限合夥)) (“**FIIF**”) is a limited partnership incorporated in the PRC. The general partner of FIIF is CS Capital Co., Ltd. (國投招商投資管理有限公司) (“**CS CAPITAL**”). FIIF has 34 limited partners, among whom the Ministry of Finance of the PRC (中華人民共和國財政部) and State Development & Investment Corporation (國家開發投資集團有限公司) (a company wholly-owned by the State-owned Assets Supervision and Administration Commission of the State Council (國務院國有資產監督管理委員會)) holds 26.04% and 10.41% of the partnership interest respectively, and none of the other limited partners holds more than 10% of the partnership interest of FIIF. FIIF has over RMB48.01 billion of assets under management. CS CAPITAL is an independent private equity fund manager. CS CAPITAL and its affiliates manage over RMB100 billion of capital from diversified investors, including financial institutions, insurance companies, private enterprises, state-owned enterprises. CS CAPITAL focuses on four investment sectors: life science, intelligent NEV, smart manufacturing as well as information & communication technology. To the best of our Directors’ knowledge, information and belief, each of FIIF, its general partner and limited partners is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shanghai Haoyao Information Technology Partnership (Limited Partnership) and Beijing Longmaide Venture Capital Fund (Limited Partnership)

Each of Shanghai Haoyao Information Technology Partnership (Limited Partnership) (上海灝藥信息科技合夥企業(有限合夥)) and Beijing Longmaide Venture Capital Fund (Limited Partnership) (北京龍脈得創業投資基金(有限合夥)) is a limited liability partnership established in the PRC in June 2019 and February 2018, respectively, and the general partner of which is Beijing Anlong Venture Capital Fund (Limited Partnership) (北京安龍創業投資基金(有限合夥)), which is in turn ultimately controlled by Ms. Liu Ying (劉穎), an Independent Third Party. Beijing Anlong Venture Capital Fund (Limited Partnership) focused on the investment in emerging enterprises in the medical and biopharma industries, including I-Mab Biopharma (a company listed on NASDAQ Global Market, stock code: IMAB) and Connect Biopharma Holdings Limited (a company listed on NASDAQ Global Market, stock code: CNTB).

Shanghai Haoyao Information Technology Partnership (Limited Partnership) has two partners, including (i) Beijing Anlong Venture Capital Fund (Limited Partnership), which is also the general partner and holds 0.03% of the partnership interest, and (ii) Tibet Longmaide Equity Investment Center (Limited Partnership) (西藏龍脈得股權投資中心(有限合夥)) (an investment holding platform controlled by Mr. Huang Tao (黃濤), an Independent Third Party), which holds 99.97% of the partnership interest. Shanghai Haoyao Information Technology Partnership (Limited Partnership) has over US\$5 million of assets under management.

Beijing Longmaide Venture Capital Fund (Limited Partnership) has 8 limited partners, among whom Ningbo Meishan Free Trade Port Zone Tengyun Yuancheng Equity Investment Partnership (Limited Partnership) (寧波梅山保稅港區騰雲源晟股權投資合夥企業(有限合夥)) (an investment holding platform controlled by Mr. Huang Tao (黃濤), an Independent Third Party) and Lhasa Dongyi Investment Co., Ltd. (拉薩東儀投資有限公司) (an investment holding platform controlled by Chinese Academy of Sciences (中國科學院)) holds 25.93% and 23.57% of the partnership interest, respectively, and none of the other limited partners holds more than 20% of the partnership interest of Beijing Longmaide Venture Capital Fund (Limited Partnership). Beijing Longmaide Venture Capital Fund (Limited Partnership) has over RMB424.243 million of assets under management.

To the best of our Directors' knowledge, information and belief, each of Shanghai Haoyao Information Technology Partnership (Limited Partnership), Beijing Longmaide Venture Capital Fund (Limited Partnership), its general partner and limited partners is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Mr. Lin Anpeng (林安鵬)

Mr. Lin is an individual [REDACTED] Investor. Mr. Lin is experienced in equity investments and has invested in different biopharmaceutical and healthcare companies, including but not limited to, Aishike (Suzhou) Biology Engineering Co., Ltd. (艾視科(蘇州)生物工程有限公司), Shanghai Chuangzhi Pharmaceutical Technology Co., Ltd. (上海創執醫藥科技有限公司) and Beijing Maidekang Health Technology Co., Ltd. (北京邁德康健康科技有限公司). He is a supervisor of both Laekna Pharmaceutical and Laekna Therapeutics.

Novartis Pharma AG

Novartis Pharma AG is a company organized under the laws of Switzerland and is part of the Novartis Group. Novartis AG is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide. The shares of Novartis AG are traded on the Swiss Stock Exchange (Stock code: NOVN) and on the New York Stock Exchange (Stock code: NVS).

CMBI Private Equity Series B SPC on behalf of and for the account of Health Innovation Fund I SP

CMBI Private Equity Series B SPC on behalf of and for the account of Health Innovation Fund I SP (the “Fund”) is segregated portfolio under CMBI Private Equity Series B SPC that invests in private equity portfolios. CMBI Private Equity Series B SPC is an exempted company with limited liability and registered as a segregated portfolio company in the Cayman Islands. Its management share is 100% held by CMB International Private Investment Limited, a Cayman Islands limited company, which is in turn wholly-owned by CMB International Investment Management Limited, a limited company established in the BVI. CMB International Investment Management Limited is wholly-owned by CMB International Capital Corporation Limited, and the latter is an indirect wholly-owned subsidiary of China Merchants Bank Co., Limited, a company listed on the Stock Exchange (Stock code: 3968).

The investment objective of the Fund is primarily to achieve long-term capital appreciation, principally through equity, equity-related and debt investment (including convertible securities and warrants) in [REDACTED] companies with a focus on healthcare industry.

Each of CMBI Private Equity Series B SPC and its ultimate beneficial owner is an Independent Third Party.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shenzhen Capital Group Company, Ltd. and HTYL Investment Holdings Limited

HTYL Investment Holdings Limited (“HTYL”) is a company incorporated under the laws of the BVI and is ultimately controlled by Shenzhen Capital Group Company, Ltd. (深圳市創新投資集團有限公司), which was established in 1999 by the Shenzhen Municipal Government and is ultimately controlled by the State-owned Assets Supervision and Administration Commission of the Shenzhen Municipal Government (深圳市人民政府國有資產監督管理委員會). Each of HTYL and its ultimate beneficial owner is an Independent Third Party and is an investment fund whose primary purpose is to make equity investments, with a focus on innovative growth-oriented enterprises.

Shenzhen Capital Group Company, Ltd. is a Sophisticated Investor, with a focus on venture capital investment to nurture entrepreneurship and innovation and is an Independent Third Party. As of January 30, 2022, it had invested in 1,420 projects with an aggregate investment amount of approximately RMB81.9 billion. HTYL Investment Holdings Limited focuses on investing in biomedical and healthcare companies, including Shanghai Zhimeng Pharmaceutical Technology Co., Ltd. (上海摯盟醫藥科技有限公司), Jingfang Pharmaceutical Technology (Shanghai) Co., Ltd. (勁方醫藥科技(上海)有限公司) and Qiyu Biotechnology (Shanghai) Co., Ltd. (啟愈生物技術(上海)有限公司). Each of Shenzhen Capital Group Company, Ltd. and its ultimate beneficial owner is an Independent Third Party.

Chengdu Infinity Kechuang Jingrong Venture Capital Partnership (Limited Partnership) and Infinity-HB Ventures Fund LP

Chengdu Infinity Kechuang Jingrong Venture Capital Partnership (Limited Partnership) (成都英飛科創菁蓉創業投資合夥企業(有限合夥)) is a limited liability partnership established in the PRC in February 2020, and its general partner is Chengdu Konggang Yingfei Jingrong Venture Investment Management Co., Ltd. (成都空港英飛菁蓉創業投資管理有限公司). To the best of our Directors’ knowledge, information and belief, each of Chengdu Infinity Kechuang Jingrong Venture Capital Partnership (Limited Partnership), its general partner and limited partners is an Independent Third Party.

Chengdu Infinity Kechuang Jingrong Venture Capital Partnership (Limited Partnership) has 3 limited partners, among whom Zhuhai Infinity Chuangye Investment Fund (Limited Partnership) (珠海英飛尼迪創業投資基金(有限合夥)) (an investment holding platform ultimately controlled by Zhuhai People’s Government State-owned Assets Supervision and Administration Commission Committee (珠海市人民政府國有資產監督管理委員會)) holds 46.67% of the partnership interest, and none of the other limited partners holds more than one-third of the partnership interest of Chengdu Infinity Kechuang Jingrong Venture Capital Partnership (Limited Partnership). It has RMB150 million of assets under management.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Infinity-HB Ventures Fund LP is a limited partnership established in the Cayman Islands. It has invested in Pillar Biosciences, Inc, a next-generation-sequencing tumor diagnosis enterprise based in the United States. Its largest limited partner is Huafa Group, a leading state-owned enterprise based in Zhuhai, China, and its other limited partners include iClick Interactive Asia Group Ltd (a company listed on NASDAQ Global Market, stock code: ICLK) and other individual investors. The general partner of Infinity-HB Ventures Fund LP is Infinity-HB Investment Management Company Limited, a limited liability company incorporated in the Cayman Islands. To the best of our Directors’ knowledge, information and belief, each of Infinity-HB Ventures Fund LP, its general partner and limited partners is an Independent Third Party.

Infinity-HB Ventures Fund LP has 11 limited partners, among whom Hong Kong Huafa Investment Holdings Limited (香港華發投資控股有限公司) (an investment holding platform ultimately controlled by Zhuhai People’s Government State-owned Assets Supervision and Administration Committee (珠海市人民政府國有資產監督管理委員會) through Zhuhai Huafa Group Co., Ltd. (珠海華發集團有限公司)) and Tetris Media Limited (an investment holding platform ultimately wholly-owned by iClick Interactive Asia Group Ltd (a company listed on NASDAQ Global Market, stock code: ICLK)) holds 62.42% and 18.73% of the partnership interest respectively. None of the other limited partners holds more than 10% of the partnership interest of Infinity-HB Ventures Fund LP. It has over US\$16 million of assets under management.

Each of Chengdu Konggang Yingfei Jingrong Venture Investment Management Co., Ltd. and Infinity-HB Investment Management Company Limited is ultimately controlled by Infinity Equity Management Company Limited (“**Infinity Equity**”), a limited liability company incorporated in Hong Kong. Infinity Equity is one of the top Chinese enterprises specializing in investment management and the equity investment platform of Huafa Group, a leading state-owned enterprise based in Zhuhai, China. It is an internationally renowned investment management institution with state-owned enterprises and Israeli characteristic resources. Infinity Equity currently has a total AUM of more than RMB8 billion. Their portfolio covers sectors of TMT (science and technology, media, communications), healthcare and life sciences, energy conservation and environmental protection, advanced manufacturing and new materials and other areas.

Shenzhen Leaguer Infinity Innovation Investment Fund (Limited Partnership)

Shenzhen Leaguer Infinity Innovation Investment Fund (Limited Partnership) (深圳力合英飛創新創業投資合夥企業(有限合夥)), specializes in making investments in the early and growth companies in tech sector, is a limited liability partnership established in the PRC in December 2017 and its general partner is Shenzhen Leaguer Infinity Venture Investment Co., Ltd. (深圳力合英飛創業投資有限公司), which is ultimately controlled by Research Institute of Tsinghua University in Shenzhen (深圳清華大學研究院).

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shenzhen Leaguer Infinity Innovation Investment Fund (Limited Partnership) has 6 limited partners, among whom Zhuhai Infinity Chuangye Investment Fund (Limited Partnership) (珠海英飛尼迪創業投資基金(有限合夥)) (an investment holding platform indirectly controlled by Zhuhai People’s Government State-owned Assets Supervision and Administration Commission Committee (珠海市人民政府國有資產監督管理委員會)) holds 34% of the partnership interest, and none of the other limited partners holds more than one-third of the partnership interest of Shenzhen Leaguer Infinity Innovation Investment Fund (Limited Partnership). It has over RMB490.48 million of assets under management.

Jiangsu Yanyuan Oriental Venture Capital Investment Partnership (LP)

Jiangsu Yanyuan Oriental Venture Capital Investment Partnership (LP) (江蘇燕園東方創業投資合夥企業(有限合夥)) is a limited liability partnership incorporated in the PRC in December 2017 and its general partner is Hangzhou Yanyuan Fangrong Investment Management Co., Ltd. (杭州燕園方融投資管理有限公司) which is controlled as to 45% ultimately by Zhejiang Eastern Finance Holding Group Co., Ltd. (浙江東方金融控股集團股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 600120) and 55% by Mrs. Liu Zeng (劉增) (“**Mrs. Liu**”). Mrs. Liu is the beneficial owner of Hangzhou Yanyuan Fangrong Investment Management Co., Ltd..

Mrs. Liu is a sophisticated investor and has extensive investment experience in the healthcare industry. She is the director of Jiangsu Yahong Meditech Co., Ltd. (江蘇亞虹醫藥科技股份有限公司) (a company listed on the Shanghai Stock Exchange (stock code: 688176)). Mrs. Liu is an Independent Third Party (other than her interests in the Company as disclosed in this section).

Jiangsu Yanyuan Oriental Venture Capital Investment Partnership (LP) has no beneficial owner, and the fund has 6 limited partners and 1 general partner, among whom Zhejiang Eastern Finance Holding Group Co., Ltd (an investment holding platform which Zhejiang Provincial International Trade Group Co., Ltd (浙江省國際貿易集團有限公司) holds 48.52% of its equity interests) and Ningbo Yanchuang Yaoshang Venture Capital Investment Partnership (LP) (寧波燕創姚商創業投資合夥企業(有限合夥)) holds 49.98% and 24.99% respectively of the partnership interest, and none of the other limited partners holds more than 10% of the partnership interest of Jiangsu Yanyuan Oriental Venture Capital Investment Partnership (LP). The fund has over RMB200 million of assets under management.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Yanyuan Group

Yanyuan Group consists of Ningbo Yanyuan Innovation Venture Capital Investment Partnership (LP) (寧波燕園創新創業投資合夥企業(有限合夥)), Ningbo Yanchuang Yaoshang Yangming Venture Capital Investment Partnership (LP) (寧波燕創姚商陽明創業投資合夥企業(有限合夥)), Ningbo Rongshun Yanyuan Venture Capital Investment Partnership (LP) (寧波榮舜燕園創業投資合夥企業(有限合夥)), Ningbo Yanchuang Xiangshang Venture Capital Partnership (Limited Partnership) (寧波燕創象商創業投資合夥企業(有限合夥)), Ningbo Yanchuang Borong Venture Capital Partnership (Limited Partnership) (寧波燕創勃榮創業投資合夥企業(有限合夥)) and Yanchuang Biotech Investment L.P. (collectively referred to as the “**Yanyuan Group**”).

Ningbo Yanyuan Innovation Venture Capital Investment Partnership (LP) (寧波燕園創新創業投資合夥企業(有限合夥)) is a limited partnership incorporated in the PRC and its beneficial owner is Mrs. Liu. The general partner of the partnership is Ningbo Yaoshang Yanchuang Private Equity Fund Management Co., Ltd. (寧波姚商燕創私募基金管理有限公司) (“**Yaoshang Yanchuang**”), the beneficial owner of which is Mrs. Liu. Ningbo Yanyuan Innovation Venture Capital Investment Partnership (LP) has 9 limited partners and 1 general partner, among whom Mr. Tao Jinxiang (陶金祥) and Mr. Rong Weijun (戎偉軍) (each of whom is an Independent Third Party) holds 28.57% and 28.57% of the partnership interest, and none of the other limited partners holds more than 10% of the partnership interest of Ningbo Yanyuan Innovation Venture Capital Investment Partnership (LP). The fund has around RMB140 million of assets under management.

Ningbo Yanchuang Yaoshang Yangming Venture Capital Investment Partnership (LP) (寧波燕創姚商陽明創業投資合夥企業(有限合夥)) is a limited partnership incorporated in the PRC and the fund has no beneficial owner. Its general partner is Yaoshang Yanchuang, the beneficial owner of which is Mrs. Liu. Ningbo Yanchuang Yaoshang Yangming Venture Capital Investment Partnership (LP) has 9 limited partners and 1 general partner, among whom Ningbo Yanchuang Chenqian Venture Capital Investment Partnership (LP) (寧波燕創晨乾創業投資合夥企業(有限合夥)) (an investment holding platform collectively held by 22 limited partners and 1 general partner, none of them holds more than 10% partnership interest), Ningbo Zhihui Shouke Equity Investment Partnership (LP) (寧波智慧首科股權投資合夥企業(有限合夥)) (an investment holding platform in which Mr. Gao Yankang (高炎康) holds 20.67% partnership interest and the other partnership interests are collectively held by 20 limited partners and 1 general partner), Yuyao Industrial Investment Development Co., Ltd. (餘姚市工業(中小企業)投資發展有限公司) and Ningbo Venture Capital Investment Guiding Fund Management Co., Ltd. (寧波市創業投資引導基金管理有限公司) holds 34.62%, 20.31%, 15.38% and 14.62% of the partnership interest respectively, and none of the other limited partners holds more than 10% of the partnership interest of Ningbo Yanchuang Yaoshang Yangming Venture Capital Investment Partnership (LP). The fund has around RMB650 million of assets under management.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Ningbo Rongshun Yanyuan Venture Capital Investment Partnership (LP) (寧波榮舜燕園創業投資合夥企業(有限合夥)) is a limited partnership incorporated in the PRC and its beneficial owner is Mrs. Liu. The general partner of the partnership is Yaoshang Yanchuang, the beneficial owner of which is Mrs. Liu. Ningbo Rongshun Yanyuan Venture Capital Investment Partnership (LP) has 17 limited partners and 1 general partner, among whom Mr. Fang Yesheng (方葉盛) (an Independent Third Party) holds 12.72% of the partnership interest, and none of the other limited partners holds more than 10% of the partnership interest of Ningbo Rongshun Yanyuan Venture Capital Investment Partnership (LP). The fund has around RMB159 million of assets under management.

Ningbo Yanchuang Xiangshang Venture Capital Investment Partnership (LP) (寧波燕創象商創業投資合夥企業(有限合夥)) is a limited partnership incorporated in the PRC, and the fund has no beneficial owner. The general partner of Ningbo Yanchuang Xiangshang Venture Capital Investment Partnership (LP) is Ningbo Yanchuang Deheng Private Equity Fund Management Co., Ltd. (寧波燕創德恒私募基金管理有限公司), the beneficial owner of which is Mrs. Liu. Ningbo Yanchuang Xiangshang Venture Capital Investment Partnership (LP) has 20 limited partners and 1 general partner, among whom Xiangshan Industrial Investment Group Co., Ltd. (象山縣工業投資集團有限公司) (an investment holding platform wholly-owned by Xiangshan State-owned Asset Management Center (象山縣國有資產管理中心)) holds 19.35% of the partnership interest respectively, and none of the other limited partners holds more than 10% of the partnership interest of Ningbo Yanchuang Xiangshang Venture Capital Investment Partnership (LP). The fund has RMB310 million of assets under management.

Ningbo Yanchuang Borong Venture Capital Investment Partnership (LP) (寧波燕創勃榮創業投資合夥企業(有限合夥)) is a limited partnership incorporated in the PRC, whose beneficial owner is Mrs. Liu. Its general partners are Yaoshang Yanchuang and Ningbo Yanyuan Yaoshang Equity Investment Management Co., Ltd (寧波燕園姚商股權投資管理有限公司). Both of the general partners are controlled by Mrs. Liu. Ningbo Yanchuang Borong Venture Capital Investment Partnership (LP) has 9 limited partners and 2 general partners, among whom Mr. Wang Hua Jun (王華軍), Mr. Ye Zheyu (葉哲宇) and Mr. Zhou Yin (周寅) (each of whom is an Independent Third Party) holds 29.61%, 22.21% and 14.80% of the partnership interest, and none of the other limited partners holds more than 10% of the partnership interest of Ningbo Yanchuang Borong Venture Capital Investment Partnership (LP). The fund has around RMB135 million of assets under management.

Yanchuang Biotech Investment L.P. is a limited partnership incorporated in the Cayman Islands. Its general partner is Yanchuang Future Cayman Corp., a company incorporated in the Cayman Islands, the beneficial owner of which is Mrs. Liu.

Apart from Yanchuang Future Cayman Corp., Yanchuang Biotech Investment L.P. has 3 limited partners, among whom Yanchuang Technology Cayman Ltd. (an investment holding platform indirectly wholly-owned by Ms. Wu Rong (吳蓉), an Independent Third Party) and SHNZ Investment Limited holds 81.29% and 14.57% of the partnership interest respectively, and the other limited partner holds less than 10% of the partnership interest of Yanchuang Biotech Investment L.P.. The fund has around US\$33.13 million of assets under management.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

HongRun Limited

HongRun Limited is a limited company incorporated in the BVI with limited liabilities and is owned as to 50% and 50% by Qingsheng Zhu and James Lijing He, each a private investor and an Independent Third Party, respectively.

CDIB Yida Healthcare Private Equity (Kunshan) Enterprise (Limited Partnership)

CDIB Yida Healthcare Private Equity (Kunshan) Enterprise (Limited Partnership) (昆山華創毅達生醫股權投資企業(有限合夥)) is a limited liability partnership established in the PRC in June 2019 and its general partner is Huachuang Yida (Kunshan) Equity Investment Management Co., Ltd. (華創毅達(昆山)股權投資管理有限公司), which is ultimately controlled by CDIB Private Equity (Hong Kong) Corporation Limited, a limited liability company incorporated in Hong Kong. CDIB Yida Healthcare Private Equity (Kunshan) Enterprise (Limited Partnership) is a professional healthcare fund focusing on investment in private-stage companies in areas such as biotechnology, medical devices and *in vitro* diagnostics.

CDIB Yida Healthcare Private Equity (Kunshan) Enterprise (Limited Partnership) has 14 limited partners, among whom (i) CDIB Venture Capital (Hong Kong) Corporation Limited (an investment holding platform ultimate-owned by China Development Financial Holding Corporation (中華開發金控)) holds 29.35% of the partnership interest, (ii) Jiangsu Hi-tech Investment Group Co., Ltd. (江蘇高科技投資集團有限公司) (an investment holding platform wholly-owned by Jiangsu Province People’s Government (江蘇省人民政府)) holds 19.65% of the partnership interest, (iii) Kunshan High-tech Group Co., Ltd. (昆山高新集團有限公司) (an investment holding platform wholly-owned by Kunshan Government State-owned Assets Supervision and Administration Office (昆山市政府國有資產監督管理辦公室)) holds 10% of the partnership interest, and (iv) Kunshan Industrial Development Guidance Fund Partnership (Limited Partnership) (昆山市產業發展引導基金合夥企業(有限合夥)) (an investment holding platform controlled by Kunshan Venture Holding Group Co., Ltd. (昆山創業控股集團有限公司)) holds 10% of the partnership interest, and none of the other limited partners holds more than 10% of the partnership interest of CDIB Yida Healthcare Private Equity (Kunshan) Enterprise (Limited Partnership). It has over RMB422 million of assets under management.

To the best of our Directors’ knowledge, information and belief, each of CDIB Yida Healthcare Private Equity (Kunshan) Enterprise (Limited Partnership), its general partner and limited partners is an Independent Third Party.

Sushang United PE Investment Fund (Limited Partnership)

Sushang United PE Investment Fund (Limited Partnership) (蘇州蘇商聯合產業投資合夥企業(有限合夥)) is a limited liability partnership established in the PRC in July 2017 and its executive partner is Shanghai Qianyue Investment Management Co., Ltd. (上海謙越投資管理有限公司), a limited liability company established in the PRC.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Sushang United PE Investment Fund (Limited Partnership) has 9 limited partners, among whom (i) Ningbo Meishan Free Trade Port Zone Jincheng Shazhou Equity Investment Co., Ltd. (寧波梅山保稅港區錦程沙洲股權投資有限公司) (an investment holding platform controlled by Mr. Shen Wenrong (沈文榮), an Independent Third Party) holds 22.71% of the partnership interest, (ii) Jiangsu Xinyangzi Shipbuilding Co., Ltd. (江蘇新揚子造船有限公司) (a member of Yangzijiang Shipbuilding (Holdings) Limited, a company listed on Singapore Stock Exchange (Stock code: BS6) and Taiwan Stock Exchange (Stock code: 911609)) holds 20.52% of the partnership interest, and (iii) Jiangsu Yonggang Group Co., Ltd. (江蘇永鋼集團有限公司) (an investment holding platform ultimately controlled by Ms. Wu Huifang (吳惠芳), an Independent Third Party) holds 16.26% of the partnership interest, and none of the other limited partners holds more than 10% of the partnership interest of Sushang United PE Investment Fund (Limited Partnership). It has over RMB110 million of assets under management.

Sushang United PE Investment Fund (Limited Partnership) aims to integrate the resources in Jiangsu Province to promote economic restructuring and industrial upgrading in China and Jiangsu Province. It focuses on exploring high quality investment targets in up-and-coming industries, such as new materials, electronic components, intelligent hardware, mobile Internet, big data, artificial intelligence, financial technology and high-end manufacturing. It has an investment scale of approximately RMB996 million and its portfolio includes Suzhou Terui Pharmaceutical Co., Ltd. (蘇州特瑞藥業股份有限公司).

Worldstar Global Holdings Limited

Worldstar Global Holdings Limited (“**Worldstar**”) is a company incorporated in the BVI on December 9, 2005, which focuses on equity investment opportunities in emerging industries, such as medicine and food technology. The total issued share capital of Worldstar is held by Mr. Lui Yiu Wah Alexander, an Independent Third Party. Worldstar has invested in Akeso, Inc., a company listed on the Main Board of the Stock Exchange (stock code: 9926).

10. Public Float

The Shares held by OrbiMed Asia Partners III, L.P., GP Healthcare Capital, Inc. and Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership) will not be considered as part of the public float for the purpose of Rule 8.08 of the Listing Rules as (i) OrbiMed Asia Partners III, L.P. will be a substantial shareholder of our Company; and (ii) the shares held by GP Healthcare Capital, Inc. and Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership) are deemed to be held by GP Healthcare Capital Co., Ltd. (上海金浦醫療健康股權投資基金管理有限公司), a substantial shareholder of our Company. Therefore, each of them is a core connected person of our Company upon the [REDACTED]. To our Director’s best knowledge, save as disclosed above, Shares held by each of the other [REDACTED] Investors will be counted towards the public float for the purpose of Rule 8.08 of the Listing Rules after the [REDACTED].

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Dr. Lu, our executive Director, Chairman and Chief Executive Officer, is entitled to exercise the voting rights attached to the Shares held by himself. He is also the settlor of the Family Trust. Further, Ms. Xie, our executive Director, is entitled to exercise the voting rights attached to the Shares held by (i) the ESOP Trusts, and (ii) Linbell Technology Holdings Limited, a limited liability company wholly-owned by herself. As such, Shares held or controlled by Dr. Lu (including those held under the Family Trust) (representing approximately [REDACTED]% of our issued share capital), and the ESOP Trusts and Linbell Technology Holdings Limited (in aggregate representing approximately [REDACTED]% of our issued share capital), will not be counted towards public float after the [REDACTED] (without taking into account Shares which may be issued under the [REDACTED]).

Save as disclosed above, to the best of our Directors’ knowledge, all other Shareholders are not core connected persons of our Company. As a result, these Shareholders will aggregately hold approximately [REDACTED]% of our issued share capital (upon completion of the [REDACTED] without taking into account the Shares which may be issued under the [REDACTED]), which will be counted towards the public float. As a result, over 25% of our issued share capital with a market capitalization of at least HK\$375 million 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.

11. Compliance with Guidance Letters

On the basis that (i) the consideration for the [REDACTED] Investments was settled more than 28 clear days before the date of our first submission of the [REDACTED] application in relation to the [REDACTED] to the Stock Exchange; and (ii) all special rights granted to the [REDACTED] Investors will be terminated on the consummation of the [REDACTED], except for the redemption right which has been suspended immediately prior to the first submission of the [REDACTED] application form to the Stock Exchange for the purpose of the [REDACTED] and will only be exercisable upon the earliest of (i) the withdrawal of the [REDACTED] application by the Company, (ii) the rejection of the [REDACTED] application by the Stock Exchange, or (iii) the Company failing to complete the [REDACTED] within nine months after the first submission of the [REDACTED] application by the Company to the Stock Exchange, the Sole Sponsor confirms 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.

PRC REGULATORY REQUIREMENTS

Our PRC Legal Adviser has confirmed that (i) the PRC companies in our Group as described in this section have been duly established, (ii) all necessary regulatory approvals and registrations in respect of the incorporation and capital changes of the PRC companies have been obtained in accordance with PRC laws in all material respects, and (iii) all share transfers and changes in the registered capital of the PRC subsidiaries have complied with all applicable PRC laws in all material respects.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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 mean (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. 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.

As advised by our PRC Legal Adviser, Laekna Therapeutics is already a foreign-invested enterprise since its establishment, and Laekna Pharmaceutical was incorporated by Laekna Therapeutics. As such, the M&A Rules are not applicable and we did not seek prior CSRC approval for this [REDACTED].

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 14, 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.

Our PRC Legal Adviser confirmed that Ms. Xie and two other individuals (i.e. Mr. Lin and Mr. Lin Dianhai (林殿海), shareholders of Rococean Technology Holdings Limited) who are PRC citizens and indirectly hold Shares in the Company have duly completed the registrations in respect of his/her shareholding in our Group in accordance with SAFE Circular 37.

[REDACTED] SHARE OPTION SCHEME

Our Company adopted the [REDACTED] Share Option Scheme on April 11, 2018 (which was subsequently amended on October 30, 2019, April 20, 2021 and March 31, 2022). The purpose of the [REDACTED] Share Option Scheme is to provide incentives to directors and employees of the Group or any other third party that the Board considers as contributed or will contribute to the Company. The principal terms of the [REDACTED] Share Option Scheme are set out in the section headed “Statutory and General Information – D. [REDACTED] Share Option Scheme” in Appendix IV. The Company will comply with the applicable Listing Rules for Shares to be granted to the grantees who are connected persons of the Company after [REDACTED].

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

[REDACTED] SHARE OPTION SCHEME

Our Company [has conditionally adopted] a [REDACTED] Share Option Scheme by Shareholders’ resolutions dated [●]. 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 section headed “Appendix IV – Statutory and General Information – E. [REDACTED] Share Option Scheme”. 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.

As of the Latest Practicable Date, no option had been granted or agreed to be granted under the [REDACTED] Share Option Scheme.

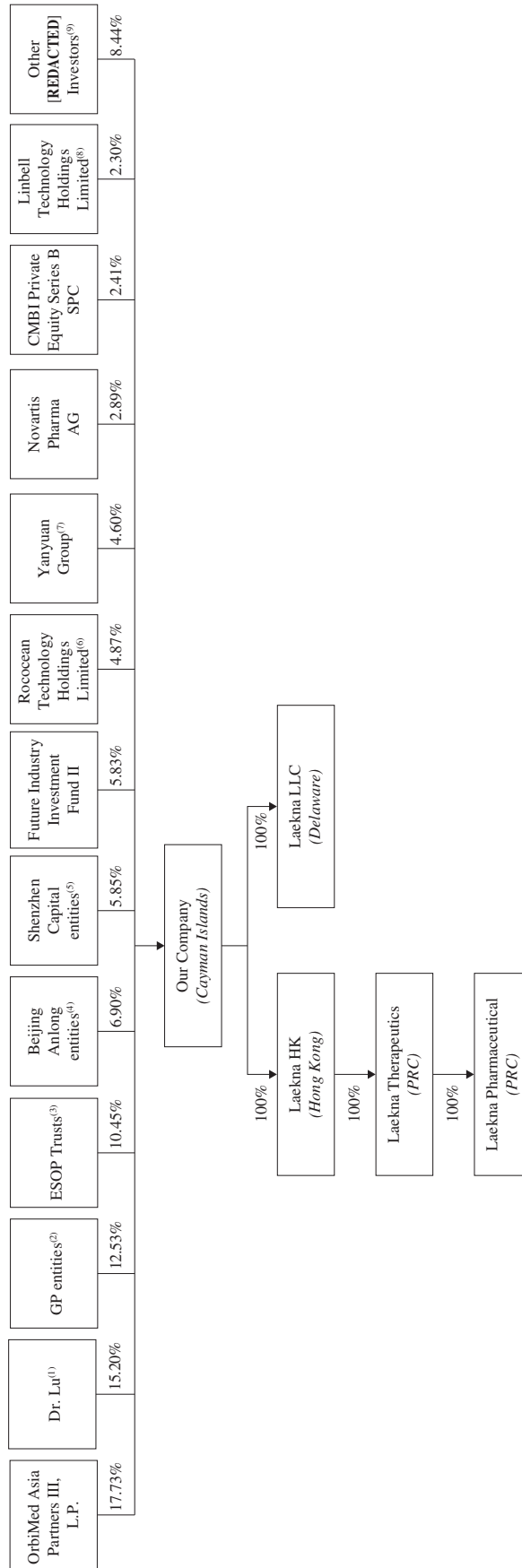
[REDACTED] AND CONVERSION

On [●], our Shareholders resolved to, among other things, conduct the [REDACTED] pursuant to which each share in our then issued and unissued share capital was split into [ten] shares of the corresponding class with a 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) [REDACTED] designated as Shares; (ii) [REDACTED] designated as Series Seed Preferred Shares; (iii) [REDACTED] designated as Series A Preferred Shares; (iv) [REDACTED] designated as Series B Preferred Shares; (v) [REDACTED] designated as Series C Preferred Shares; and (vi) [REDACTED] designated as Series D Preferred Shares. Our Shareholders also resolved to, immediately upon completion of the [REDACTED], conduct the Conversion, pursuant to which each Preferred Share shall be converted into ordinary Share on a one-to-one basis.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR STRUCTURE IMMEDIATELY PRIOR TO THE [REDACTED]

The following chart sets forth our corporate and shareholding structure immediately prior to completion of the [REDACTED] and the [REDACTED].



HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

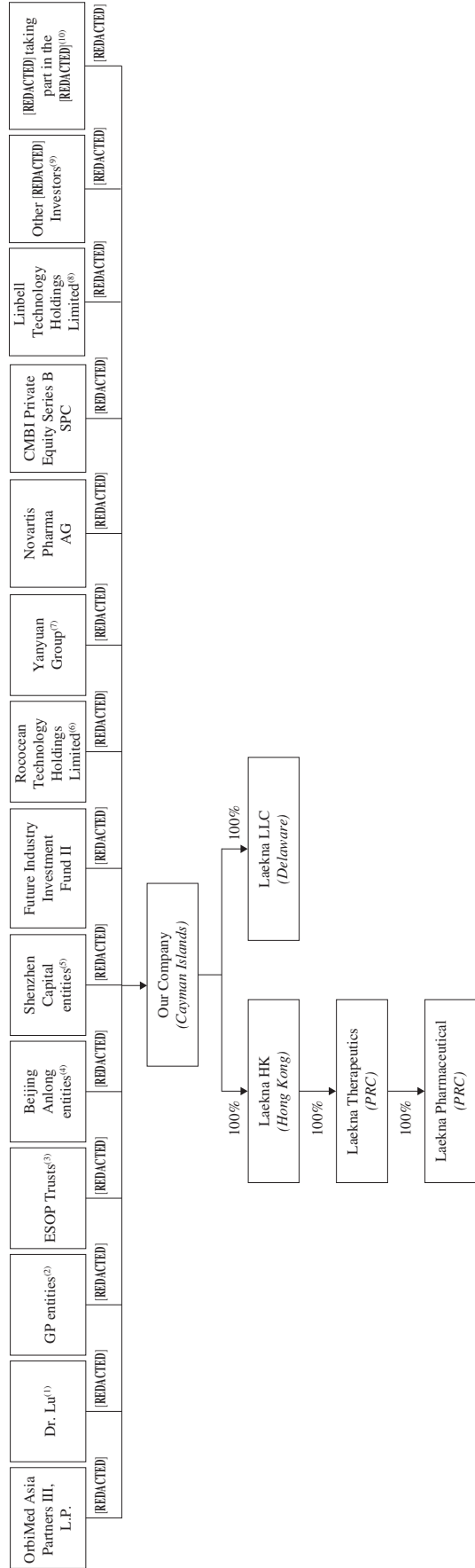
Notes:

1. Includes Shares held by Dr. Lu beneficially and Shares held by the Family Trust, which is in turn wholly-owned by The Bryn Mawr Trust Company of Delaware as trustee of the Family Trust, which Dr. Lu is the settlor.
2. GP entities include GP Healthcare Capital, Inc. and Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership). The sole shareholder of GP Healthcare Capital, Inc. is Shanghai GP Healthcare Equity Investment Enterprise (Limited Partnership) (上海金浦醫療健康股權投資企業(有限合伙)). The general partner of both Shanghai GP Healthcare Equity Investment Enterprise (Limited Partnership) and Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership) is GP Healthcare Capital Co., Ltd. (上海金浦醫療健康股權投資基金管理有限公司).
3. Includes Shares held by Laekna Wonderland Trust and Laekna Halley Trust. Pursuant to the trust deed dated [●], Futu Trustee Limited (the trustee of the ESOP Trusts) will exercise their voting rights attached to the Shares held by the ESOP Trusts in accordance with the instructions of Ms. Xie, our executive Director.
4. Beijing Anlong entities include Shanghai Haoyao Information Technology Partnership (Limited Partnership) and Beijing Longmaide Venture Capital Fund (Limited Partnership), the general partner of which is Beijing Anlong Venture Capital Fund (Limited Partnership) (北京安龍創業投資基金(有限合伙)), which is in turn ultimately controlled by Ms. Liu Ying (劉穎).
5. Shenzhen Capital entities include Shenzhen Capital Group Company, Ltd. (深圳市創新投資集團有限公司) and HTYL Investment Holdings Limited, which is ultimately controlled by Shenzhen Capital Group Company, Ltd. as well.
6. Rococean Technology Holdings Limited is a limited liability company incorporated in the BVI and is owned as to 94.74% by Mr. Lin. Mr. Lin is a supervisor of both Laekna Pharmaceutical and Laekna Therapeutics. The rest of the shareholding interests of Rococean Technology Holdings Limited is held by Mr. Lin Dianhai (林殿海), father of Mr. Lin and a former Director.
7. Yanyuan Group includes Ningbo Yanyuan Innovation Venture Capital Investment Partnership (LP), Ningbo Yanchuang Yaoshang Yangming Venture Capital Investment Partnership (LP), Ningbo Rongshun Yanyuan Venture Capital Investment Partnership (LP), Ningbo Yanchuang Xiangshang Venture Capital Partnership (Limited Partnership), Ningbo Yanchuang Borong Venture Capital Partnership (Limited Partnership) and Yanchuang Biotech Investment L.P., which are ultimately controlled by Mrs. Liu Zeng (劉增).
8. Linbell Technology Holdings Limited is a limited liability company incorporated in the BVI and is wholly-owned by Ms. Xie, our executive Director.
9. This includes all our other [REDACTED] Investors, who are Independent Third Parties. For 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 above.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR STRUCTURE IMMEDIATELY FOLLOWING THE [REDACTED]

The following chart sets forth our corporate and shareholding structure immediately following completion of the [REDACTED], Conversion and [REDACTED], assuming the [REDACTED] are not exercised.



Notes (1) to (9): Please refer to the notes contained under the sub-section headed “– Our Structure Immediately Prior to the [REDACTED]” in this section.

Note (10): The above chart does not take into account of subscription of Shares by our existing Shareholders or their close associates.

BUSINESS

OVERVIEW

Founded in 2016, we are a science-driven, clinical-stage biotechnology company. We have established a comprehensive R&D infrastructure to accelerate the development of molecules from discovery to registrational trials. We have initiated one clinical trial and another five clinical trials for our Core Products LAE002 and LAE001. Among these six clinical trials, three multi-regional clinical trials (MRCTs) are designed to address medical needs in the standard of care (SOC)-resistant cancers.

Our Market Opportunities

Although the field of cancer treatment has developed significantly in the past decade, a large proportion of cancer patients find themselves in the absence of effective or safe treatments. The quality of life of those patients is severely affected primarily attributable to SOC resistance and/or intolerable toxicity, resulting in a large unmet medical need and socioeconomic burden. Among those cancers of unmet medical needs, platinum-resistant ovarian cancer (PROC), metastatic castration-resistant prostate cancer (mCRPC), HR+/HER2-metastatic breast cancer (HR+/HER2- mBC) and triple negative breast cancer (TNBC) are some of the diseases with limited SOC options and undesirable treatment outcomes.

- PROC. According to Frost & Sullivan, the global and China incidence of ovarian cancer is expected to increase from 319.8 thousand and 56.2 thousand in 2021 to 374.2 thousand and 62.7 thousand in 2030, respectively. The SOC mainly consists of debulking surgery and platinum-based chemotherapy. Although platinum-based chemotherapy is normally effective at inducing an initial response, more than 80% of patients with epithelial ovarian cancer who achieve a full remission following first-line therapy will develop recurrent disease. PROC is broadly defined as ovarian cancer recurrence within six months of completing platinum-based chemotherapy, either in the primary or recurrent setting. PROC is generally associated with low response rates to standard chemotherapy with the overall response rate (ORR) of 10% to 15%, and median progression-free survival (PFS) of 3.5 months only, indicating limited effective treatment options and poor prognosis.
- mCRPC. According to Frost & Sullivan, the global and China incidence of prostate cancer is expected to increase from 1,451.5 thousand and 120.9 thousand in 2021 to 1,815.1 thousand and 199.3 thousand in 2030, respectively. Patients with prostate cancer that have relapsed after local therapy or that have distant metastasis usually respond to androgen deprivation therapy (ADT). However, despite receiving ADT, most of these patients eventually experience disease progression and develop castration-resistant prostate cancer (CRPC) within a median of 18 to 24 months from receiving ADT. A substantial majority of CRPC will develop into mCRPC. The current treatment regimen for mCRPC comprises of abiraterone acetate or enzalutamide, and abiraterone acetate requires co-medication with corticosteroids to manage adverse effects. Ultimately, almost all patients with mCRPC will develop drug resistance with limited treatment options.

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- HR+/HER2- mBC and TNBC. According to Frost & Sullivan, the global and China incidence of breast cancer is expected to increase from 2,301.2 thousand and 336.3 thousand in 2021 to 2,666.4 thousand and 372.4 thousand in 2030, respectively. It is estimated that 60% of patients with breast cancer have HR+/HER2- molecular signature in China. The endocrine/anti-estrogen therapies in combination with CDK4/6 inhibitors have emerged as first- and second-line treatment for patients with HR+/HER2- breast cancer. However, 15% to 20% of patients are intrinsically resistant to treatment, and another 30% to 40% patients will develop acquired resistance to treatment over time, according to Frost & Sullivan. TNBC is a type of breast cancer that is estrogen receptor negative, progesterone receptor negative and human epidermal growth factor receptor 2 negative based on immunohistochemistry, which accounted for approximately 15% of the total breast cancer population globally. TNBC is primarily treated with systemic therapies (chemotherapies), immune checkpoint inhibitors (ICIs) and other targeted therapies. However, current treatments have relatively poor prognosis, high risk of recurrence, and no significant survival benefit, indicating huge unmet medical needs for the treatment of TNBC.

Our R&D Approach

To address these medical needs, we have developed our clinical and pre-clinical pipeline through a combination of internal discovery and asset in-licensing efforts. Based on our knowledge-based R&D approach, we have implemented a “Tri-Pillar” product development model that consists of internal discovery, business development and translational research.

- Internal discovery. Our internal drug discovery primarily focuses on identifying innovative immunology therapies for cancer and liver fibrosis. Our most advanced internally discovered cancer candidate is LAE102, a potent and selective ActRIIA mAb that has demonstrated anti-tumor activity in pre-clinical animal models and increased body weight in cancer-bearing animals. Our most advanced internally discovered liver fibrosis candidate is LAE105, which targets aHSC depletion and has advanced into proof-of-mechanism pre-clinical studies.
- Business development. We apply a disciplined approach for bolstering our existing pipeline and expanding our capabilities. We focus on clinically proven assets in cancer treatment where we have accumulated specialized knowledge and experience. As such, we obtained global rights from Novartis Pharma AG (“**Novartis**”) on four clinical-stage drug candidates with a clinical proof-of-concept, namely LAE002, LAE001, LAE005 and LAE003. We will continue to expand our drug portfolio and explore partnership through strategic collaborations to maximize the value of our pipeline.

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- Translational research. We devote substantial resources to conducting translational research on our in-licensed product candidates to expand their clinical applications. Our translational studies include indication expansions through combination therapies or providing targeted treatments through patient stratification. Specifically, we are conducting a Phase I/II trial for LAE001, prednisone and LAE002 combination therapy targeting drug-resistant mCRPC patients as second- to fourth-line treatments and a Phase I/II trial for LAE002 and LAE005 combination therapy for TNBC patients. We also redesigned LAE001’s Phase I/II clinical trials to specifically target mCRPC patients without prior abiraterone acetate treatment.

We believe that this “Tri-Pillar” model will enable us to allocate our resources efficiently and effectively, and thus generate a pipeline of risk-mitigated products with clinical and commercial potential.

Our Pipeline

We have strategically developed a pipeline of 15 innovative product candidates, including our Core Products LAE002 and LAE001. Our drug candidates are developed or aim to be developed as both monotherapy and combination therapy with a focus on the treatment of cancers and liver fibrosis. We have the exclusive global rights to develop, manufacture and commercialize LAE002, LAE001, LAE005 and LAE003 under our licensing agreement with Novartis. The following chart summarizes the development status of our clinical-stage drug candidates and selected pre-clinical-stage drug candidates as of the Latest Practicable Date.

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Drug Candidate	Target Mechanism	Indications	Lead Discovery	Proof of Mechanism	CMC IND Enabling	Phase I	Phase II	Commercial Rights	Upcoming Major Milestones	Licensors/Partner
Cancer	+ Paclitaxel	AKT + Chemotherapy PROC (second- to sixth-line treatment)	MRCT (U.S. and China) <i>Registration⁽¹⁾</i>					Global	NDA submission with the FDA and NMPA in 4Q 2023	NOVARTIS
	+ LAE001 + Prednisone	AKT + CYP17A mCRPC following SOC Treatment (second- to fourth-line treatment)	MRCT (U.S. and South Korea) ⁽²⁾						Phase II read-out in 2Q 2023	NOVARTIS
	+ Sintilimab + Chemotherapy	AKT + PD-1 PD-1/PD-L1 Resistant Solid Tumors							Phase I read-out in 4Q 2023	NOVARTIS Innovvent
	LAE002 + Chemotherapy	AKT + PD-L1 TNBC (second- to third-line treatment)							Phase I read-out in 1Q 2023	NOVARTIS
	+ Nab-Paclitaxel	AKT + PD-L1 + chemotherapy Locally Advanced or Metastatic HR+/HER2-Breast Cancer (second- to third-line treatment)	MRCT (U.S. and China)						NDA submission with the FDA and NMPA in 2H 2025	NOVARTIS
	+ Fulvestrant	AKT + ER							Phase II read-out in 3Q 2023	NOVARTIS
	LAE001	CYP17A/CYP11B2 (first-line treatment) mHSPC							Progression into clinical stages in the U.S. by 1Q 2023	NOVARTIS
	LAE102	ActRIIA Cancer							IND application with FDA or NMPA by 4Q 2024	
	LAE109	NK / T regulator Cancer							IND application with FDA or NMPA by 2Q 2024	
	LAE111	NK / Ø regulator Cancer							IND application with FDA or NMPA by 2Q 2024	
LAE113	NK / T regulator Cancer							IND application with FDA or NMPA by 2Q 2024		
LAE117	NK / T regulator Cancer							IND application with FDA or NMPA by 2025		
LAE112	TAA Cancer							IND application with FDA or NMPA by 3Q 2024		
LAE119	Low molecular weight compounds Cancer							IND application with FDA or NMPA by 4Q 2024		
LAE120	Low molecular weight compounds Cancer							IND application with FDA or NMPA by 4Q 2024		
LAE104	aHSC depletion Liver Fibrosis								IND application with FDA or TGA by 2025	
LAE105	aHSC depletion Liver Fibrosis								IND application with FDA or TGA by 2025	
LAE106	Conditional TGFβ blocker Liver Fibrosis								IND application with FDA or TGA by 2025	
LAE003 ⁽⁷⁾	AKT HHT/Proteus Syndrome								IND application with FDA and/or NMPA by 3Q 2023	NOVARTIS



Core Product

 Internally Discovered

 Global Rights Exclusively Licensed

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Notes:

- (1) The global MRCT Phase II trial would be the registrational trial and appropriate to support product registration. According to the written confirmation issued by FDA in February 2019 and by NMPA in February 2020, FDA and NMPA agreed that this global MRCT Phase II trial would be the registrational trial and appropriate to support drug registration if the clinical results demonstrate good efficacy and safety profile. We aim to make NDA submissions to the FDA and NMPA in the fourth quarter of 2023.
- (2) The trial is a Phase I/II MRCT covering clinical sites in the U.S. and South Korea. Phase I study was completed in the U.S. in February 2021. We plan to complete the patient recruitment in both the U.S. and South Korea by March 2023, and obtain the preliminary clinical results from the U.S. and South Korea in the second quarter of 2023. Furthermore, the Phase III registrational trial for the same indication is planned to be a MRCT in the U.S., Asia and Europe, and we expect to initiate this MRCT in the U.S. first in the second half of 2023 and submit an NDA to the FDA and NMPA in 2025.
- (3) This is a Phase I/II study with collaboration with Innovent in China, and currently in Phase I stage with patients enrolling. We plan to complete the Phase I study with preliminary results in the fourth quarter of 2023.
- (4) This is a Phase I/II study in China, and currently in Phase I stage with patients enrolling. We plan to initiate the Phase II study in China in the first quarter of 2024 and complete the Phase II study in China in the fourth quarter of 2025. This study is planned to be expanded to a MRCT in China and the U.S. at the registrational stage.
- (5) LAE002+fulvestrant Phase Ib/III study does not require a Phase II clinical trial prior to beginning registrational III clinical trials. This is a Phase Ib/III study in China and the U.S., and currently in Phase Ib stage in China and the U.S. with patients enrolling. We plan to complete the Phase Ib part in China and the U.S. with preliminary results in the second quarter of 2023 and initiate the MRCT Phase III study in China and the U.S. in the second half of 2023, with top-line results expected in the first half of 2025 and NDA submissions to the FDA and the NMPA in the second half of 2025.
- (6) This is a Phase I/II study of LAE001 for mCRPC conducted only in China. We completed the Phase I study of LAE001 for mCRPC in China on September 13, 2021. We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC. As part of our clinical development strategy for LAE001 in prostate cancer and based on the clinical data from trials on mCRPC, we plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S. and apply the NDA for mHSPC with the NMPA and the FDA in 2027.
- (7) LAE003 has been conducted in several Phase I, Phase II clinical trials in various cancer indications prior to our in-licensing. We plan to repurpose the drug for rare disease indications with partners.

Glossary & abbreviations:

PROC: platinum-resistant ovarian cancer; mCRPC: metastatic castration-resistant prostate cancer; mHSPC: metastatic hormone-sensitive prostate cancer; ER: estrogen receptor; TNBC: triple negative breast cancer; HHT: hereditary hemorrhagic telangiectasia

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- Core Product LAE002. LAE002 is an ATP competitive AKT inhibitor. We in-licensed LAE002 from Novartis in 2018. Prior to our in-licensing, 11 clinical trials had been conducted to demonstrate the safety and efficacy profiles of LAE002 by Novartis and GSK plc. In the Phase I/II study conducted by Novartis, LAE002 showed potential anti-tumor efficacy in PROC patients. In pre-clinical studies, LAE002 has demonstrated its ability to restore platinum/paclitaxel sensitivity in PROC cell lines. After the in-licensing, we also identified the therapeutic potential of combining LAE002, prednisone and LAE001 and observed their synergistic anti-tumor efficacy in mCRPC patients as second- to fourth-line treatments. According to Frost & Sullivan, there are two AKT inhibitors that have entered registrational clinical trials globally.
- Core Product LAE001. LAE001 is an androgen synthesis inhibitor that inhibits both CYP17A1 and CYP11B2. We in-licensed LAE001 from Novartis in 2017. According to Frost & Sullivan, LAE001 is the only dual CYP17A1/CYP11B2 inhibitor in clinical trials for the treatment of prostate cancer globally. Prolonged cumulative doses or short-term high dose exposure to prednisone may lead to adverse events. Our completed Phase I study showed safety, preliminary anti-tumor efficacy and potential clinical benefits for LAE001 monotherapy without the use of prednisone in mCRPC patients. We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC. As part of our clinical development strategy for LAE001 in prostate cancer and based on the clinical data from trials on mCRPC, we plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S. and apply the NDA for mHSPC with the NMPA and the FDA in 2027.
- LAE005. LAE005 is developed to be a highly affinitive, ligand-blocking, humanized anti-PD-L1 IgG4 antibody. In pre-clinical and clinical studies, LAE005 demonstrated its binding avidity to PD-L1 and anti-tumor activities. Specifically, we are evaluating the therapeutic potential of the combination therapy of LAE002 and LAE005 in patients with TNBC. We believe LAE005 has the potential to serve as an effective therapy for the treatment of TNBC when combined with other synergistic mechanisms.
- LAE003. LAE003 is developed to be a potent ATP competitive AKT inhibitor. In the pre-clinical studies, LAE003 showed potency and selectivity to AKT1, AKT2 and AKT3. LAE003 is currently at the clinical stage for the treatment of cancer and we are re-purposing it for the treatment of hereditary hemorrhagic telangiectasia and proteus syndrome. We expect LAE003 to be our lead drug candidate in the rare disease therapeutic area.

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- LAE102. LAE102 is our most advanced internally discovered drug candidate for cancer treatment. It is a potent and selective activin receptor type IIA (ActRIIA) mAb that shows anti-tumor activity and ability to increase the bodyweight of cancer-bearing animals in pre-clinical animal models.
- LAE105. LAE105 is our most advanced internally discovered drug candidate for liver fibrosis treatment, which targets activated hepatic stellate cells (aHSC) depletion and has entered into proof-of-mechanism pre-clinical studies.

Our Team and Vision

Our stable and seasoned core management team is instrumental to our continuous growth and development. Our core management team has established a long track record of accomplishment, leadership and deep knowledge in their respective fields. In addition, they share the common mission of discovering and delivering novel therapies to benefit patients worldwide. Our founder and Chief Executive Officer Dr. Chris Lu, Chief Medical Officer Dr. Yong Yue, and Chief Scientific Officer Dr. Justin Gu have known each other since college for 40 years and have worked extensively together, which lays solid foundation for our research and development as well as to create synergistic cooperation within our team.

With a vision to lead global innovation and deliver novel therapies to patients worldwide, we have established an integrated team located in both China and the U.S. This arrangement allows us to be at the forefront of medical research and knowledge, conduct MRCTs efficiently and execute business development strategies. We are building in-house GMP-compliant manufacturing facilities in eastern China and aim to construct a supply chain system by leveraging our CMO partners in the U.S. and other regions. We have also established a clinical development and medical affairs function that allows us to rapidly execute our clinical trials and navigate the global regulatory environment to shorten the time to market for our product candidates. Since our inception, we have obtained over eight IND approvals from the FDA and NMPA and have initiated six clinical trials, including three MRCTs across China, the U.S. and other jurisdictions.

STRENGTHS

We believe the following strengths differentiate us from our competitors.

ATP Competitive AKT Inhibitor LAE002 in Registrational Clinical Trials with Potentially Better Clinical Efficacy and Favorable Safety Profile

LAE002, one of our Core Products, is an ATP-competitive AKT inhibitor. We have the exclusive global rights to develop, manufacture and commercialize LAE002 under our licensing agreement with Novartis. The upregulation of AKT pathway activity has been associated with SOC resistance in a number of cancers. AKT inhibitors have demonstrated their ability to reverse drug resistance in numerous clinical studies and showed their potential to address the urgent unmet medical needs in those selected cancers. Leveraging our in-depth

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knowledge and expertise of the AKT pathway activation, we have independently initiated five combination therapy clinical programs to evaluate the therapeutic potential of LAE002 in a variety of drug-resistant cancers, including PROC, mCRPC, breast cancer and PD-1/PD-L1 resistant solid tumors. According to Frost & Sullivan, the global and China market size of AKT inhibitors is expected to reach US\$12,154.0 million and RMB14,674.4 million in 2030, respectively.

Prior to our in-licensing of LAE002, 11 clinical trials have already been conducted to evaluate the efficacy and safety of LAE002. Specifically, in the Phase I/II study of LAE002 in combination with carboplatin and paclitaxel for the treatment of PROC sponsored by Novartis, the overall response rate (ORR) was 32.1% and the median progression-free survival (PFS) was 7.1 months. We are conducting a registrational Phase II MRCT of LAE002 in combination with chemotherapy for PROC in the U.S. and China, and the preliminary data showed a favorable efficacy profile. As of the data cut-off date of February 13, 2022, a total of 44 subjects were evaluated for treatment response, including 30 subjects in arm 1 (LAE002 plus paclitaxel) and 14 subjects in arm 2 (paclitaxel). The ORRs in arm 1 and arm 2 are 33% and 14%, respectively.

Furthermore, according to Frost & Sullivan, there are two AKT inhibitors that have entered registrational clinical trials globally. LAE002 demonstrated its strengths in potency, bioavailability exposure and toxicity compared with ipatasertib and capivasertib. In addition, the early phase clinical studies demonstrated that LAE002 had relatively lower rate of adverse events, such as hyperglycemia, skin rash, diarrhea, etc., than the other AKT inhibitors.

		LAE002 afuresertib (ATP Competitive)	GDC-0068 ipatasertib (ATP Competitive)	AZD-5363 capivasertib (ATP Competitive)
Study Ph1		25, 75, 100, 125, 150 mg QD	100, 200, 400, 600, 800 mg QD	80 - 600 mg BID Continued dosing 480, 640 mg BID 4d/7d dosing 640, 800 mg BID 2d/7d dosing
Recommended Ph2 Dose (RP2D)		125 mg QD	600 mg QD	480 mg BID 4/7 days
Cancer Type & Patients Enrolled		Hematologic tumors 73 pts	Solid tumors 52 pts (breast cancer – 31%, colorectal cancer – 27%, prostate cancer – 12%, chondrosarcoma – 4%, ovarian cancer – 4%, other – 22%)	Solid tumors Part A & B - 90 pts (colorectal – 29%, pleura – 8%, lung – 7%, cervix – 6%, colon – 6%, other – 45%) Part C – 59 pts (solid tumor patients with PIK3CA mutation)
AUC0-24 ng-h/mL /Cmax ng/mL /Ctrough ng/mL	Initial State	AUC 2378/Cmax 175	AUC 2670/ Cmax 488	n/a
	Steady State	AUC 7405/Cmax 531/Ctrough259 (Cycle 1 day 8)	AUC 4450/Cmax 748 (Cycle 1 Day 15)	AUC 7952/Cmax 1426/Ctrough 357 (Day 4 on 4/7d)
Major Adverse Events @RP2D >= G3		G3 6.8% Neutropenia 4.1% Rash 2.7% Odynophagia 2.7% Fatigue 0% Hyperglycemia	G3 17.2% Diarrhea 3.4% Hyperglycemia 3.4% Hyperphosphatemia 3.4% Astheria	G3 & G4 20% Hyperglycemia 12% Diarrhea 10% Maculopapular Rash 7% Fatigue 7% Hypokalemia
Efficacy Single Agent		ORR 8.8%, DCR 63% 1 CR, 4 PR, 33 SD all confirmed	ORR not available, DCR 34% 16 SD	ORR not available, DCR 30% 27 SD ORR 5.6%, in PIK3CA mutation pts

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Note: No head-to-head comparison clinical study was conducted 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.

This table includes information summarized from selected Phase I clinical trials conducted for the three AKT inhibitors. We believe the clinical trials selected are the most relevant clinical trials for the purpose of comparison because each of the clinical trials selected used the relevant AKT inhibitor as monotherapy and assessed a wide range of doses despite that they were conducted for different indications. As the first-in-human studies for LAE002, ipatasertib and capivasertib, the ORR and/or other efficacy data listed above from each of such clinical trials were for the whole enrolled patient group of the relevant clinical trial and such data for each cancer type being studied were not available.

Glossary & abbreviation: Ph: Phase; Pts: patients; Cmax: maximum concentration; Ctrough: trough concentration; DCR: disease control rate

Source: Frost & Sullivan analysis, Company data, Spencer et al. 2014, BLOOD 124(14), Saura et al, 2017, Cancer Discovery, Banerji et al, 2018, Clin Cancer Res; 24(9)

In our clinical trials, we also explored and discovered the therapeutic potential of the combination of LAE002 and LAE001 and observed their synergistic anti-tumor efficacy for the treatment of drug-resistant mCRPC. The second-generation androgen receptor antagonist enzalutamide has been approved for the treatment of mCRPC due to its significant improvement in overall survival. Unfortunately, not all patients with mCRPC are responsive to enzalutamide, and even in responders, benefits are limited by the development of drug resistance within one to two years' treatment. We are evaluating LAE002 in combination with LAE001 and chemotherapy for drug-resistant mCRPC patients. In the completed Phase I study, as of the data cut-off date of February 24, 2022, the median and maximum treatment periods without tumor progression of evaluable patients in RP2D cohort are 8.6 and 15.6 months, respectively. Among the 14 evaluable patients, two patients had a prostate-specific antigen (PSA) response. Among the five patients with measurable lesions, one achieved PR and two achieved SDs. This result suggests that the combination of LAE002 plus LAE001 and prednisone has a favorable efficacy profile in patients with drug-resistant mCRPC compared to the results of previous studies, where mCRPC patients who failed first- to third-line SOC had only two to four months of progression-free survival.

We believe LAE002 has the potential to become an effective therapy for drug-resistant breast cancer in the future and benefit a large population of patients. AKT activations such as PTEN loss and PI3KCA mutations have been reported to correlate with in approximately 60% of breast cancers, according to Frost & Sullivan. Phase II clinical studies conducted by multi-national companies, including Roche and AstraZeneca, have demonstrated favorable efficacy of their combination therapy of AKT inhibitors (i.e., ipatasertib and capivasertib) in the treatment of HR+/HER2- mBC and TNBC, respectively. We have observed preliminary anti-cancer activities in the Phase I combination trial of LAE002 plus LAE005 in TNBC patients. Another ongoing Phase Ib combination trial of LAE002 plus fulvestrant in HR+/HER2-mBC is expected to achieve comparable efficacy and safety clinical results, given LAE002's similar mechanism of action and safety profiles compared with ipatasertib and capivasertib.

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CYP17A1/CYP11B2 Inhibitor LAE001 Exhibits Favorable Efficacy Profile for Prostate Cancer

LAE001, our other Core Product, is a dual CYP17A1/CYP11B2 inhibitor. According to Frost & Sullivan, LAE001 is currently the only CYP17A1/CYP11B2 dual inhibitor candidate in clinical trials for prostate cancer treatment globally. We have the exclusive global rights to develop, manufacture and commercialize LAE001 under our licensing agreement with Novartis. We have completed our Phase I study and we are conducting a Phase II clinical trial to evaluate the efficacy and safety of LAE001 for mCRPC in China. We plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S., and submit NDA for LAE001 for the indication of mHSPC to the FDA and NMPA in 2027.

The current SOC for mHSPC and mCRPC consists mainly of chemotherapies and anti-androgen therapies including abiraterone acetate and enzalutamide. However, both abiraterone acetate and enzalutamide have long-term side effects and almost all mHSPC and mCRPC patients eventually develop acquired resistance, leaving them without effective treatment options. Abiraterone acetate, a CYP17A1 enzyme inhibitor, is currently approved only for use in combination with prednisone. However, a prolonged administration or high dose even for a short-term exposure of prednisone can cause severe adverse effects.

Given abiraterone acetate as a CYP17A1 enzyme inhibitor is not able to address CYP11B2 enzyme, it requires co-medication with corticosteroids to manage mineralocorticoid excess related adverse effects. In comparison, LAE001 has exhibited its high potency and selectivity against both the CYP17A1 and CYP11B2 enzymes in the pre-clinical studies. The CYP11B2 inhibitory activity of LAE001 could potentially reduce mineralocorticoids, which demonstrates its potential as a monotherapy without the co-administration with prednisone.

In a completed Phase I clinical trial sponsored by us, in the 50 mg BID (RP2D) Cohort, among 20 evaluable patients, 16 patients (80%) achieved over 50% reduction in PSA response and 12 patients (60%) achieved over 90% reduction in PSA response. In addition, LAE001 monotherapy demonstrated favorable safety profile in avoiding hyperaldosteronism associated symptoms.

The table below sets forth the clinical results of abiraterone combination therapy, LAE001 monotherapy for mCRPC. Although these were not head-to-head analyses, we believe that valuable insight can nonetheless be drawn from the comparison of our LAE001 with the abiraterone therapies.

Trial ID and phase	NCT00473512 Phase II	NCT00474383 Phase II	NCT00485303 Phase II	NCT03843918 Phase I
Study treatment	Abi+Dexamethasone	Abi+Prednisone/ Prednisolone	Abi+Prednisone/ Prednisolone	LAE001
Patients (n)	42	47	58	20
Prior treatment				
Abi/Enza naïve	Yes	Yes	Yes	Yes
Docetaxel naïve	Yes	No (all 47 patients failed docetaxel)	No (all 58 patients failed docetaxel)	No (4/20 patients failed docetaxel)
Median time to PSA progression (months)	7.4	5.6	5.6	12.9
PSA response				
>50% from baseline	67%	51%	36%	80%
>90% from baseline	19%	15%	16%	60%

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Note: No head-to-head comparison clinical study was conducted 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.

Glossary & abbreviation:

Abi: abiraterone; Enza: enzalutamide

Source: Company data G Attard, et al. 2009; AHM Reid, et al. 2010; AC Danila et al. 2010

Deep Understanding into Fundamental Disease Biology and Clinical Practice Empowers Our Internal Discovery, Business Development and Translational Research

Backed by strong science-driven discovery, we aim to develop highly differentiated therapies. We prudently select and evaluate potential drug targets with strong biological and disease associations. We have implemented a “Tri-Pillar” product development model that leverages our in-depth understanding of disease pathogenesis, our business development network and our translational research capabilities. The “Tri-Pillar” strategy revolves around our science-driven R&D approach and is fueled by our unique scientific insight and in-depth knowledge into clinical practice and unmet needs.

- Internal discovery. We have a deep knowledge of disease biology, extensive experience in cutting-edge biological research, and an in-depth understanding of the clinical practice and medical needs. These enable us to identify therapeutic areas in hard-to-treat diseases and build a product pipeline with a risk-mitigated profile to address clinical pain points. We have assembled a seasoned and cross-national R&D team to support our continuous multi-source pipeline expansion. Our early discovery research is spearheaded by our Chief Scientific Officer, Dr. Justin Gu, an industry veteran with over 20 years of experience at multinational pharmaceutical companies, who has discovered multiple drug candidates during his tenure at the China Novartis Institute for Biomedical Research. Our internal drug discovery primarily focuses on identifying innovative immunology therapies for cancer and liver fibrosis. LAE102 is our most advanced internally discovered drug candidate for cancer treatment, a potent and selective ActRIIA mAb that has demonstrated anti-tumor activity in pre-clinical animal models and body weight gain in cancer-bearing animals. LAE105 is our most advanced internally discovered drug candidate for liver fibrosis treatment, which targets aHSC depletion and has advanced into proof-of-mechanism pre-clinical studies.
- Business development. Over the past five years, we had a proven track record of building a global network and value-creating strategic partnerships and collaborations. We have established a number of global and regional partnerships with leading pharmaceutical companies, including Novartis and Innovent. Our partnerships cover various business collaboration models, including in-licensing and clinical collaboration. Our business development and R&D teams work closely to identify attractive business opportunities to optimize our pipeline structure in accordance with our product development strategy and R&D approach. Leveraging our understanding and scientific insights into cancer biology, we have successfully

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in-licensed four clinically validated assets with strong combinatorial potential from Novartis, spearheaded by LAE002 and LAE001. In 2021, we entered into a collaboration agreement with Innovent to explore and maximize the potential value of the combination of LAE002 and sintilimab for patients with solid tumors in China. We believe such collaborations with leading pharmaceutical companies are a testament to our strong R&D capabilities.

- Translational research. We devote substantial resources to conduct translational researches on our licensed product candidates to expand their clinical applications. Our translational studies include expanding indications through combination therapies or providing more precise treatments through patient stratification. We are independently exploring multiple combination therapies for LAE002 that have not been previously validated to expand into. These efforts include studies of LAE002 in combination with LAE001 and prednisone for drug-resistant mCRPC patients as second- to fourth-line treatments, and LAE002 in combination with LAE005 for TNBC. In addition, following the in-licensing of LAE001, we have conducted extensive pre-clinical studies in collaboration with leading principal investigators (PIs) and key opinion leaders (KOLs) as well as research institutions to explore the monotherapy potential of LAE001. After obtaining favorable pre-clinical data, we redesigned the Phase I clinical trial of LAE001 specifically for patients with mCRPC who have not received abiraterone acetate therapy.

Leveraging our “Tri-Pillar” product development model, we have quickly built a broad and diversified pipeline of innovative internally discovered and in-licensed drug candidates focused on cancer and liver fibrosis with potential to address significant unmet medical needs.

Highly Integrated Operations that Well-position us to Capture International Business Opportunities

We have established an integrated R&D function in both China and the U.S. We have been able to stay at the forefront of biology and pharmaceutical research, source attractive business development opportunities, execute and closely manage complex MRCTs. Specifically, we have six clinical studies focusing on drug-resistant cancers, three of which are MRCTs. For the other three, we are conducting early phase clinical studies in China and we plan to expand the registrational trial once early phase clinical studies demonstrate proof of concept results.

As of the Latest Practicable Date, we had 95 employees in China and the U.S. Our clinical development and business development team in the U.S. are responsible for supervising and coordinating with CROs to support our clinical studies in the U.S., as well as seeking potential partners for collaboration. Our team in the U.S. also independently executes its day-to-day operations with respect to drug asset acquisition, corporate services and general functions. We have devoted significant resources, such as management time and attention, as well as financial and human resources, and taken certain integration measures in order to integrate operations in the U.S. and China. For example, we established an executive working group comprised of senior management personnel in China and the U.S. to foster close communications on our

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strategic plans and day-to-day operations. With an aim to ensure that the U.S. team can share our resources and information, we have held a number of events to enhance the communication between our employees in the U.S. and China, and we have dispatched talents to the U.S. to support its operations. The interactions between our U.S. and China operations are a dynamic and mutually beneficial process with a goal to maximize our Group's performance as a whole.

Our management team provides us a strong presence in the network of pharmaceutical industry. Our management team has over six decades of combined experience working with multinational pharmaceutical companies, contributing to our successful in-license of four drug candidates from Novartis and our clinical collaboration with Innovent. Armed with our business development expertise and network, we can seek out-licensing opportunities to optimize our product pipeline and increase our return on invested capital. With presence in the key pharmaceutical markets and leveraging the expertise we have accumulated through our operations over the years, we are well positioned to capture strong industry growth opportunities in China and worldwide. Our clinical development and regulatory teams have extensive knowledge and experience in designing and executing clinical trials at all stages in indications with significantly unmet medical needs. In addition, our regulatory experience enables us to file IND applications and communicate with drug regulators more efficiently.

Leveraging on our integrated operation and collaborations with industry-leading CROs, SMOs and CDMOs, our teams of experts strive to accelerate drug development and bring promising therapies to China and worldwide. We entrust our seasoned clinical development team and lead local clinical trial partners to implement and execute our clinical development plan swiftly and conduct MRCTs. Since our inception, we have initiated six clinical trials and completed two clinical trials around the globe. In addition, we collaborate with PIs, KOLs, and physicians in clinical studies and basic research. With the support from frontline investigators, we strive to identify and validate new biomarkers, stratify patient populations, and expand addressable indications for our drug candidates. We also gain first-hand knowledge of clinical practice through our communication with leading medical scientists around the world, enabling us to identify unmet needs in overlooked disease areas. We have built strong business partnerships with leading CROs, CMOs and CDMOs in the U.S. and other regions. Furthermore, we are building in-house manufacturing facilities in eastern China to support the anticipated launches of our drug candidates.

Seasoned Management Team with a Proven Track Record of R&D, Supported by Strategic Investors and Healthcare Specialists

We have assembled a seasoned management team with extensive experience and expertise covering the full cycle of the clinical development process, from pre-clinical study design and clinical trial execution to regulatory processes and manufacturing. Our core management team has established a long track record of accomplishment, leadership and deep knowledge in their respective fields. In addition, they share the common mission of discovering and delivering novel therapies to benefit patients worldwide.

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Our founder, Chairman and Chief Executive Officer, Dr. Chris Lu, is a seasoned pharmaceutical researcher with over 20 years of industry experience. He has a strong track record of developing successful drug candidates of both biologics and small molecules. With deep scientific knowledge and know-how in disease biology, translational research and drug development, he has co-invented more than 10 drug candidates, including bimagrumab, an antibody drug that earned “Breakthrough Therapy” designation from the FDA. In addition, Dr. Lu has extensive experience in the initiation and management of external collaboration with hospitals, academic institutes and CROs. He served as the executive director leading discovery biology platform and liver disease drug discovery at China Novartis Institute for BioMedical Research, and as the principal scientist and group head at Wyeth Research. Dr. Lu authored or co-authored more than 20 publications in peer reviewed journals.

Our Chief Medical Officer, Dr. Yong Yue has over 20 years of experience in oncology clinical development and ample clinical practice experience in China, Europe and the United States. Dr. Yue received his Doctor of Medical Science degree from the University of Geneva in Switzerland. Dr. Yue authored and co-authored more than 20 peer-reviewed publications.

Our Chief Scientific Officer, Dr. Justin Gu, has over 20 years of drug discovery experience in biotechnology and pharmaceutical companies with strong scientific background in cancer and liver disease. Before joining us, he served as a director of lead discovery at China Novartis Institute for BioMedical Research. Dr. Gu is an experienced drug-hunter and key co-inventor of several pre-clinical drug candidates, some of which have successfully advanced into clinical studies. Dr. Gu holds a Doctor of Philosophy degree in biochemistry from the Ohio State University and was a post-doctorate fellow at Massachusetts Institute of Technology before entering into the pharmaceutical industry.

We are also supported by our strong scientific advisory board consisting of leading scientists, physicians and industry veterans who have played key roles in shaping our R&D strategies and our involvement with the medical and industry communities. We are further supported by strategic and healthcare specialist investors such as Novartis and OrbiMed. They have provided us with invaluable guidance on product development, insights on strategic opportunities and the latest biomedical researches and clinical practices.

STRATEGIES

We are committed to becoming an innovative biopharmaceutical company that can bring novel therapies to cancer and liver fibrosis patients worldwide. To achieve our vision, we plan to pursue the following significant opportunities and execute our key strategies accordingly:

Rapidly Advancing the Development of Our Existing Drug Candidates and Portfolio towards Commercialization

Leveraging our strong in-house clinical and development capabilities, we plan to continue to rapidly advance our existing clinical and pre-clinical drug candidates to achieve commercialization. To ensure smooth execution of our R&D process and to pursue a highly

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efficient timetable towards commercialization, we have been and will continue to leverage on the massive patient pool in China and abroad. We will also continue to execute an innovative, tailored clinical trial design for each of our drug candidates by leveraging existing clinical data obtained through our in-license arrangements with other multinational pharmaceutical companies and strengthening our relationships with key external parties, including PIs, KOLs, CROs, SMOs, CDMOs, hospitals and others. We expect that our leading research in PROC, mCRPC and liver fibrosis treatments will continue to witness major milestones for our existing drug candidates in the near future.

We expect to continue to achieve and deliver major development milestones for our Core Products and key drug candidates, including LAE002, LAE001, LAE005 and LAE003 to further explore their potential. Particularly, we have formulated the following plans regarding our clinical-stage drug candidates.

- LAE002. We have initiated a global MRCT Phase II registrational trial in both the U.S. and China to treat PROC with LAE002, in a combination therapy with paclitaxel. As of the Latest Practicable Date, we had completed more than 95% of enrollment in both the U.S. and China. We aim to make NDA submissions to the FDA and NMPA in the fourth quarter of 2023.

We initiated the Phase II trial of the Phase I/II MRCT study of LAE001 and prednisone plus LAE002 or docetaxel/prednisone plus LAE002 in patients with mCRPC following SOC treatment in the U.S. in June 2021. We initiated the same study in South Korea in September 2022. We plan to complete the patient recruitment in both the U.S. and South Korea by March 2023, and obtain the preliminary clinical results from the U.S. and South Korea in the second quarter of 2023. Furthermore, the Phase III registrational trial for the same indication is planned to be a MRCT in the U.S., Asia and Europe, and we expect to initiate this MRCT in the U.S. first in the second half of 2023 and submit an NDA to the FDA and NMPA in 2025.

In addition, we are also actively exploring to further expand the indication of LAE002. We are with Innovent in exploring a combination therapy with sintilimab targeting patients with solid tumors with prior PD-1/PD-L1 treatments. We received the IND approval for this Phase I/II study from the NMPA in January 2022, and we initiated the Phase I study in June 2022. We plan to complete the Phase I study and the analysis of the preliminary results in the fourth quarter of 2023. We are also conducting a Phase Ib/III trial in China and the U.S. for the treatment of locally advanced or metastatic HR+/HER2- breast cancer with LAE002, in a combination therapy with fulvestrant. We plan to complete the Phase Ib part in China and the U.S. and the analysis of the preliminary results in the second quarter of 2023 and initiate the MRCT Phase III study including China and the U.S. in the second half of 2023, with top-line results expected to become available in the first half of 2025 and NDA submissions to the FDA and the NMPA in the second half of 2025.

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- LAE001. We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC. As part of our clinical development strategy for LAE001 in prostate cancer and based on the clinical data from trials on mCRPC, we plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S. and apply the NDA for mHSPC with the NMPA and the FDA in 2027.
- LAE005. We have initiated a Phase I/II trial in China for the treatment of TNBC in combination with LAE002 and nab-paclitaxel to continue to leverage the clinical value and explore AKT's potential. We aim to obtain the preliminary clinical results in the first quarter of 2023. We plan to initiate the Phase II study in China in the first quarter of 2024 and complete the Phase II study in China in the fourth quarter of 2025. This study is planned to be expanded to a MRCT trial in China and the U.S. at the registrational stage.
- LAE003. We are re-purposing LAE003 for rare diseases such as hereditary hemorrhagic telangiectasia and Proteus syndrome. To further discover the therapeutic potential of LAE003, we are exploring potential opportunities to cooperate with global partners on the development of LAE003.

Actively Exploring Potential Combination Therapy Opportunities to Fully Unlock Clinical Value of Our Product Pipeline

To recognize the distinct values of our clinical drugs and fully capture their clinical potential, we will continue to actively explore potential combination therapy opportunities among our pipeline and with existing approved drugs as well as conventional therapies.

Our experience in executing and developing combination therapies among our pipeline, such as LAE002 and LAE001, to treat the second-generation A/AR drug-resistant mCRPC has well demonstrated our ability to unleash the clinical value of our innovative pipeline products. Studies have shown that prostate cancer progression is associated with an increased frequency of PTEN deletion, suggesting that in addition to the androgen/androgen receptor signaling pathway, PTEN deletion leads to castration resistance in prostate cancer during androgen deprivation therapy. LAE002, a strong AKT inhibitor, overcomes the PTEN deficiency-mediated increase in AKT activity. We hypothesized that combining LAE002 with LAE001 and androgen synthesis inhibitors may have therapeutic effects for patients with PTEN-deficient mCRPC. To validate our hypothesis, we designed and conducted a series of combination trials of LAE002 and LAE001, the latest of which being the Phase II MRCT currently being conducted in the U.S. and South Korea. We expect to expand our drugs' indications, improve efficacy via synergies, and potential lower toxicity. Besides, to complement our product portfolio and realize synergies via a combination strategy, we expect to continue our in-licensing activities and seek long-term collaborations to bring in high-value, disruptive and differentiated products with clinical values and attractive risk-return profiles.

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In addition, we plan to continue to explore combination opportunities with marketed drugs, as represented by PD-1/PD-L1 and conventional treatments. Acknowledging the resistance and limited efficacy of PD-1/PD-L1 therapies to a large group of patients, we have been and will continue to discover combination therapies by leveraging our differentiated small molecules with clear proof of concept. We are currently conducting clinical studies of LAE002 in combination with sintilimab or LAE005 to treat TNBC and solid tumors after anti-PD-1/PD-L1 therapy, respectively. To further our current studies of LAE002 in combination with paclitaxel and docetaxel, we will also keep exploring the possibility of combination therapies with endocrine therapy to treat hormone-related cancers without any or optimal solutions. Furthermore, we also intend to initiate clinical developments in HR+/HER2- breast cancer.

Consistently Expanding Our Innovative Drug Pipeline through In-House Discovery to Address Broader Underserved Patients

The global drug clinical development landscape has become increasingly competitive. Based on our deep industry knowledge, seasoned experience in the R&D process, and the know-how accumulated from our successful clinical development, we will continue to seek more innovative solutions in the field of cancer and liver fibrosis with significant unmet medical needs. To leverage our knowledge in these disease areas and build synergies between programs targeting both disease indications, we are focusing our research on immune cells that are important for immune surveillance in cancer and fibrosis reversal in liver fibrosis. We are developing multiple monoclonal and bispecific antibodies against key regulatory pathways of NK cells and T cells and bifunctional NK engagers against cancer cells and activated hepatic stellate cells. These innovative molecules are in various stages of drug discovery, and we plan to have at least one molecule to enter the clinical stage each year on average, starting in 2023.

- Cancer drug candidates. Immuno-oncology therapies have been innovative as cancer treatments over the past decade. Although ICIs have been approved for first- and second-line treatment for a variety of cancer indications worldwide, most patients with solid tumors do not respond to or eventually develop resistance to ICI therapy. We are developing immuno-oncology agents that target the mechanisms that mediate resistance to first-generation ICIs. Among these, we are particularly interested in the inhibitory receptors expressed by cancer infiltrating lymphocytes (i.e., LAE102, LAE109, LAE111, LAE113 and LAE117) and ligands/receptors expressed on or produced by cancer cells (i.e., LAE112). We believe that these inhibitory pathways represent targets for developing anti-tumor agents that could reverse resistance to ICIs.

Our most advanced candidate is LAE102, an activin receptor ActRIIA mAb. As a member of the TGF β family, activin is attracting an increasing interest due to its multifunctional role in cancer development, particularly its immunomodulatory function. In several cancer types, high expression of activin is associated with shorter survival. LAE102 is a potent and selective ActRIIA mAb that shows anti-tumor activity and its ability to increase the bodyweight of cancer-bearing animals in pre-clinical animal models.

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- Liver fibrosis drug candidates. In addition to our pre-clinical-stage cancer drug candidates, we are also developing a number of pre-clinical drug candidates for liver fibrosis which represent another huge unmet medical need. Recent evidence suggests that liver fibrosis can be reversed by regulating the immune system. We have established a proprietary aHSC depletion platform to remove aHSC for fibrosis regression. Bi-functional aHSC-NK engagers or regulators (i.e., LAE104 and LAE105) with aHSC killing and anti-fibrosis activity have been developed. We have also designed and validated a TGF β inhibitor, LAE106, active only in fibrotic tissues. All of these molecules have the potential to provide innovative solutions to slow or prevent the progression of liver fibrosis, and their utility may be expanded to other fibrotic diseases.

Further Enhancing Our Capabilities as Our Clinical Studies Progress and Business Develops

With our existing operations in both China and the U.S., we plan to further enhance our capabilities by building our platform with comprehensive coverage of the full cycle of the clinical development process, complemented by synergistic business development activities. We have adopted and intend to accomplish the following multi-layered plans to support our global strategy.

- R&D. We are dedicated to leveraging our expertise to further enhance our drug discovery and clinical development capabilities. Currently, we have two R&D centers in China and the U.S. We will continue to expand both facilities to take advantage of talents, technology and information acquired in both regions to feed and sustain the continued growth of our pipeline. Besides, we plan to actively engage with PIs, KOLs, CROs, SMOs, CDMOs and hospitals to carry out and expand global multi-center trials for our existing candidates and ultimately to pursue a global registration strategy.
- Manufacturing. We plan to establish strong manufacturing capabilities to support the near-term launch of our innovative product candidates. To achieve this goal, we plan to build a cGMP-compliant manufacturing site in eastern China, focusing on manufacturing small molecule products. We will also collaborate with leading CMOs and CDMOs to complement our in-house CMC capabilities. Besides, we also plan to diversify our supply chain for equipment and raw materials to reduce cost and increase manufacturing efficiency.
- Sales and Marketing. We target to build sales and marketing capabilities through a combination of an in-house strategy and partnering with leading industry participants, especially our existing licensing and collaboration partners. With respect to our in-house efforts, we intend to build a sales and marketing team of about 50 members to provide dedicated coverage of Class III Grade A hospitals in top-tier cities in China. Upon successful launch of our products and continuous penetration in these targeted hospitals, we will further expand our reach into

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lower-tier cities to maximize the commercial value of our drug candidates. With respect to external partnerships, we will explore out-licensing opportunities especially in lower-tier cities in China or other key global markets. Further, we will keep actively seeking and maintaining collaborations with other top global and local healthcare companies, academic institutions, and scientific research centers to promote our marketing activities in different targeted regions, including the Europe, Japan, and other regions.

- Business Development. We will keep seeking strategic collaborations that bring value to our pipeline. We plan to continue to seek assets through in-licensing arrangements, both in clinical and preclinical stage that complement our pipeline. A strong emphasis will continue to be placed on assets that could offer us global development and commercialization rights, have potential combination synergies with our current pipeline, and/or have first-in-class potential. As our late-stage assets are close to commercialization, we will also seek assets with commercial synergies with our late-stage pipeline. We will also consider pursuing business collaborations with other global partners in terms of joint development and commercialization of our drug candidates in international markets.

Continuing to Attract and Retain Top Talents and Become a World-Class Global Organization

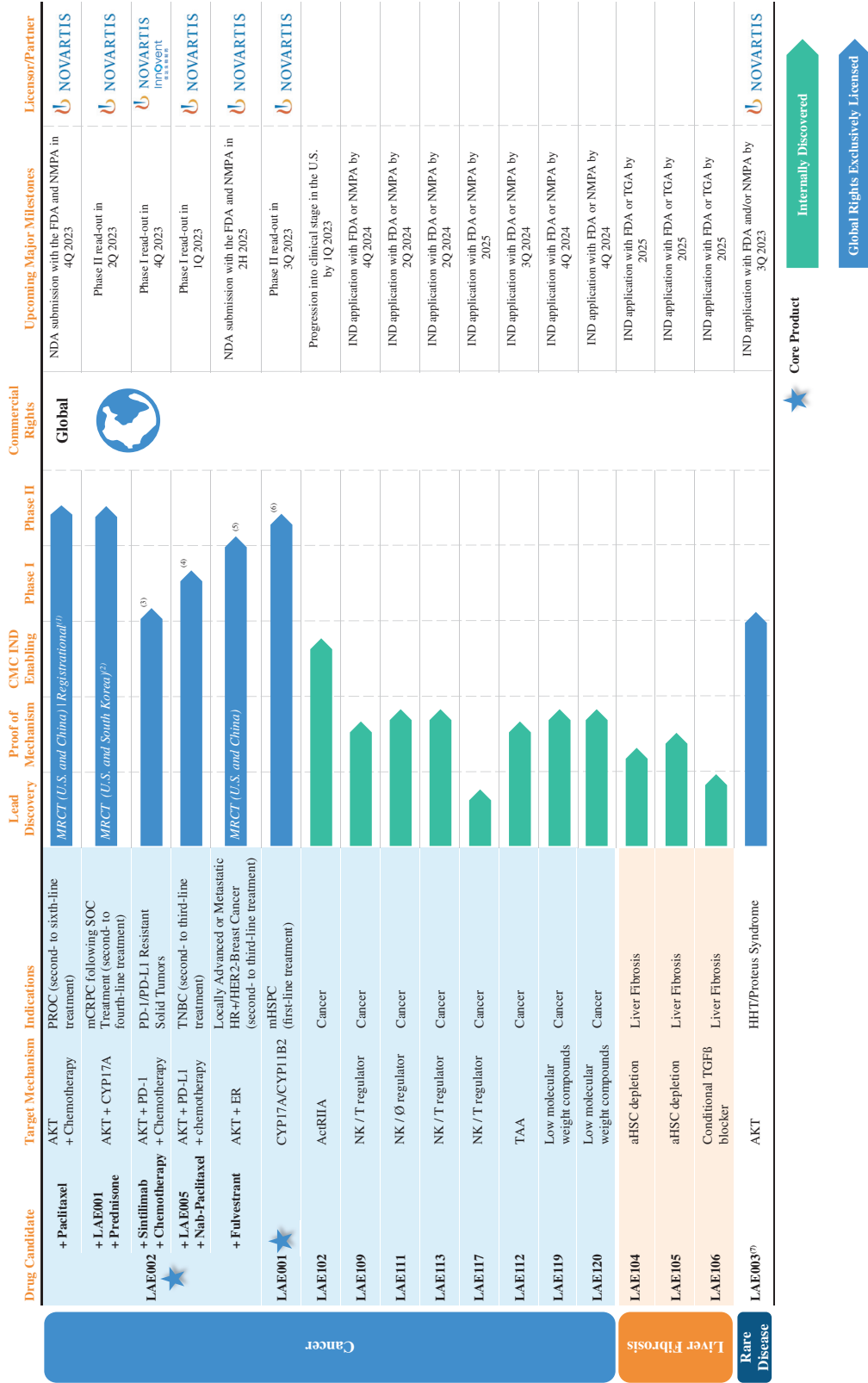
We place a strong emphasis on talent recruitment and retention. We recognize that talents are key to our future success and sustainable growth. To support our aspiration to becoming a world-class organization, we will continue to recruit and train top talents especially those with experience from large multinational pharmaceutical companies and with expertise in clinical development, R&D, CMC and commercialization of our drug candidates. To achieve that end, we will continue to foster our culture of innovation, collaboration and efficiency and refine our organizational structure to empower our leaders and team members to take ownership of their respective work and reward their contributions. We will also strive to provide the training to nurture our young members to become future key opinions in the pharmaceutical industry. Our highly skilled talents in both China and the U.S. will work closely to transform us into a world-class organization.

DRUG CANDIDATES

As of the Latest Practicable Date, we have strategically designed and developed a diversified pipeline of 15 programs with R&D and commercialization rights. Our pipeline includes four in-licensed clinical-stage assets and 11 pre-clinical stage assets.

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



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Notes:

- (1) The global MRCT Phase II trial would be the registrational trial and appropriate to support product registration. According to the written confirmation issued by FDA in February 2019 and by NMPA in February 2020, FDA and NMPA agreed that this global MRCT Phase II trial would be the registrational trial and appropriate to support drug registration if the clinical results demonstrate good efficacy and safety profile. We aim to make NDA submissions to the FDA and NMPA in the fourth quarter of 2023.
- (2) The trial is a Phase I/II MRCT covering clinical sites in the U.S. and South Korea. Phase I study was completed in the U.S. in February 2021. We plan to complete the patient recruitment in both the U.S. and South Korea by March 2023, and obtain the preliminary clinical results from the U.S. and South Korea in the second quarter of 2023. Furthermore, the Phase III registrational trial for the same indication is planned to be a MRCT in the U.S., Asia and Europe, and we expect to initiate this MRCT in the U.S. first in the second half of 2023 and submit an NDA to the FDA and NMPA in 2025.
- (3) This is a Phase I/II study with collaboration with Innovent in China, and currently in Phase I stage with patients enrolling. We plan to complete the Phase I study with preliminary results in the fourth quarter of 2023.
- (4) This is a Phase I/II study in China, and currently in Phase I stage with patients enrolling. We plan to initiate the Phase II study in China in the first quarter of 2024 and complete the Phase II study in China in the fourth quarter of 2025. This study is planned to be expanded to a MRCT in China and the U.S. at the registrational stage.
- (5) LAE002+fulvestrant Phase Ib/III study does not require a Phase II clinical trial prior to beginning registrational III clinical trials. This is a Phase Ib/III study in China and the U.S., and currently in Phase Ib stage in China and the U.S. with patients enrolling. We plan to complete the Phase Ib part in China and the U.S. with preliminary results in the second quarter of 2023 and initiate the MRCT Phase III study in China and the U.S. in the second half of 2023, with top-line results expected in the first half of 2025 and NDA submissions to the FDA and the NMPA in the second half of 2025.
- (6) This is a Phase I/II study of LAE001 for mCRPC conducted only in China. We completed the Phase I study of LAE001 for mCRPC in China on September 13, 2021. We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC. As part of our clinical development strategy for LAE001 in prostate cancer and based on the clinical data from trials on mCRPC, we plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S. and apply the NDA for mHSPC with the NMPA and the FDA in 2027.
- (7) LAE003 has been conducted in several Phase I, Phase II clinical trials in various cancer indications prior to our in-licensing. We plan to repurpose the drug for rare disease indications with partners.

Glossary & abbreviations:

PROC: platinum-resistant ovarian cancer; mCRPC: metastatic castration-resistant prostate cancer; mHSPC: metastatic hormone-sensitive prostate cancer; ER: estrogen receptor; TNBC: triple negative breast cancer; HHT: hereditary hemorrhagic telangiectasia

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CLINICAL STAGE CANDIDATES

Core Product LAE002: An ATP Competitive AKT Inhibitor

Overview

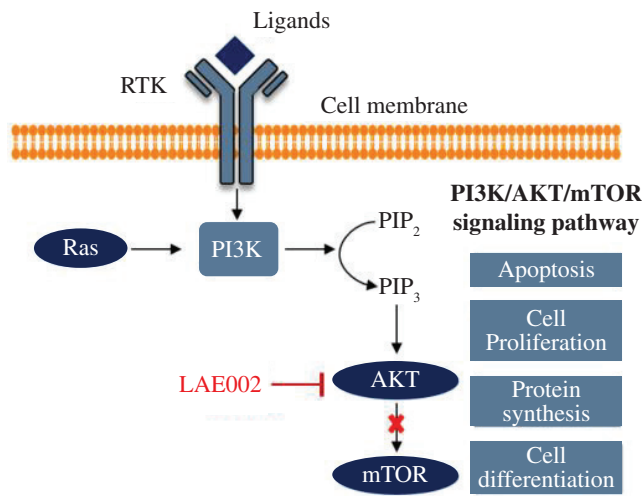
LAE002 is an ATP competitive AKT inhibitor. We in-licensed LAE002 from Novartis in 2018. Prior to our in-licensing, 11 clinical trials had been conducted to demonstrate the safety and efficacy profiles of LAE002 by Novartis and GSK plc. In particular, in a Phase I/II study conducted by Novartis, LAE002 showed potential anti-tumor efficacy in PROC patients. In pre-clinical studies, LAE002 has demonstrated its ability to restore platinum/paclitaxel sensitivity in PROC cell lines. After the in-licensing, we also identified the therapeutic potential of combining LAE002, prednisone and LAE001 and observed their synergistic anti-tumor efficacy in mCRPC patients as second- to fourth-line treatments. According to Frost & Sullivan, there are two AKT inhibitors that have entered registrational clinical trials globally.

Mechanism of Action

AKT is a serine/threonine-protein kinase with three isoforms (AKT1, AKT2 and AKT3) that participate in multiple pathways regulating several cellular processes, including survival, proliferation, tissue invasion, and metabolism. Aberrant activation of the AKT pathway occurs in almost every type of human malignancy, suggesting that deregulation of these pathways may be required for carcinogenesis. The importance of AKT-mediated pathways in tumor proliferation and survival renders AKT kinases promising targets for therapeutic intervention. Somatic activation of the PI3K/AKT signaling pathway most commonly occurs through activating mutations in PIK3CA (which encodes the catalytic p110 α kinase subunit) or through loss-of-function mutations, deletions or promoter methylation silencing of the tumor suppressor gene PTEN (a negative regulator of PI3K). Less frequently, mutations in AKT (e.g., AKT1 E17K) can be a transforming and potentially targetable event across various solid tumors. Non-clinical data suggest that blocking AKT activity can inhibit the proliferation of tumor cells, and may either induce an apoptotic response or sensitize tumors to undergo apoptosis in response to other cytotoxic agents. LAE002 is an oral, low nanomolar pan-AKT kinase inhibitor that has been shown to inhibit the proliferation of a range of tumor cell lines from multiple histologies, including breast, hematological, colon, ovarian, and prostate. Resistance to cytotoxic chemotherapy may be mediated by various mechanisms, including induction of AKT activity, which leads to a pro-survival/anti-apoptotic state.

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The diagram below sets forth the mechanism of action of LAE002.



Notes: RTK: receptor protein tyrosine kinase; mTOR: mammalian target of rapamycin; PIP₂: phosphatidylinositol(4,5) bisphosphate; PIP₃: phosphatidylinositol-3,4,5-triphosphate

Source: Frost & Sullivan analysis

Market Opportunity and Competition

Market Opportunities of LAE002 in Combination with Chemotherapy for PROC

According to Frost & Sullivan, the global and China incidence of ovarian cancer is expected to increase from 319.8 thousand and 56.2 thousand in 2021 to 374.2 thousand and 62.7 thousand in 2030 respectively. The current SOC mainly consists of debulking surgery and platinum-based chemotherapy. Although platinum-based chemotherapy is effective at inducing an initial response, more than 80% of initially responding tumor will recur, and resistance to platinum-based therapy will eventually emerge. PROC is broadly defined as primary ovarian cancer recurrence within six months of completing platinum-based chemotherapy, either in the primary or recurrent setting.

Many patients continue to respond to second-line platinum-based chemotherapy, and following the response, the guideline-recommended approach for many patients is surveillance, monitoring patients for disease progression and managing their symptoms. After relapse, it is observed that patients respond moderately or poorly to subsequent chemotherapy, with later lines of therapy leading to progressively shorter treatment-free intervals.

We are currently evaluating LAE002 in combination with chemotherapy for PROC, which has shown favorable efficacy and safety profiles. We believe LAE002 in combination with chemotherapy has the potential to be the SOC in second-line treatment for PROC.

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Market Opportunities of LAE002 in Combination with LAE001 + prednisone or Chemotherapy for mCRPC

According to Frost & Sullivan, the global and China incidence of prostate cancer is expected to increase from 1,414.3 thousand and 114.3 thousand in 2020 to 1,815.1 thousand and 199.3 thousand in 2030, respectively. Most of the prostate cancer patients receiving androgen deprivation therapy eventually experience disease progression and develop CRPC within a median of 18 to 24 months from receiving the therapy, and a substantial majority of CRPC will be developed into mCRPC.

The current treatments for mCRPC can be broadly classified into four categories based on their mechanisms of action: (i) anti-microtubule drugs such as docetaxel. Docetaxel acts mainly through the suppression of microtubule dynamic assembly and disassembly. Docetaxel has shown relatively more serious side effects as a chemotherapy drug, including allergic reactions, myelosuppression, digestive tract reactions, fluid retention and angioedema, cardiovascular toxicity, fatigue and tearing; (ii) radiation therapies such as xofigo (Radium 223 dichloride), an alpha particle-emitting pharmaceutical, which is a radiotherapeutic drug that the FDA only approved for the treatment of mCRPC with bone metastases. It may not be suitable for treating mCRPC patients with visceral metastases; (iii) CYP17A1 enzyme irreversible inhibitors such as abiraterone; and (iv) AR inhibitors such as enzalutamide.

The second-generation anti-androgen agent enzalutamide has been approved for the treatment of mCRPC, in both post- and pre-docetaxel settings, due to the significant improvement in overall survival rate. More recently, enzalutamide also showed impressive results in the treatment of men with non-mCRPC. Unfortunately, not all patients with mCRPC are responsive to enzalutamide, and even in responders, benefits are limited by the development of drug resistance, which may be caused by PTEN/PIK3CA/AKT alterations. We are evaluating the combination therapy of LAE002 with LAE001 and prednisone or LAE002 with chemotherapy for drug-resistant mCRPC patients, which is intended to benefit patients with PTEN/PIK3CA/AKT alterations.

Market Opportunities of LAE002 in Combination with Immune Checkpoint Inhibitors (ICIs) for Multiple Solid Tumors

In the cancer-immunity cycle, the immune checkpoint proteins act as accomplices to help tumors resist immunity-induced apoptosis and promote tumor progression. Although ICIs have been approved for the treatment of a variety of cancer indications worldwide, only a limited proportion of patients would respond to immunotherapies. For instance, the objective response rate to PD-1/PD-L1 therapy was 30-45% in melanoma, 15-20% in NSCLC, 13% in head and neck carcinoma, and 22-25% in kidney cancer. This necessitates an improved immunotherapy regimen that could further exploit the immune system for cancer treatment. As a serine/threonine kinase, AKT is viewed as a potential new target for cancer treatment. The results of multiple pre-clinical studies have shown that inhibiting AKT can restore the sensitivity of cancer cells to oncology therapies.

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Among these solid tumors, TNBC is a type of breast cancer that is tested estrogen receptor (ER) negative, progesterone receptor (PR) negative and human epidermal growth factor receptor 2 (HER2) negative based on immunohistochemistry (IHC). It is characterized by a shorter overall survival rate and an early peak in distant recurrences three years after diagnosis. According to Frost & Sullivan, the global incidence of TNBC increased from 306.7 thousand in 2017 to 345.2 thousand in 2021 at a CAGR of 3.0%, and the incidence of TNBC in China increased from 47.3 thousand in 2017 to 50.4 thousand in 2021 at a CAGR of 1.6%. Currently, TNBC is primarily treated with systemic therapy (chemotherapy), ICIs and antibody-drug conjugates. In the early study, the ORR of the ICIs treated PD-L1 expression group (CPS \geq 10) is 52.7% only, indicating there is still a large proportion of patients who do not respond to ICIs (initial resistance). Although pembrolizumab treatment has improved median PFS in PD-L1 expression group for patients with metastatic TNBC (9.7 months in the pembrolizumab treatment group vs. 5.6 months in the placebo group), the initial responders eventually develop resistance to ICIs therapy (secondary resistance). Therefore, both primary- and secondary-resistant to ICI treatment account for the majority of TNBC patients. Our combination therapy of LAE002 and LAE005 is expected to improve the clinical efficacy of ICIs by reducing the AKT activity in cancer cells and also selectively activated T-cells, which can suppress tumor growth and reduce metastasis.

We are currently evaluating the efficacy and safety of the combination of LAE002 and sintilimab or ICIs in patients with specific types of PD-1/PD-L1 drug-resistant solid tumors. We believe our combination therapy will provide an innovative treatment option for patients with solid tumors who are resistant to treatment with PD-1/PD-L1 inhibitors.

Market Opportunities of LAE002 in Combination with Estrogen Receptor Antagonists for HR+/HER2- Breast Cancer

According to Frost & Sullivan, it is estimated that 60% of patients with breast cancer have HR+/HER2- molecular signature in China. The treatment and management of HR+/HER2- breast cancer largely depend on early diagnosis and timely medical intervention. The endocrine/anti-estrogen therapies in combination with CDK4/6 inhibitors have emerged as first- and second-line treatment for patients with HR+/HER2- breast cancer. However, 15–20% of tumors are intrinsically resistant to treatment, and another 30–40% acquire resistance to treatment over time. Combination therapies based on LAE002 and estrogen receptor antagonists are being explored in clinical trials in patients with various types of drug-resistant HR+/HER2- breast cancer. We believe that the new treatment options will be well-positioned to capture the large therapeutic potential and opportunity and address unmet medical demands of HR+/HER2- breast cancer.

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Competitive Landscape

According to Frost & Sullivan, no AKT inhibitor candidates are currently approved for commercialization globally. A summary of the global competitive landscape of AKT inhibitors under clinical development for cancer, as well as their indications of interest, is set forth below:

Pipeline Globally				
INN/Drug Code	Company	Phase*	First Post Date**	Indication***
Capivasertib	AstraZeneca	III	2019/6/25	Prostate Cancer (III, HSPC), locally advanced or metastatic breast cancer (III), triple negative breast neoplasms (III), Non-Hodgkin Lymphoma (II), endometrial cancer (II), meningioma (II)
LAE002 (Afuresertib)	Laekna	II (Registrational)	2020/5/5	PROC (II), mCRPC(II), Locally advanced or metastatic HR+/HER2-breast cancer (Ib/II), PD-1/PD-L1 inhibitor resistant solid tumor (I/II)
Ipatasertib	Roche	II	2020/07/13	NSCLC (II), gastric cancer (II), ovarian cancer (II, R/R epithelial OC), glioblastoma multiforme (I/II), endometrial cancer (I/II)
TAS-117	Taiho Oncology	II	2021/2/25	Advanced or metastatic solid tumors (excluding primary brain tumors) harboring germline PTEN inactivating mutations
M2698	EMD Serono	I	2013/10/29	Solid tumors
TAS0612	Taiho Oncology	I	2020/10/14	Advanced or metastatic solid tumors
WGI-0301	HaichangBiotech	I	2022/3/07	Advanced Solid Tumors

Notes:

- * Phase refers to the drug’s most advanced phase stage of all ongoing studies.
- ** First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced. Information as of March 6, 2023.
- *** The chart shows cancer indications only.

Source: ClinicalTrials.gov, Frost & Sullivan analysis

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The following table presents the status of AKT inhibitor candidates at clinical-stage in China:

Pipeline in China				
INN/Drug Code	Company	Phase*	First Post Date**	Indication***
Capivasertib	AstraZeneca	III	2020/10/9	Metastatic CSPC (III), Metastatic CRPC (III), TNBC (III), HR+/HER2-Locally Advanced or Metastatic Breast Cancer (III)
LAE002 (Aføresertib)	Laekna	II (Registrational)	2020/11/19	PROC (including fallopian tube carcinoma and primary peritoneal carcinoma) (II), TNBC (I/II), HR+/HER2- Locally Advanced or Metastatic Breast Cancer (Ib/III), PD-1/P1-L1 resistant solid tumor (I/II)
NTQ1062	Chia Tai Tianqing	I	2021-08-18	Advanced solid tumor

Notes:

- * Phase refers to the drug’s most advanced phase stage of all ongoing studies.
- ** First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced. Information as of March 6, 2023.
- *** The chart shows cancer indications only.

Source: CDE, Frost & Sullivan analysis

The following sets forth the global and China competitive landscape of our Core Product LAE002:

AKT Targeting Drug Clinical Data for Prostate Cancer

Company	Drug	NCT number	Phase	Indication	No. of patients	Treatment Line	Intervention/ Treatment	Median Follow-up Duration (month)	Median Overall Survival (month)	Median Progression-Free Survival (month)	Objective Response Rate	Adverse Event Rate (≥G3)
Roche	Ipatasertib	NCT03072238	III	mCRPC	1101	1L	Ipatasertib + Abiraterone	19.0	NA	18.5 (PTEN loss tumor by immunohistochemistry population) 19.2 (intention-to-treat population)	61%	70%
		NCT01485861	I/II	CRPC	253	2L	Ipatasertib + Abiraterone	NA	400mg – 18.92 200mg – 21.5	400mg ipatasertib – 8.18 200mg ipatasertib – 8.31	400mg – 32.4% 200mg – 23.1%	400mg – 64.3% 200mg – 50.6%
AstraZeneca	Capivasertib	NCT04493853 (Ongoing)	III	HSPC	1000	1L	Capivasertib + Abiraterone	NA	NA	NA	NA	NA
		NCT02121639 (ProCAID)	II	mCRPC	150	≥1L	Capivasertib + Docetaxel	23.7	31.2	7.0	NA	62.2%
		NCT02525068	I	mCRPC	15	≥2L	Capivasertib + Enzalutamide	NA	NA	NA	20%	NA
		NCT04087174	I	mCRPC	15	≥2L	Capivasertib + Abiraterone	NA	NA	NA	20%	NA
Laekna	LAE002 (Aføresertib)	NCT04060394*	I/II	mCRPC	15	≥2L	LAE001 or docetaxel/ prednisone + afuresertib	12.5	NA	NA	NA	67%

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Note:

- * The results are from the completed Phase I study, and Phase II study is ongoing.

Only trials with results published by March 6, 2023 were included. Trial data were obtained from the literature and public information, not head-to-head trials, and comparisons are for informational purposes only. AstraZeneca is currently conducting a Phase III clinical trial of capivasertib for mHSPC.

AKT Targeting Drug Clinical Data for PROC

Company	Drug	NCT number	Phase	Indication	No. of patients enrolled	Treatment Line	Intervention/ Treatment	Median Follow-up Duration (month)	Median Overall Survival (month)	Median Progression-Free Survival (month)	Overall Response Rate	Adverse Event Rate (≥G3)
Laekna	LAE002 (Afuresertib)	NCT01653912	I/II	PROC	59	≥2L	Afuresertib + Carboplatin + Paclitaxel	NA	NA	7.1	32.1% (RECIST) 52% (CA-125)	76%
		NCT04374630* (Ongoing)	II	PROC	61	≥2L	Afuresertib + Paclitaxel	NA	NA	NA	33%	NA

Note:

- * Information as of March 6, 2023.

Only trials with results published by March 6, 2023 were included. Trial data were obtained from the literature and public information, not head-to-head trials, and comparisons are for informational purposes only.

AKT Targeting Drug Clinical Data for TNBC

Company	Drug	NCT number	Phase	Indication	No. of Patients	Treatment Line	Intervention/ Treatment	Median Follow-up Duration (month)	Median Overall Survival (month)	Median Progression-Free Survival (month)	Objective Response Rate	Adverse Event Rate (≥G3)
Roche	Ipatasertib	NCT02162719 (LOTUS)	II	TNBC	166	1L	Ipatasertib + Paclitaxel	19.0	25.8m	6.2m	40%	28% (SAE)
		NCT03337724 (IPATunity130)	III	TNBC (cohort A), HR+HER2 - BC, cohort B)	cohortA - 255	≥1L	Ipatasertib + Paclitaxel	NA	NA	7.4	39%	46%
AstraZeneca	Capivasertib	NCT02423603 (PAKT)	II	TNBC/mBC	140	1L/2L	Capivasertib + Paclitaxel	18.2	19.1	5.5 (intention-to-treat subgroup) 7.6 (PIK3CA/ AKT1/ PTEN - Altered subgroup)	34.8% (intention-to-treat subgroup) 35.3% (PIK3CA/ AKT1/ PTEN - Altered subgroup)	54%
		NCT03742102 (BEGONIA)	I/II	mTNBC	220 (E)	1L	Capivasertib + durvalumab + paclitaxel (Arm2)	NA	NA	NA	53.5%	73%
		NCT03997123 (CAPitello-290)	III	TNBC	800 (E)	≥1L	Capivasertib + Paclitaxel	NA	NA	NA	NA	NA

Note: Information as of March 6, 2023. Only trials with results published by March 6, 2023 were included. Trial data were obtained from the literature and public information, not head-to-head trials, and comparisons are for informational purposes only. The Phase III trial of capivasertib for TNBC is ongoing.

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AKT Targeting Drug Clinical Data for HR+/HER2-BC

Company	Drug	NCT number	Phase	No. of patients	Indication	Treatment Line	Intervention/ Treatment	Median Follow-up Duration (month)	Median Overall Survival (month)	Median Progression-Free Survival (month)	Objective Response Rate	Adverse Event Rate (≥G3)
Roche	Ipatasertib	NCT03337724 (IPATunity130)	III	146	TNBC (cohort A), HR+HER2-mBC, cohort B)	1L	Ipatasertib + Paclitaxel	12.9	NA	9.3	47%	55%
		NCT03959891	Ib	60	HR+/HER2- mBC	≥2L	Fulvestrant + Ipatasertib + Palbociclib	NA	NA	NA	17%	NA
AstraZeneca	Capiasertib	NCT04305496 (CAPItello-291)	III	834	HR+/HER2- mBC	≥1L	Capiasertib + Fulvestrant	NA	NA	7.2	22.9% (28.8% in AKT pathway-altered population)	Diarrhea-9.3%, maculopapular rash-6.2%, rash-5.4%, hyperglycemia 2.3%, stomatitis 2.0%
		NCT01992952	II	140	ER+mBC after AI	≥2L	Capiasertib + Fulvestrant	4.9	23.7m	10.3m	29%	NA

Note:

* Information as of March 6, 2023.

Only trials with results published by March 6, 2023 were included. Trial data were obtained from the literature and public information, not head-to-head trials, and comparisons are for informational purposes only. The Phase III trial of capivasertib for HR+/HER2- is ongoing.

Source: clinical trials, literature review, Frost & Sullivan analysis

AKT Targeting Drug Clinical Data – Other Indications

Company	Drug	NCT number	Phase	No. of patients	Indication	Treatment Line	Intervention/ Treatment	Median Follow-up Duration (month)	Median Overall Survival (month)	Median Progression-Free Survival (month)	Objective Response Rate	Adverse Event Rate (≥G3)
Roche	Ipatasertib	NCT01562275	Ib	66	Solid tumors, Expansion in PTEN deficient, TNBC, or endometrial CA	≥1L	Ipatasertib + Cobimetinib	NA	NA	NA	5%	NA
		NCT01362374	I	122	Solid tumors	≥1L	Ipatasertib + A docetaxel; B mFOLFOX6; C paclitaxel; D enzalutamide	NA	NA	NA	NA	A – 77.8% B – 76.5% C – 51.9% D – 44.1%
		NCT01090960	I	52	Solid tumors	≥2L	Ipatasertib	NA	NA	NA	ORR 0% DCR 34%	Total NA; Grade 3 diarrhea – 17.2%
AstraZeneca	Capiasertib	NCT02338622	I	56	Solid Tumors	≥2L	Capiasertib + Olaparib	NA	NA	NA	25%	NA
		NCT02208375	I/II	30	TNBC, Ovarian, primary peritoneal, fallopian tube, or Endometrial	≥1L for metastasis disease; ≥2L for others	Capiasertib + Olaparib	NA	NA	NA	24% overall; 50% endometrial	NA
		NCT01226316	I	Part A & B – 90 Part C – 59	Solid tumors + PIK3CA mutation	≥2L	Capiasertib	NA	NA	NA	ORR 0%; DCR 30%	Total NA; 20% Hyperglycemia
Taiho Oncology	TAS-117	NCT03017521	II	13	Solid tumors	≥2L	TAS-117	6.6	4.8	1.4	8%	15%
EMD Serono	M2698	NCT01971515	I	101	Solid tumors	≥2L	M2698 + tamoxifen	NA	NA	5.5	NA	19%
Laekna	LAE002 (Afuersertib)	NCT01476137	I	20	Solid Tumors + Myeloma	≥1L	Afuersertib + Trametinib				5%	
		NCT00881946	I/II	73	AML, ALL/CLL, NHL, HL, LCH, MM	≥2L	Afuersertib	NA	NA	NA	8.8% (MM)	NA

Note: Information as of March 6, 2023. Only trials with results published by March 6, 2023 were included. Trial data were obtained from the literature and public information, not head-to-head trials, and comparisons are for informational purposes only.

Source: clinical trials, literature review, Frost & Sullivan analysis

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Competitive Advantages

High Potency and Selectivity

LAE002 is a potent pan-AKT inhibitor that inhibits all three AKT isoforms (AKT1, AKT2 and AKT3). Currently, there are two AKT inhibitors in the late stage clinical development for anti-cancer treatment in China, namely LAE002 and AstraZeneca's capivasertib. The following table sets forth a comparison of potency, PK/PD and *in vivo* efficacy of LAE002, ipatasertib and capivasertib on the inhibition of AKI in the pre-clinical studies. The results shows that LAE002 has a strong potency of AKT inhibition comparable to ipatasertib and capivasertib.

	LAE002 afuresertib (ATP Competitive) Laekna	GDC-0068 ipatasertib (ATP Competitive) Roche	AZD-5363 capivasertib (ATP Competitive) AstraZeneca
AKT inhibition (IC ₅₀)	0.08 nM (AKT1) 1.35 nM (AKT2) 16.67 nM (AKT3) 0.2 nM (AKT1E17K)	0.21 nM (AKT1) 26.73 nM (AKT2) 129.40 nM (AKT3)	0.25 nM (AKT1) 1.38 nM (AKT2) 41.59 nM (AKT3)
Cellular potency (LNCaP, pPRAS40, IC ₅₀)	237 nM 104 nM	273 nM 157 nM	336 nM 220 nM
PK/PD (pPRAS40 reduction, xenograft)	@ 100 mg/kg, 60% reduction	@ 100 mg/kg (~2.6 uM plasma conc), 87% reduction	@ 300 mg/kg, 90% reduction
<i>In vivo</i> xenograft model efficacy	BT474: 61% TGI @ 100 mg/kg; HCC1954; >100% TGI @ 100 mg/kg; SKOV3: 97% TGI @ 100 mg/kg	PC3 xenograft, 79% TGI @ 100 mg/kg	BT474: 39% TGI @ 100 mg/kg, QD; 80% TGI @ 100 mg/kg, BID

Note: No head-to-head comparison clinical study was conducted between the drug candidates above. Clinical trials of a drug cannot be directly compared to the clinical trials of another drug candidates and may not be representative of the overall data.

Glossary & abbreviation:

IC₅₀: the concentration where half maximal inhibition is reached; conc: concentration

Source: Frost & Sullivan analysis, Company data

In the further investigation of LAE002 inhibition on a broad panel of 49 *in vitro* expressed human protein kinases, LAE002 minimally inhibited 12 other kinases (IC₅₀ = 1 to 10 μM) and potently inhibited four additional kinases including: PKA (1.2 nM), ROCK1 (110 nM), p70S6K (200 nM), and RSK (320 nM). When LAE002 was evaluated against a panel of 230 unique kinases in an additional experiment, 0.5 μM LAE002 demonstrated over 50% inhibition of 18 kinases, including, among other, members of the AGC kinase family such as PKA, PKC, and PKG. In a further investigation of the inhibition of the PKC and PKG kinase isoforms, LAE002 inhibited PKG1α, PKG1β, PKCη, PKCβ1, PKCθ and PKCδ with IC₅₀ values of 0.9, 4.0, 210, 430, 510, and 1,000 nM, respectively. These pre-clinical results support the low off-target activities for LAE002 that have been translated into relatively low rate of adverse events typically reported in other AKT inhibitors clinical trials, such as hyperglycemia, diarrhea, skin rashes, etc.

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Aeterna Zentaris has conducted two Phase III clinical trials of perifosine, another AKT inhibitor, for colon cancer and relapsed and refractory multiple myeloma in combination with bortezomib-dexamethasone. In 2012, it was announced that perifosine failed the Phase III clinical trial for treatment of colon cancer because of the lack of significant difference in the primary endpoints, including the median overall survival and median progression free survival between the perifosine treatment group and the placebo group. In 2013, Aeterna Zentaris announced the discontinuation of Phase III clinical trial of perifosine for the treatment of relapsed and refractory multiple myeloma because it was highly unlikely that the study would achieve a significant difference in its primary endpoint for the progression free survival. However, we believe it will not affect our clinical development plan of LAE002 based on the following: (i) according to Frost & Sullivan, the selectivity of AKT inhibitors is closely related to its therapeutic effect on cancer. LAE002's selectivity is much higher than perifosine. Our pre-clinical studies showed that LAE002 can directly inhibit PI3K or PDK1 in enzymatic assays while perifosine cannot and (ii) LAE002 has different target indications compared to perifosine and the therapeutic effect of AKT inhibitors varies in different cancers.

Anti-Tumor Efficacy and Favorable Safety Profile

According to Frost & Sullivan, there are two AKT inhibitors that have entered registrational clinical trials globally. Roche's Phase III clinical trials of ipatasertib were discontinued. LAE002 demonstrated its advantages in three fields, including potency, tumor inhibition exposure and toxicity, as compared with the other two AKT inhibitors (i.e., Roche's ipatasertib and AstraZeneca's capivasertib) from early phase clinical trials, based on public data (not a head-to-head study), as further elaborated in the table below.

		LAE002 afuresertib (ATP Competitive)	GDC-0068 ipatasertib (ATP Competitive)	AZD-5363 capivasertib (ATP Competitive)
Study Ph1		25, 75, 100, 125, 150 mg QD	100, 200, 400, 600, 800 mg QD	80 - 600 mg BID Continued dosing 480, 640 mg BID 4d/7d dosing 640, 800 mg BID 2d/7d dosing
Recommended Ph2 Dose (RP2D)		125 mg QD	600 mg QD	480 mg BID 4/7 days
Cancer Type & Patients Enrolled		Hematologic tumors 73 pts	Solid tumors 52 pts (breast cancer – 31%, colorectal cancer – 27%, prostate cancer – 12%, chondrosarcoma – 4%, ovarian cancer – 4%, other – 22%)	Solid tumors Part A & B - 90 pts (colorectal – 29%, pleura – 8%, lung – 7%, cervix – 6%, colon – 6%, other – 45%) Part C – 59 pts (solid tumor patients with PIK3CA mutation)
AUC0-24 ng-h/mL /Cmax ng/mL /Ctrough ng/mL	Initial State	AUC 2378/ Cmax 175	AUC 2670/ Cmax 488	n/a
	Steady State	AUC 7405/Cmax 531/Ctrough259 (Cycle 1 day 8)	AUC 4450/Cmax 748 (Cycle 1 Day 15)	AUC 7952/Cmax 1426/Ctrough 357 (Day 4 on 4/7d)
Major Adverse Events @RP2D >= G3		<u>G3 (all dose level)</u> 6.8% Neutropenia 4.1% Rash 2.7% Odynophagia 2.7% Fatigue 0% Hyperglycemia	<u>G3</u> 17.2% Diarrhea 3.4% Hyperglycemia 3.4% Hyperphosphatemia 3.4% Asthenia	<u>G3 & G4</u> 20% Hyperglycemia 12% Diarrhea 10% Maculopapular Rash 7% Fatigue 7% Hypokalemia
Efficacy Single Agent		ORR 8.8%, DCR 63% 1 CR, 4 PR, 33 SD all confirmed	ORR not available, DCR 34% 16 SD	ORR not available, DCR 30% 27 SD ORR 5.6%, in PIK3CA mutation pts

Note: No head-to-head comparison clinical study was conducted between the drug candidates above. Clinical trials of a drug cannot be directly compared to the clinical trials of another drug candidates and may not be representative of the overall data.

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This table includes information summarized from selected Phase I clinical trials conducted for the three AKT inhibitors. We believe the clinical trials selected are the most relevant clinical trials for the purpose of comparison because each of the clinical trials selected used the relevant AKT inhibitor as monotherapy and assessed a wide range of doses despite that they were conducted for different indications. As the first-in-human studies for LAE002, ipatasertib and capivasertib, the ORR and/or other efficacy data listed above from each of such clinical trials were for the whole enrolled patient group of the relevant clinical trial and such data for each cancer type being studied were not available.

Glossary & abbreviation: Ph: Phase; Pts: patients; Cmax: maximum concentration; Ctrough: trough concentration; DCR: disease control rate

Source: Frost & Sullivan analysis, Company data, Spencer et al. 2014, BLOOD 124(14), Saura et al, 2017, Cancer Discovery, Banerji et al, 2018, Clin Cancer Res; 24(9)

Synergistic Effects in Combination with Other Therapies

In several clinical trials, the combination of LAE002 with other therapies also exhibits favorable efficacy results, such as the completed Phase II study of LAE002 in combination with carboplatin and paclitaxel for the treatment of PROC sponsored by Novartis and the registrational Phase II MRCT study of LAE002 in combination with paclitaxel for PROC sponsored by us. For details of efficacy profiles, see “– Summary of Clinical Trial Results” section below.

Phase II clinical studies conducted by multinational companies, including Roche and AstraZeneca, have demonstrated favorable efficacy of their combination therapy of AKT inhibitors (i.e., ipatasertib and capivasertib) in the treatment of HR+/HER2- mBC and TNBC, respectively. We have observed positive preliminary anti-cancer effects with the combination trial of LAE002 plus LAE005 and nab-paclitaxel in TNBC in the Phase I study. Another ongoing combination trial of LAE002 plus estrogen receptor antagonists in HR+/HER2- mBC is expected to achieve comparable clinical efficacy and safety clinical results given LAE002’s similar mechanism of action and safety profiles compared with ipatasertib and capivasertib.

Summary of Clinical Trial Results

The following table sets forth an overview of the key clinical studies of LAE002:

Name of Trial	Trial ID	Sponsor	Site	Design	Study Arm	Status	Competent Authority	Indication	Planned Patient Enrollment	Actual Patient Enrollment
Registrational Phase II MRCT study to assess the efficacy and safety of LAE002 plus paclitaxel versus paclitaxel in patients with PROC	NCT04374630	the Company	U.S. and China	Open-label, randomized, active-controlled trial	Two arms (the combination treatment arm and the paclitaxel treatment arm) for efficacy and safety evaluation	Active, ongoing	FDA and NMPA	PROC	141	134 (as of the Latest Practicable Date)

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Name of Trial	Trial ID	Sponsor	Site	Design	Study Arm	Status	Competent Authority	Indication	Planned Patient Enrollment	Actual Patient Enrollment
Phase I/II study of LAE002 in combination with carboplatin and paclitaxel in subjects with PROC	NCT01653912	Novartis	Australia, Russian Federation and United Kingdom	Open-label trial	Single arm of combination treatment (LAE002 + carboplatin + paclitaxel) for safety, tolerability and efficacy evaluation	Completed	FDA	PROC	59	59 (Data cut-off date is July 1, 2015)
Phase I/II MRCT study of LAE001/prednisone plus LAE002 in patients with mCRPC following SOC treatment	NCT04060394	the Company	Phase I: U.S., Phase II: U.S. and South Korea	Open-label trial	Single arm of combination treatment (LAE001/ prednisone + LAE002) for safety and tolerability evaluation	Phase I: completed Phase II: active, ongoing	Phase I: FDA, Phase II: FDA and Ministry of Food and Drug Safety of South Korea	mCRPC following SOC treatment	Phase I: 24; Phase II: 40;	Phase I: 14 (Data cut-off date is February 2021); Phase II: 34 (as of the Latest Practicable Date)
Phase I/II clinical trial of LAE002 in combination with sintilimab and chemotherapy for PD-1/PD-L1 resistant solid tumors	NCT05383482	the Company	China	Open-label trial	Two arms of combination treatment (LAE002 + sintilimab + nab-paclitaxel and LAE002 + sintilimab + docetaxel) for efficacy and safety evaluation	Active, ongoing	NMPA	PD-1/PD-L1 resistant solid tumors	Phase I: 18-42 Phase II: 50-125	Phase I: 11 (as of the Latest Practicable Date)
Phase I/II clinical trial of LAE002 in combination with LAE005 and nab-paclitaxel for TNBC	CTR20210500, CTR20210475	the Company	China	Open-label, randomized trial	Single arm of combination treatment (LAE002 + LAE005 + nab-paclitaxel) for efficacy and safety evaluation	Active, ongoing	NMPA	TNBC	Phase I: 21 Phase II: 80;	Phase I: 21 (as of the Latest Practicable Date)
Phase Ib/III study evaluating efficacy and safety of LAE002 plus fulvestrant in patients with locally advanced or metastatic HR+/HER2- breast cancer	NCT04851613	the Company	U.S. and China	Phase Ib: open-label trial Phase III: randomized, double-blind, placebo-controlled trial	Single arm of combination treatment (LAE002 + fulvestrant) for efficacy and safety evaluation	Active, ongoing	FDA and NMPA	Locally advanced or metastatic HR+/HER2- breast cancer	Phase Ib: 20	Phase Ib: 15 (as of the Latest Practicable Date)

Registrational Phase II MRCT Study to Assess the Efficacy and Safety of LAE002 Plus Paclitaxel versus Paclitaxel in Patients with PROC Sponsored by us

Overview. This study is an open-label, randomized, active-controlled registrational Phase II MRCT study to assess the efficacy and safety of LAE002 plus paclitaxel versus paclitaxel in patients with PROC. The primary endpoint is the PFS based on response evaluation criteria in solid tumors. This trial is regulated by the FDA and the NMPA.

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Trial design. Approximately 141 patients with PROC are planned to be enrolled and randomized with a 2:1 ratio in an open-label manner to the two arms (94 patients in the combination treatment arm and 47 patients in the paclitaxel treatment arm) for efficacy and safety evaluation. The study will consist of three periods. The first period is a screening period, during which patients are screened for eligibility according to the inclusion and exclusion criteria. The second period is a treatment evaluation period with a randomized, open-label, two-arm parallel design (from starting study treatment until patients have progressive disease, unacceptable toxicity, death, or withdrawal of consent). The PK study will be applied to both the combination treatment and control arms. The third period is a follow-up period.

Trial status. We initiated this study in July 2020. We have generated and are currently analyzing the following data from China and the U.S. We have enrolled a total of 134 subjects as of the Latest Practicable Date, with 90 in arm 1 (LAE002 plus paclitaxel) and 44 in arm 2 (paclitaxel only), and plan to complete enrollment with 141 subjects in March 2023. As of the data cut-off date (February 13, 2022), a total of 61 subjects were randomized with 44 subjects having at least two tumor assessments. Among these subjects, 30 were in arm 1 (LAE002 plus paclitaxel), and 14 were in arm 2 (paclitaxel only). This study is currently ongoing and actively recruiting patients.

Safety data. As of the data cut-off date (February 13, 2022), the most severe common adverse events (reported in $\geq 10\%$ of patients) in both arms were neutrophil count decreased (24.4% vs 33.3%), white blood cell count decreased (19.5% vs 16.7%) and anemia (9.8% vs 11.1%).

Efficacy data. As of the data cut-off date (February 13, 2022), a total of 44 subjects were evaluated for treatment response. There are 30 subjects in arm 1 (LAE002 plus paclitaxel) and 14 subjects in arm 2 (paclitaxel alone), respectively. The ORRs in arm 1 and arm 2 are 33% and 14%, respectively, including two subjects who achieved CR in arm 1, eight and two subjects had confirmed PRs in arm 1 and arm 2, respectively, 15 and nine subjects had SD in arm 1 and arm 2, respectively, and four and two subjects had PD in arm 1 and arm 2, respectively.

Phase I/II Study of LAE002 in Combination with Carboplatin and Paclitaxel in Subjects with PROC Sponsored by Novartis

Overview. This study was an open-label, Phase I/II of LAE002 combined with carboplatin and paclitaxel in subjects with platinum-resistant or refractory ovarian cancer. The primary objective of the study was to determine the safety, tolerability and efficacy of the triplet combination. This trial is regulated by the Therapeutic Goods Administration (TGA) in Australia, the Ministry of Health (Minzdrav) in the Russian Federation and the Medicines and Healthcare Products Regulatory Agency in the United Kingdom.

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Trial design. This was an open-label study in subjects with ovarian cancer. Phase I was a 3 + 3 dose-escalation to define an MTD with once-daily LAE002 in combination with carboplatin area under curve (AUC) 5 and paclitaxel 175 mg/m² in an every three-week schedule. Evaluation of available safety data from at least three subjects that had completed three weeks of study was required prior to defining a new dose and starting the next cohort. Phase II was a dose-expansion study and the primary endpoint is ORR.

Trial Status. Novartis initiated this study on November 13, 2012, and completed this study on July 1, 2015. 59 patients were enrolled, including 28 recurrent PROC patients. 29 patients were enrolled in Phase I study, and 30 patients were enrolled in Phase II study.

Safety data. As of the data cut-off date (July 1, 2015), safety data are available for all 59 subjects. All 59 subjects experienced at least one AE related to study treatment, and most AEs were Grade 3 or lower. The blood and lymphatic (37.3%), gastrointestinal (22.0%), and skin (23.7%) system organ classes accounted for most of these higher-Grade TRAEs.

Efficacy data. Of the 28 recurrent PROC subjects enrolled, the ORR shown was 32.1%. PFS was 7.1 months.

Phase III MRCT Study of LAE001/prednisone Plus LAE002 in Patients with mCRPC Following SOC Treatment Sponsored by us

Overview. The Phase I study evaluates LAE001/prednisone plus LAE002 in patients with mCRPC following SOC treatment (androgen/androgen receptor and chemotherapy). The primary endpoint of the Phase I study is the safety and tolerability of LAE001/prednisone and LAE002 as combination therapies. The Phase I trial is regulated by the FDA.

Trial design. The Phase I trial is a dose-escalation study to identify the recommended Phase II dose (RP2D) of LAE001/prednisone plus LAE002 in mCRPC patients. There are two cohorts in the Phase I study. In Cohort 1, LAE001 (75 mg, BID) plus prednisone (5 mg, BID) and LAE002 (100 mg, QD) will be administered in cycles of 28 days. In Cohort 2, LAE001 (75 mg, BID) plus prednisone (5 mg, BID) and LAE002 (125 mg, QD) will be administered in cycles of 28 days.

Trial status. We initiated the Phase I study in December 2019, and completed the Phase I study in February 2021, when all the primary endpoints were met. A total of 14 subjects were enrolled. Among these subjects, eight were enrolled into cohort 1 (LAE001 75 mg BID + prednisone 5 mg BID + LAE002 100 mg QD), and six were enrolled into cohort 2 (LAE001 75 mg BID + prednisone 5 mg BID + LAE002 125 mg QD). Results from the Phase I study are summarized below. FDA has no objection for us to initiate the Phase II study in the U.S. We also received the IND approval to initiate the Phase II study in South Korea in March 2022. We expect to enroll approximately 40 patients and are actively recruiting patients in the Phase II study in the U.S. and South Korea. As of the Latest Practicable Date, we had enrolled 19 patients in the U.S. and 15 patient in South Korea. The Phase II trial is regulated by the FDA and Ministry of Food and Drug Safety of South Korea.

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In the Phase II trial, the anti-tumor efficacy of LAE001/prednisone plus LAE002 will be assessed in mCRPC patients who have progressed on, or who are intolerant of, no more than three prior standard treatments for mHSPC, or nmCRPC, or mCRPC, including at least one anti-androgen treatment and no more than one chemotherapy. The patients will be enrolled for the Phase II study to receive LAE001/prednisone plus LAE002 using RP2D established in the Phase I study. The primary endpoint of the Phase II study is the radiological progression-free survival (rPFS) based on the change in tumor per response evaluation criteria in solid tumors and radiological progression-free survival (rPFS) based changes per prostate cancer working group 3 (PCWG3).

Safety data. For the completed Phase I study, Grade 3 or above AEs were reported in 10 (71.4%) subjects, and drug-related Grade 3 and above AEs were reported in five (35.7%) subjects (one subject with mental status change, two subjects with generalized rash, one subject with alanine aminotransferase (ALT)/aspartate transaminase (AST) increased and one subject with thrombocytopenia). The AE of Grade 4 thrombocytopenia was reported in one (7.1%) subject and was related to LAE002. The dose of LAE001 75 mg BID/prednisone 5 mg BID and LAE002 125 mg QD was determined as the RP2D for the Phase II study. In RP2D cohort, four patients reported Grade 3 AEs, among which one was not related with any study treatment. No Grade 4 or Grade 5 AEs reported in RP2D cohort.

Efficacy data. As of the data cut-off date (February 24, 2022), 14 patients received study treatment for the Phase I study. The median and maximum treatment periods without tumor progression of evaluable patients in RP2D cohort are 8.6 and 15.6 months, respectively. Two patients had a prostate-specific antigen (PSA) response. Among five patients with measurable lesions, one achieved PR and two had SDs.

Phase I/II Clinical Trial of LAE002 in Combination with Sintilimab and Chemotherapy for PD-1/PD-L1 Resistant Solid Tumors Sponsored by us

Overview. This is a Phase I/II study to evaluate the safety and efficacy of LAE002 in combination with sintilimab and chemotherapy to treat certain PD-1/PD-L1 resistant solid tumor patients in China. The primary endpoint of the Phase I dose-escalation study is MTD and RP2D. The primary endpoint of the Phase II is ORR. This study is regulated by the NMPA.

Trial status. We received IND approval for this study from the NMPA in January 2022. We initiated the Phase I study in June 2022. As of the Latest Practicable Date, 11 patients were enrolled. We plan to complete the Phase I study with preliminary results in the fourth quarter of 2023.

Phase I/II Clinical Trial of LAE002 in Combination with LAE005 and Nab-Paclitaxel for TNBC Sponsored by us

Overview. This study is an open-label, randomized parallel Phase I/II clinical trial. Phase I dose-escalation study is to evaluate the safety and efficacy of LAE002 in combination with LAE005 and nab-paclitaxel in advanced solid tumors in China. The Phase II study is to

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evaluate the safety and efficacy of LAE002 in combination with LAE005 and nab-paclitaxel in locally advanced or metastatic TNBC. The primary endpoint of the Phase I study is MTD and RP2D. The primary endpoint of the Phase II study is ORR. This study is regulated by the NMPA.

Trial Status. We initiated this study in July 2021. The Phase I study is currently recruiting patients with positive preliminary anti-cancer efficacy results. As of the Latest Practicable Date, 21 patients were enrolled in the Phase I study.

Phase Ib/III Study Evaluating Efficacy and Safety of LAE002 Plus Fulvestrant in Patients with Locally Advanced or Metastatic HR+/HER2- Breast Cancer Sponsored by us

Overview. This is a Phase Ib/III study to evaluate the efficacy and safety of the combination therapy with LAE002 plus fulvestrant in patients with HR+/HER2- breast cancer who have failed one to two prior lines of endocrine therapy and CDK4/6 inhibitor (up to 1 therapy), and chemotherapy (up to 1 chemotherapy).

Trial Design. The Phase Ib part is a single-arm, open-label, proof-of-concept study to evaluate anti-tumor efficacy, safety, tolerability and pharmacokinetics of the combination therapy of LAE002 plus fulvestrant. The primary endpoint of the Phase Ib part is the investigator-assessed ORR of the LAE002 plus fulvestrant combination therapy in HR+/HER2- breast cancer. 20 patients will be enrolled in this part. There will be a safety run-in period during the first 28-days of treatment (Cycle 1) of the first six enrolled patients to evaluate the safety of the initial treatment doses. Patients will receive LAE002 125 mg oral administration, QD in combination with fulvestrant 500 mg intramuscular injection on day one and day 15 of Cycle 1, and fulvestrant 500 mg intramuscular injection on day one of each subsequent four-week cycle.

The Phase III part is a multi-center, randomized, double-blind, placebo-controlled registrational study with two parallel treatment arms to further assess the anti-tumor efficacy and safety of LAE002 combined with fulvestrant (experimental arm) versus placebo combined with fulvestrant (control arm) in patients with HR+/HER2- breast cancer who have failed 1 to 2 prior lines of endocrine therapy (ET), and/or CDK4/6 inhibitor (up to 1 therapy), and/or chemotherapy (up to 1 chemotherapy). The primary endpoint of the Phase III part is the investigator-assessed PFS of the experimental arm and control arm. The major secondary endpoints include the OS, ORR, DOR, DCR and safety. A total of 252 patients will be randomized in a 1:1 ratio to the two parallel treatment arms, namely LAE002 plus fulvestrant and placebo plus fulvestrant. The treatment doses of the study will be based on doses and schedule established in the Phase Ib part.

Trial status. We initiated the Phase I study in China and the U.S. in May 2022. This study is currently recruiting patients with no preliminary clinical results for analysis. As of the Latest Practicable Date, 15 patients were enrolled.

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Post-Licensing R&D Activities

In the Phase I/II Study of LAE002 in combination with carboplatin and paclitaxel in patients with PROC sponsored by Novartis, as of the data cut-off date (July 1, 2015), all 59 subjects experienced at least one AE related to study treatment, and most AEs were Grade 3 or lower. The blood and lymphatic (37.3%), gastrointestinal (22.0%), and skin (23.7%) system organ classes accounted for most of these higher-Grade TRAEs. Of the 28 recurrent PROC subjects enrolled, the ORR shown was 32.1% and PFS was 7.1 months. The clinical data obtained by Novartis suggest that LAE002 has a manageable safety and favorable safety profile for solid tumors, consistent with AKT pathway inhibition. Based on Novartis’ study, we designed the registrational Phase II MRCT study to assess the efficacy and safety of LAE002 plus paclitaxel versus paclitaxel in patients with PROC. Based on the results of Roche’s AKT inhibitor study for mCRPC and AstraZeneca’s AKT inhibitor study for breast cancer, we designed clinical studies of LAE002 to evaluate its therapeutic potential on the treatment of mCRPC and breast cancer, respectively. We are also evaluating LAE002’s therapeutic potential in PD-1/L1 drug-resistant solid tumors based on the characteristics of AKT pathways.

When we in-licensed LAE002 from Novartis, several clinical trials had been conducted by Novartis to evaluate the safety and efficacy of LAE002. In these trials, LAE002 was generally well-tolerated in patients and exhibited favorable evidence of efficacy. LAE002 was also being evaluated in an ongoing Phase I/II clinical trial combined with carboplatin and paclitaxel in subjects with PROC. Since our in-license of LAE002 from Novartis, we have designed a Phase I/II study of LAE001 and prednisone plus LAE002 or docetaxel/prednisone plus LAE002 in patients with mCRPC following SOC treatment. We have completed the Phase I clinical trial in the U.S. and have initiated the Phase II clinical trial to evaluate LAE002 in combination with other therapies as second-line treatment for various indications in the U.S. and South Korea. We are also conducting another four clinical trials, please see “– Summary of Clinical Trial Results” section for further details. The trial designs of the clinical studies we conducted were different from Novartis’. For these clinical trials and other trials we have initiated for LAE002, our R&D team as the sole sponsor, is responsible for the formulation of trial design and the preparation and management of trial implementation, including the selection of vendors and clinical sites, preparation of standards of practice, guidelines and other documents, provision of training to investigators, screening and recruitment of patients, follow-up visits, collection, verification and analysis of trial data.

Licenses, Rights and Obligations

On May 9, 2018, we entered into a license agreement with Novartis. According to the license agreement, Novartis grants us an exclusive, royalty-bearing, sub-licensable and assignable license regarding the licensed patents and data to develop, use, manufacture or have manufactured and/or commercialize LAE002 in any and all therapeutic, prophylactic and/or diagnostic uses in humans worldwide. For more details, please see “– Collaboration and Licensing Arrangements – Collaboration with Novartis – LAE002 and LAE003 License Agreement” in this section.

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Clinical Development Plan

We have initiated a global MRCT Phase II registrational trial in both the U.S. and China to treat PROC with LAE002, in a combination therapy with paclitaxel. As of the Latest Practicable Date, we had completed more than 95% of enrollment in both the U.S. and China. We aim to make NDA submissions to the FDA and NMPA in the fourth quarter of 2023. If the Phase II study cannot fulfil registrational purposes, we will then conduct a randomized, controlled, double blinded Phase III trial or another equivalent trial subject to our clinical trial results and our communication with the NMPA and the FDA.

We initiated the Phase II clinical trial of the Phase I/II MRCT study of LAE001 and prednisone plus LAE002 or docetaxel/prednisone plus LAE002 in patients with mCRPC following SOC treatment in the U.S. in June 2021. We initiated the same study in South Korea in September 2022. We plan to complete the patient recruitment in both the U.S. and South Korea by March 2023, and obtain the preliminary clinical results from the U.S. and South Korea in the second quarter of 2023. Furthermore, we plan to design a randomized, controlled, double blinded Phase III registrational MRCT or another equivalent MRCT subject to our Phase II clinical trial results and our communication with the NMPA, for the same indication in the U.S., Asia and Europe. We expect to initiate this MRCT in the U.S. first in the second half of 2023 and submit an NDA to the FDA and NMPA in 2025.

In addition, we are also actively exploring to further expand the indication of LAE002. We are collaborating with Innovent in a combination therapy with sintilimab targeting patients with solid tumors with prior PD-1/PD-L1 treatments. We received the IND approval for this Phase I/II study from the NMPA in January 2022 and initiated the Phase I study in June 2022. We plan to complete the Phase I study and the analysis of the preliminary results in the fourth quarter of 2023. We are also conducting a Phase Ib/III trial in China and the U.S. for the treatment of locally advanced or metastatic HR+/HER2- breast cancer with LAE002, in a combination therapy with fulvestrant. We plan to complete the Phase Ib part in China and the U.S. and the analysis of the preliminary results in the second quarter of 2023 and initiate the MRCT Phase III study including China and the U.S. in the second half of 2023, with top-line results expected to become available in the first half of 2025 and NDA submissions to the FDA and the NMPA in the second half of 2025.

We are aware that a Phase III clinical trial of capivasertib, an AKT kinase inhibitor, has met primary endpoints in HR+ HER2- advanced or metastatic breast cancer. Although capivasertib is taking a randomized, controlled, double blinded approach in its registrational trial, we believe that risk of being requested by the NMPA to modify the design of our clinical trial is low on the following basis: (i) our trial design has already been approved by the NMPA for registrational purpose and is non-inferior to that of capivasertib, and (ii) our preliminary clinical results are favorable and it is highly likely that the endpoints of the Phase Ib/III clinical study will be met without a need to conduct additional studies. We believe that this will not materially impact our development and commercialization plan for LAE002 as we have taken the advancement of capivasertib's R&D progress into consideration when formulating such a plan for LAE002.

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Material Communications with Competent Authorities

For the registrational Phase II MRCT study to assess the efficacy and safety of LAE002 plus paclitaxel versus paclitaxel in patients with PROC sponsored by us, we filed an IND application to the FDA in October 2019 and received its approval after its 30-days review. We filed another IND application to the NMPA in June 2020 and received its approval in August 2020. According to the written confirmation issued by FDA in February 2019 and by NMPA in February 2020, FDA and NMPA agreed that this global MRCT Phase II trial would be the registrational trial for the registration purpose, on the basis that: (i) our pre-clinical studies suggest that increased AKT activity could be a primary mechanism of resistance to platinum and taxane therapy, and that resistance can be reversed by AKT inhibitors; and (ii) the preliminary efficacy of paclitaxel, carboplatin and LAE002 combination was observed in PROC patients from previous proof-of-concept clinical studies and the treatment effect of paclitaxel and LAE002 combination was shown in a previous gastric cancer study, our Phase II study is appropriate to support product registration under accelerated approval if our Phase II clinical results can demonstrate an improvement in PFS over SOC considering the poor prognosis of PROC patients with their huge and urgent unmet medical needs for new treatments.

For the Phase I/II MRCT study of LAE001 and prednisone plus LAE002 or docetaxel/prednisone plus LAE002 in patients with mCRPC following SOC treatment sponsored by us, we filed an IND application to the FDA for Phase I/II study in May 2019 and received its approval after its 30-days review. We completed the Phase I study in February 2021. FDA has no objection for us to initiate the Phase II MRCT study of LAE001 and prednisone plus LAE002 or docetaxel/prednisone plus LAE002 in patients with mCRPC following SOC treatment in the U.S.. We received another approval from Ministry of Food and Drug Safety of South Korea to initiate a Phase II study of LAE001 and prednisone plus LAE002 or docetaxel/prednisone plus LAE002 in patients with mCRPC following SOC treatment in South Korea in March 2022.

For the Phase I/II study of LAE002 combined with sintilimab for PD-1/PD-L1 resistant solid tumors sponsored by us, we filed an IND application in terms of the trial design for the above study to the NMPA in November 2021, and subsequently, in January 2022, we received its IND approval from the NMPA.

For the Phase I/II study of LAE002 combined with LAE005 and nab-paclitaxel for TNBC sponsored by us, we filed an IND application in October 2020, we received its IND approval from the NMPA in December 2020.

For the Phase Ib/III study evaluating efficacy and safety of LAE002 plus fulvestrant in patients with locally advanced or metastatic HR+/HER2- breast cancer sponsored by us, we filed an IND application to FDA in May 2021. FDA has approved this study after its 30-day review. We also filed this IND for MRCT to the NMPA in June 2021 and received its IND approval from the NMPA in August 2021.

We had not received any relevant regulatory agency's concerns or objections to our clinical development plans as of the Latest Practicable Date, nor did any material unexpected or adverse changes had occurred since the date of issue of relevant regulatory approvals for LAE002.

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WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET LAE002 SUCCESSFULLY.

Core Product LAE001: A Dual CYP17A1/CYP11B2 Inhibitor

Overview

LAE001 is an androgen synthesis inhibitor that inhibits both CYP17A1 and CYP11B2. We in-licensed LAE001 from Novartis in 2017. According to Frost & Sullivan, LAE001 is the only dual CYP17A1/CYP11B2 inhibitor in clinical trials for the treatment of prostate cancer globally. As a dual CYP17A1/CYP11B2 inhibitor, LAE001 may eliminate the need for long-term prednisone use under abiraterone acetate regimens, thereby reducing the risk of cardiovascular toxicity and hepatotoxicity. Our completed Phase I study showed safety, preliminary anti-tumor efficacy and clinical benefits in mCRPC patients. We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC. As part of our clinical development strategy for LAE001 in prostate cancer and based on the clinical data from trials on mCRPC, we plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S. and apply the NDA for mHSPC with the NMPA and the FDA in 2027.

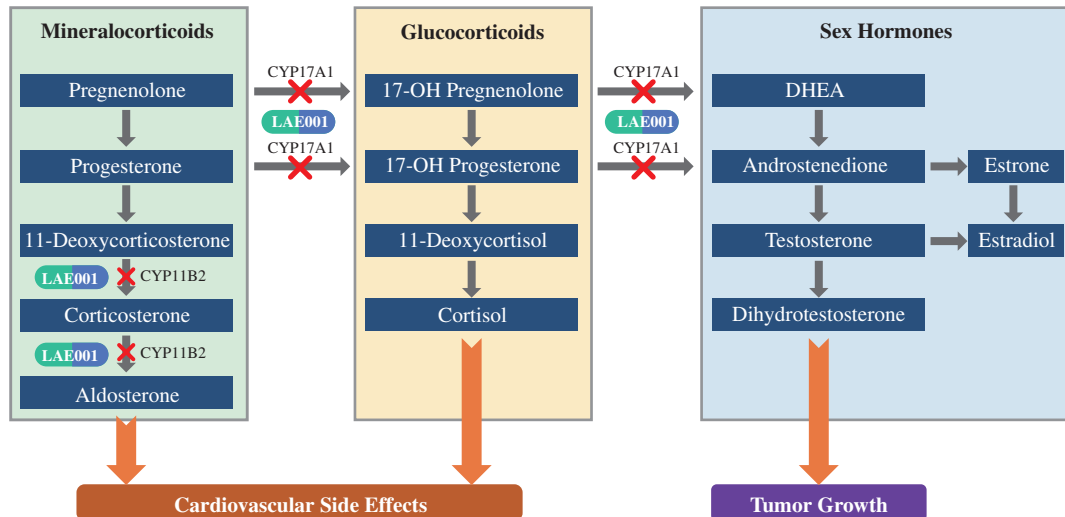
Mechanism of Action

Androgens are closely related to the growth of the prostate and the occurrence of prostate cancer. Therefore, endocrine therapy has become an effective treatment for prostate cancer. Endocrine therapy includes estrogen therapy, gonadotropin-releasing hormone analog therapy, gonadotropin – releasing hormone antagonist therapy, and androgen suppressive therapy, among which the androgen suppressive therapy can be used alone for the treatment of early-stage prostate cancer or combined with surgery for adjuvant therapy. Androgen therapy is one of the main methods of clinical treatment of prostate cancer, which involves the intervention of the androgen signaling pathway. CYP11B2 enzyme is one of the enzymes in the steroidogenesis pathway and is responsible for the catalysis of last three steps in the aldosterone biosynthetic cascade. It is encoded by the CYP11B2 gene located on human chromosome 8q21-22. The genetic element of cardiovascular disorders has emerged as a risk factor for the progression of these disorders. Among these genetic elements, CYP11B2 genetic variants and haplotypes play a registrational role in the susceptibility, progression, survival, and therapeutic response of many cardiovascular disorders such as hypertension, coronary heart disease, atrial fibrillation, cardiomyopathy, heart failure, and other disorders.

Abiraterone, a CYP17A1 enzyme inhibitor, can block the synthesis of androgens to improve patients’ survival in both mCRPC and mHSPC. Abiraterone acetate, a CYP17A1 enzyme inhibitor, is currently approved only for use in combination with prednisone. Adverse events resulting from cumulative doses of prednisone administered over a long period of time or from high doses even for a short-term exposure include altered bone metabolism, immunosuppression, increased risk of hyperglycemia and diabetes mellitus, hepatotoxicity, decreases in mood and cognitive function, and muscle weakness. LAE001, a dual inhibitor of CYP17A1 and CYP11B2 (aldosterone synthase), can block both androgen and aldosterone synthesis to reduce prednisone-related side effects.

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The following diagram illustrates the mechanism of action of LAE001:



Glossary & abbreviation:

DHEA: dehydroepiandrosterone

Source: Company data

Market Opportunity and Competition

Market Opportunities of LAE001 for mHSPC

According to Frost & Sullivan, the global and China incidence of prostate cancer is expected to increase from 1,451.5 thousand and 120.9 thousand in 2021 to 1,815.1 thousand and 199.3 thousand in 2030, respectively. Patients with prostate cancer that have relapsed after local therapy or that have distant metastasis usually respond to androgen deprivation therapy (ADT). HSPC is the stage of prostate cancer where the patients effectively respond to hormone therapies, typically ADT. The current SOC for mHSPC consists mainly of chemotherapies and anti-androgen therapies including abiraterone acetate and enzalutamide. However, both abiraterone acetate and enzalutamide have long-term side effects and almost all mHSPC patients eventually develop acquired resistance, leaving no effective treatment options.

As abiraterone is a CYP17A1 enzyme inhibitor that cannot address CYP11B2 enzyme, it requires co-medication with corticosteroids or GnRH analogs to manage adverse effects. In comparison, LAE001 has exhibited its high potency and selectivity against both the CYP17A1 and CYP11B2 enzymes in the pre-clinical studies. The CYP11B2 inhibitory activity of LAE001 could potentially reduce the mineralocorticoid excess effects observed with abiraterone by reducing plasma aldosterone levels. Currently, our clinical results demonstrated LAE001's therapeutic potential for the treatment of mCRPC. We plan to initiate a Phase III MRCT registrational trial of LAE001 for mHSPC in the fourth quarter of 2023 in China and the U.S., and submit NDA for LAE001 for the indication of mHSPC to the FDA and NMPA in 2027.

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Competitive Landscape

According to Frost & Sullivan, currently, there is only one CYP17A1 inhibitor approved for commercialization globally, namely abiraterone. There are 11 anti-androgen drugs in clinical trials globally and LAE001 is the only CYP17A1 and CYP11B2 inhibitor under clinical development. In China, there are five anti-androgen drugs in clinical trials and LAE001 is the only CYP17A1 inhibitor in clinical trial stage.

Marketed Anti-androgen Drug in the US and China

Approved drug	Flutamide	Bicalutamide	Nilutamide	Abiraterone	Enzalutamide	Apalutamide	Darolutamide	Rezvilutamide
Commercial name	Fugerel	Casodex	Nilandron	Zytiga	Xtandi	Erleada	Nubeqa	艾瑞恩
Mechanism	AR inhibitor	AR inhibitor	AR inhibitor	CYP17A1 inhibitor	AR inhibitor	AR inhibitor	AR inhibitor	AR inhibitor
Company	Ferring	Astra Zeneca	Concordia	Janssen Biotech	Astellas	Janssen Biotech	Bayer	Hengrui Medicine
US approval time	1989*	1995	1996	2011	2012	2018	2019	Not approved
2020 global revenue (million US dollar)	NA	388.3	NA	2,767.6	5,134.3	760.0	317.0	NA
2022 US market price (US dollar)	NA	115.0 (50mg)	285.8 (150mg)	94.8 (250mg)	113.8 (40mg)	117.8 (60mg)	106.7 (300mg)	NA
2022 US monthly treatment cost (thousand US dollar)	NA	3.5 (PFS:NA)	3.5 (PFS:21.1)	11.4 (PFS:NA)	13.6 (mCRPC PFS:19.5 nmCRPC PFS:36.6 mCSPC PFS:NA)	14.1 (mCSPC PFS:NA nmCRPC PFS:40.5)	12.8 (PFS:40.4)	NA
FDA approved indications	B2-C stage prostate cancer, D2 stage metastasis prostate cancer	Metastatic prostate cancer	Metastatic prostate cancer	mCRPC, mCSPC	CRPC, mCSPC	mCSPC, nmCRPC	nmCRPC	NA
China approval time	2003	1999	Not approved	2015	2019	2019	2021	2022
NMPA approved indications	Prostate cancer	Late stage Prostate cancer	NA	mCRPC, mCSPC	mCRPC, nmCRPC	nmCRPC, mCSPC	nmCRPC	mCSPC
China NRDL inclusion	Category B	Category B	NA	Category B	Category B	Category B	Category B	Category B
China generic drug approval status	Y	Y	NA	Y	Y	N	N	N
2020 China revenue (million RMB)	20.5	776.6	NA	1,614.3	141.5	38.9	NA	NA
2021 China market price (RMB)	NA	31.0 (50mg)	NA	108.5 (250mg)	69.6 (40mg)	332.5 (60mg)	196.7 (300mg)	NA
2021 China generic drug market price (RMB)	3.8 (250mg)	25.0 (50mg)	NA	30.0 (250mg)	48.2 (40mg)	NA	NA	NA
2021 China monthly treatment cost (thousand RMB)	NA	0.9 (PFS:NA)	NA	13.0 (PFS:NA)	8.4 (mCRPC PFS:19.5 nmCRPC PFS:36.6)	39.9 (mCSPC PFS:NA nmCRPC PFS:40.5)	23.6 (PFS:40.4)	NA
2021 China generic drug monthly treatment cost (thousand RMB)	0.3 (PFS:NA)	0.8 (PFS:NA)	NA	3.6 (PFS:NA)	5.8 (mCRPC PFS:19.5 nmCRPC PFS:36.6)	NA	NA	NA

Notes:

1. There were over 15 generic competitors of the approved anti-androgen drugs as of March 6, 2023. If the generic name of a drug is listed in the NRDL, both the original drug and the generics under such generic name will be included in the NRDL and available for reimbursement. Once a drug is included in the NRDL, it will be subject to volume-based purchasing in China.
2. Revenue includes revenue from both the original drug and generics.
3. The chart does not include ADT drugs.
4. Information as of March 6, 2023.

Source: NMPA, FDA, Frost & Sullivan analysis

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Pipeline global					
Drug name	Target	Company	Indication	Phase	First posted date
SHR3680	AR inhibitor	Hengrui Medicine	HSPC, mCRPC, advanced breast cancer	III	2018-05-09
HC-1119	AR inhibitor	Hinova Pharmaceuticals	mCRPC	III	2019-02-22
Seviteronel/VT-464	Dual CYP17A1 and AR inhibitor	Innocrin Pharmaceuticals	CRPC, HR+ breast cancer, TNBC	II	2013-12-17
Proxalutamide/GT0918	AR inhibitor	Kintor Pharma	mCRPC	II	2019-04-02
TRC253	AR inhibitor	Tracon	mCRPC	I/II	2016-12-09
ODM-208	CYP11A1	Orion Corporation/Merck	mCRPC	I/II	2018-02-19
LAE001	Dual CYP17A1 and CYP11B2 inhibitor	Laekna	mHSPC*	II	2019-02-18
ODM-209	CYP11A1	Orion Corporation	Metastatic/advanced prostate cancer, metastatic/advanced breast cancer	I/II	2019-03-18
EPI-7386	AR inhibitor	ESSA Pharmaceuticals	mCRPC	I/II	2021-10-13
TAS3681	AR inhibitor	Taiho Oncology	mCRPC	I	2015-10-02
ONC1-0013B	AR inhibitor	Avionco LLC	mCRPC	I	2017-03-03

Note: Only includes oncology drugs. The chart does not include androgen deprivation therapy (ADT) drugs or PROTAC. First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced. Information as of March 6, 2023.

* We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC. As part of our clinical development strategy for LAE001 in prostate cancer and based on the clinical data from trials on mCRPC, we plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S. and submit the NDA for mHSPC.

Pipeline in China					
Drug name	Mechanism/Target	Company	Indication	Phase	First posted date
Proxalutamide	AR inhibitor	Kintor Pharma	mCRPC	III	2018-07-02
HC-1119	AR inhibitor	Hinova Pharmaceuticals	mCRPC	III	2019-03-01
ISIS560131/AZD5312	AR inhibitor	Pyramid Laboratories	AR-V7 positive mCRPC	II	2021-04-29
LAE001	Dual CYP17A1 and CYP11B2 inhibitor	Laekna	mHSPC*	II	2019-04-25
TQB3720	AR inhibitor	Chia Tai-Tianqing Pharmaceutical	mCRPC	I	2021-01-26

Note: Only includes oncology drugs. First posted date denotes the date when the most advanced clinical stage of a clinical trial for an indication is first publicly announced. The chart does not include ADT drugs or PROTAC. Information as of March 6, 2023.

* We are currently conducting a Phase II clinical trial of LAE001 monotherapy on mCRPC. As part of our clinical development strategy for LAE001 in prostate cancer and based on the clinical data from trials on mCRPC, we plan to initiate a Phase III MRCT registrational trial for mHSPC in the fourth quarter of 2023 in China and the U.S. and apply the NDA for mHSPC.

Source: Global trials referenced *ClinicalTrials.gov*, Global trials referenced *CDE*, *Frost & Sullivan analysis*

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Competitive Advantages

High Potency and Selectivity

LAE001 is a highly potent and reversible inhibitor of CYP17A1 and CYP11B2 enzymes. It inhibits CYP17A1 from several species, and acts against the recombinant human enzyme with potency comparable to that of abiraterone based on public data. Moreover, abiraterone is a steroidal irreversible CYP17A1 inhibitor that does not inhibit CYP11B2. LAE001 inhibits both the 17 α -hydroxylase and the 17, 20-lyase activity of CYP17A1 equally, thus reducing both plasma androgens and cortisol levels like aldosterone. Also, the CYP11B2 inhibitory activity of LAE001 could potentially reduce the mineralocorticoid excess effects observed with abiraterone by reducing plasma aldosterone levels. Furthermore, because LAE001 has a high selectivity for CYP enzymes (3A4, 2C9, 2D6), it is a better combination partner compared to abiraterone.

Favorable Safety and Efficacy Profile for the Treatment of mCRPC

We demonstrated the efficacy of monotherapy of LAE001 for mCRPC after in-licensing. LAE001 monotherapy demonstrated favorable safety profile in avoiding hyperaldosteronism associated symptoms which appeared as adverse effects in the combination therapy of abiraterone and prednisone. Abiraterone acetate, a CYP17A1 enzyme inhibitor, is currently approved only for use in combination with prednisone. However, adverse events resulting from cumulative doses administered over a long period of time or from high doses even for a short-term exposure to prednisone include altered bone metabolism, immunosuppression, increased risk of hyperglycemia and diabetes mellitus, hepatotoxicity, decreases in mood and cognitive function, and muscle weakness. The table below sets forth the clinical results of abiraterone and LAE001 for the treatment of mCRPC. Although they were not head-to-head analyses, we believe that valuable insight can nonetheless be drawn from the comparison of our LAE001 with the abiraterone therapies.

Trial ID and phase	NCT00473512 Phase II	NCT00474383 Phase II	NCT00485303 Phase II	NCT03843918 Phase I
Study treatment	Abi+Dexamethasone	Abi+Prednisone/ Prednisolone	Abi+Prednisone/ Prednisolone	LAE001
Patients (n)	42	47	58	20
Prior treatment				
Abi/Enza naïve	Yes	Yes	Yes	Yes
Docetaxel naïve	Yes	No (all 47 patients failed docetaxel)	No (all 58 patients failed docetaxel)	No (4/20 patients failed docetaxel)
Median time to PSA progression (months)	7.4	5.6	5.6	12.9
PSA response				
>50% from baseline	67%	51%	36%	80%
>90% from baseline	19%	15%	16%	60%
Major AEs	Hypokalemia, hypertension, fluid overload, and migrainous headaches	Hypertension, hypokalemia, edema, hyperglycemia	Fatigue, dyspnea, AST/ALT elevation	Thrombocytopenia, hypokalemia, hypertension

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Note: No head-to-head comparison clinical study was conducted 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.

Abi: abiraterone; Enza: enzalutamide; AST: aspartate transaminase; ALT: alanine aminotransferase

Source: Company data G Attard, et al. 2009; AHM Reid, et al. 2010; AC Danila et al. 2010

Summary of Clinical Trial Results

The following table sets forth an overview of the key clinical studies of LAE001:

Name of Trial	Trial ID	Sponsor	Site	Design	Study Arm	Status	Competent Authority	Indication	Planned Patient Enrollment	Actual Patient Enrollment
Phase I/II clinical trial of LAE001 for mCRPC	NCT03843918	the Company	China	Open-label trial	Phase I: Single arm of LAE001 monotherapy treatment for safety and tolerability evaluation	Phase I: completed; Phase II: ongoing	NMPA	mCRPC	Phase I: 31; Phase II: 40	Phase I: 31 (Data cut-off date is January 15, 2022) Phase II: Two (as of the Latest Practicable Date)
Phase I clinical trial of LAE001 co-administered with prednisone for mCRPC	NCT01647789	Novartis	U.S., Belgium, Canada and Spain	Open-label trial	Single arm of combination treatment (LAE001 + prednisone) for efficacy and safety evaluation	Phase I: completed;	FDA, Belgian Federal Agency for Medicines and Health Products, Department of Health of Canada, Spanish Agency of Medicines and Medical Devices	mCRPC	74	31 (Data cut-off date is February 3, 2016)

Phase I/II Clinical Trial of LAE001 for mCRPC Sponsored by us in China

Overview. This study was a Phase I/II study of treating patients with mCRPC in China. The objective of the Phase I study is to study the safety and tolerability of LAE001 monotherapy in patients with mCRPC and determine the MTD and the RP2D of the drug. The Phase I and the Phase II part of the Phase I/II clinical trials are separate and standalone trials. The Phase I study includes Phase Ia study and Phase Ib study. The primary endpoint of Phase Ia study is the frequency and severity of adverse events, including dose-limiting toxicities (DLT). The primary endpoint of Phase Ib study is the PSA response rate. The primary endpoint of Phase II study is to determine proportion of subjects with prostate specific antigen decreasing by more than 50% after treatment. The results of the Phase I study suggested that

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the use of LAE001 monotherapy was sufficient for the treatment of mCRPC without the use of prednisone as the results demonstrated better efficacy measured using PSA response compared with the results of the Phase I clinical trial of LAE001 with prednisone for mCRPC sponsored by Novartis.

Trial design. The Phase I study is a dose-escalation study in patients with mCRPC who have never received chemotherapy or who have received chemotherapy (chemotherapy failure or intolerance) and preferentially enrolls patients who had failed chemotherapy. Since the SOC of mCRPC is chemotherapy and androgen/androgen receptor, the market potential of LAE001 as the first-line treatment would be better demonstrated if chemotherapy-naïve patients treated with LAE001 showed good outcomes. Phase Ia is a dose-escalation study to determine the RP2D level of LAE001 in mCRPC patients, whereas the Phase Ib study serves with the purpose of a proof of concept study for safety and anti-cancer efficacy of LAE001 monotherapy in mCRPC patients. The initial dose proposed for the Phase Ia study is 50 mg BID, and the escalated doses are 75 mg BID, 100 mg BID and 125 mg BID, respectively. The dose for the Phase Ib study is 50 mg BID. RP2D will be determined based on a comprehensive analysis of the safety, PK, PD and efficacy data of dose escalation. The dose for the Phase II study is to use the RP2D determined in the Phase I clinical trial. The Phase II study is a single-arm trial based on androgen deprivation therapy treatment with the primary objective of assessing the efficacy and safety of LAE001 in mCRPC patients. The Phase II study plans to enroll approximately 40 patients.

Trial status. We initiated the Phase I trial in May 2019, and completed the Phase I study on September 13, 2021. 17 subjects were enrolled in the dose-escalation Phase Ia (50 mg, 75 mg, 100 mg, and 125 mg), and the dose of 50 mg BID has been selected as the RP2D. Additional 14 subjects were enrolled in the dose-expansion Phase Ib (RP2D: 50 mg). The Phase I clinical trial has been completed (all the primary endpoints of the Phase Ia and Ib studies have been met) and we have initiated the Phase II study to further evaluate the safety and efficacy in mCRPC patient.

Safety data. As of the data cut-off date (January 15, 2022), the most common AEs were hypokalemia, hyperglycemia, anemia, hypertension, edema peripheral, platelet count decreased, aspartate aminotransferase increased, and electrocardiogram QT prolonged. Hypokalemia was reported in 26 (83.9%) subjects, and all were suspected to be related to LAE001. Hyperglycemia was reported in 15 (48.4%) subjects, and all were Grade 1, three of which were unrelated to LAE001. Anemia was observed in 12 (38.7%) subjects, and all were Grade 1 or 2, five of which were unrelated to LAE001. Hypertension was observed in 10 (32.2%) subjects, nine of which were suspected to be related to LAE001, and one subject with Grade 3 hypertension was unrelated to LAE001.

Efficacy data. As of the data cut-off date of January 15, 2022, among 27 evaluable patients, 20 patients (74%) achieved over 50% reduction in PSA response and 14 patients (52%) achieved over 90% reduction in PSA response. In the 50 mg BID RP2D Cohort, among 20 evaluable patients, 16 patients (80%) achieved over 50% reduction in PSA response and 12 patients (60%) achieved over 90% reduction in PSA response.

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Phase I Clinical Trial of LAE001 Co-Administered with Prednisone for mCRPC Sponsored by Novartis

Overview. This was an open-label, multi-center Phase I study in adult patients with mCRPC. The primary objective of the Phase I study was to estimate the MTD or RP2D of oral LAE001 when co-administered with prednisone to adult patients with mCRPC.

Trial design. Patients in the Phase I dose-escalation study were to continuously receive daily dosing of oral LAE001 capsule co-administered with prednisone twice daily for 28 days (4-week) cycles, with no breaks between cycles. The initial dose of LAE001 was 50 mg BID co-administered with 5 mg BID of prednisone for 28-day cycles. Dose escalation continued until the MTD or RP2D was estimated.

Trial status. Novartis initiated the trial on December 4, 2012, and completed the Phase I study on February 3, 2016. 31 patients were enrolled and treated in the Phase I dose-escalation study.

Safety data. The most commonly reported AE included general disorders and administration site conditions (67.7%), gastrointestinal disorders (67.7%), investigations (64.5%), musculoskeletal and connective tissue disorders (61.3%), and metabolism and nutrition disorders (51.6%). Overall, 24 patients (77.4%) had Grade 3/4 AEs and 11 patients (35.5%) had Grade 3/4 AEs suspected to be related to study drug. The most frequently reported Grade 3/4 AEs suspected to be related to the study drug included thrombocytopenia (five patients; 16.1%), platelet count decreased (three patients; 9.7%), hyponatremia (two patients; 6.5%), and hyperkalemia (two patients; 6.5%). The Grade 3/4 AEs were generally manageable by using adjusted or temporarily interrupted drug dosage, concomitant medication, and/or hospitalization or prolonged hospitalization.

Efficacy data. Overall, four patients in 200 mg BID, two patients in 100 mg BID, one patient each in 50 mg and 150 mg BID treatment arms had over 50% reduction in PSA compared to baseline, at or after 12 weeks of treatment. The median best percentage change in PSA from baseline was higher in the 50 mg BID arm (-27.6%), followed by the 200 mg BID arm (-11.9%) and 100 mg BID arm (-10.7%). RP2D of LAE001 was determined to be 100 mg BID.

Clinical Development Plan

We completed the Phase I clinical trial and initiated the Phase II clinical trial of a Phase I/II study in China to assess the safety and efficacy of LAE001 as a monotherapy at recommended Phase II dose (RP2D) in mCRPC. We expect to complete the Phase II study in China with preliminary results in the third quarter of 2023. We plan to initiate a randomized, controlled, double blinded Phase III trial or another equivalent MRCT for mHSPC in the fourth quarter of 2023 in China and the U.S. by leveraging the clinical trial results from the Phase I/II study of LAE001 monotherapy in mCRPC in China following a common development strategy of anti-androgen therapy for prostate cancer since (i) anti-androgen therapy plays an anti-tumor

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role by blocking the synthesis of androgens for both mCRPC and mHSPC patients with the same mechanism of action, (ii) mCRPC and mHSPC are late stage and early stage of prostate cancer, respectively, and if the efficacy and safety of the drug are well established in mCRPC patients, it will likely be effective in treating mHSPC patients, (iii) patients with mCRPC have limited treatment options thus mCRPC is more suitable for early phase clinical study in terms of patient enrollment, and (iv) the treatment effect in mCRPC patients could be observed in a short follow-up period compared with mHSPC patients because mCRPC patient is in a later stage of cancer with shorter life expectation length, thereby shortening drug development time. We will apply the NDA for mHSPC with the NMPA and the FDA in 2027.

Post-Licensing R&D Activities

In the Phase I clinical trial of LAE001 co-administered with prednisone for mCRPC sponsored by Novartis, 24 patients (77.4%) had Grade 3/4 AEs. The most frequently reported Grade 3/4 AEs suspected to be related to the study drug included thrombocytopenia (five patients; 16.1%), platelet count decreased (three patients; 9.7%), hyponatremia (two patients; 6.5%), and hyperkalemia (two patients; 6.5%). Four patients in 200 mg BID, two patients in 100 mg BID, one patient each in 50 mg and 150 mg BID treatment arms had over 50% reduction in PSA compared to baseline, at or after 12 weeks of treatment. The clinical data obtained by Novartis suggest that LAE001 has a manageable safety profile. The efficacy data also suggests LAE001 has a favorable efficacy profile for the treatment of prostate cancer. Based on Novartis' clinical results, we designed the clinical study of LAE001 monotherapy for PROC because of its additional activity on CYP11B2. We expect the overall side effects to be significantly improved over abiraterone acetate or prednisone, while maintaining a similar or even better efficacy against prostate cancer.

When we in-licensed LAE001 from Novartis, a number of clinical trials had been conducted by Novartis to evaluate the safety and efficacy of LAE001. Among these trials, LAE001 was generally well-tolerated in patients and showed evidence of efficacy. In particular, Novartis has completed a Phase I clinical trial in combination with prednisone for the treatment of mCRPC. After the in-licensing, we redesigned a Phase I/II clinical trial to demonstrate the efficacy of monotherapy of LAE001 for mCRPC. The trial design of the clinical study we conducted was different from Novartis'. We completed the Phase I clinical trial and initiated the Phase II clinical trial in China to assess safety and efficacy at RP2D of LAE001 in mCRPC as a monotherapy. Compared with the Phase I clinical trial of LAE001 with prednisone for mCRPC sponsored by Novartis, our LAE001 monotherapy clinical trial demonstrated better efficacy in PSA response with manageable side effects, suggesting that LAE001 monotherapy is sufficient for the treatment of mCRPC without the use of prednisone. We also designed and completed a Phase I dose-escalation and efficacy study of LAE001 and prednisone plus LAE002 or docetaxel/prednisone plus LAE002 in patients with mCRPC following the SOC treatment. We conducted clinical activities including (i) preparing the clinical trial design/framework and protocol; (ii) coordinating with the FDA for the review and

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approval of our clinical trial, (iii) coordinating all post-licensing clinical development activities, (iv) designing and coordinating the selection process for qualified CROs to assist in engaging clinical sites and coordinating clinical studies once commenced; and (v) supervising the clinical studies.

Licenses, Rights and Obligations

On June 30, 2017, we entered into a license agreement with Novartis. According to the license agreement, Novartis grants us an exclusive, royalty-bearing, sub-licensable and assignable license regarding the licensed patent and data to develop, use, manufacture or have manufactured and/or commercialize LAE001 in any and all therapeutic, prophylactic and/or diagnostic uses in humans worldwide. For more details, please see “– Collaboration and Licensing Arrangements – Collaboration with Novartis – LAE001 License Agreement” in this section.

Material Communications with Competent Authorities

For LAE001, we filed an IND application for Phase I/II clinical trial of LAE001 for mCRPC to the NMPA in October 2018 and obtained its IND approvals in January 2019. We completed the Phase I study and received the NMPA’s approval to initiate the Phase II trial for the treatment of mCRPC in September 2021. We will further consult with the NMPA and obtain their approval before initiating Phase III trials for the treatment of mHSPC.

Based on the IND approval and our ongoing communications with the NMPA, we had not received any relevant regulatory agency’s concerns or objections to our clinical development plans as of the Latest Practicable Date, nor had any material unexpected or adverse changes occurred since the date of issue of relevant regulatory approvals for LAE001.

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LAE005: A High-Affinity, Ligand-Blocking, Humanized Anti-PD-L1 IgG4 Antibody

Overview

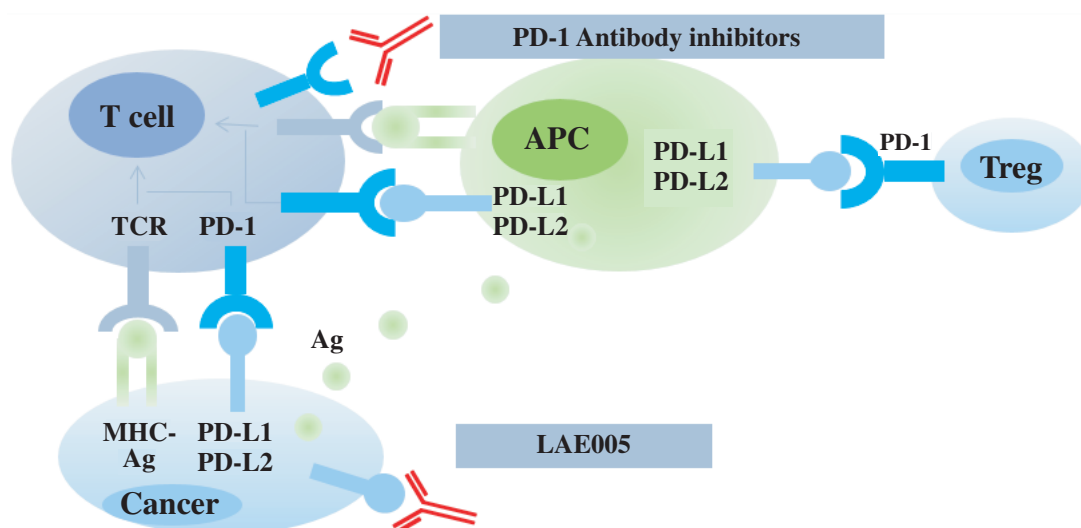
LAE005 is a high-affinity, ligand-blocking, humanized anti-PD-L1 IgG4 antibody. In the pre-clinical and clinical studies, LAE005 demonstrated its strong binding avidity to PD-L1 and compelling anti-tumor activities. Specifically, we are evaluating the therapeutic potential of the combination therapy of LAE002 and LAE005 in patients with TNBC. We believe LAE005 has the potential to serve as an effective therapy for the treatment of TNBC when combined with other synergistic mechanisms.

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Mechanism of Action

Programmed death-1 (PD-1) is a critical immune checkpoint receptor expressed on T cells upon activation. Engagement of PD-1 by its ligands, PD-L1 and PD-L2, transduces a signal that inhibits T-cell proliferation, cytokine production, and cytolytic function. During tumorigenesis, cancer cells from a wide range of tumor types exploit immune checkpoint pathways, such as PD-1/PD-L1, to avoid detection by the adaptive immune system. Monoclonal antibody (mAb) inhibitors of immunological and their corresponding ligands, including PD-1 and PD-L1, have demonstrated significant anti-tumor activity in patients with various solid tumors. LAE005 specifically binds to PD-L1 and likely leads to PD-L1 dimerization, conformational changes, and internalization from cell surface, making PD-1 no longer able to bind to PD-L1 and activate downstream signaling T-cell suppression.

The following diagram illustrates the mechanism of action of LAE005:



Glossary & abbreviation:

PD-L2: programmed death ligand-2; TCR: T-cell receptor; APC: antigen-presenting cell; Treg: regulatory T cell; MHC: major histocompatibility complex; Ag: antigen

Source: Company data

Advantage and Market Opportunity

LAE005 was tested in a binding assay on either human or non-human primate cynomolgus monkey PD-L1-transfected 300.19 cells. In three replicate experiments, LAE005 bound to human PD-L1 cell line with a KD of 0.265 ± 0.048 nM and non-human primate PD-L1 cell line with a KD of 0.559 ± 0.101 nM ($0.08 \mu\text{g/ml}$). LAE005 was tested for its ability to block the binding of PD-1 and B7.1 to PD-L1 expressed on 300.19 cells. LAE005 blocked the PD-1 ligand with an IC_{50} of 0.021 ± 0.145 nM ($0.003 \mu\text{g/ml}$) and the B7-1 ligand with an IC_{50} of 0.104 ± 0.030 nM ($0.015 \mu\text{g/ml}$).

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We believe there is a significant commercial opportunity in China for PD-1/PD-L1 class of drugs. ICIs have been revolutionized as cancer treatments over the past decade. The global PD-1/PD-L1 market has grown rapidly in the past five years, from US\$10.1 billion in 2017 to US\$34.4 billion in 2021 at a CAGR of 35.9%. Currently available clinical data suggest that some of the most prevalent cancers globally and in China, such as lung, gastric, liver and esophageal cancers, are responsive to the PD-1/PD-L1 class of drugs. Taking into account of the other cancer types (such as bladder, melanoma and kidney cancers) that are also responsive to the PD-1/PD-L1 class, the overall annual incidence of cancers potentially responsive to the treatment of PD-1/PD-L1 antibodies in China was over four million in 2021.

Despite encouraging monotherapy clinical results, anti-PD-1/PD-L1 agents as monotherapy are not always effective. A large number of patients did not benefit from anti-PD-1/PD-L1 therapy (primary resistance). Some responders relapsed after a response period (acquired resistance). Some patients had to pause the ongoing treatment because of the development of immune-related adverse events. Therefore, combinatorial therapies targeting the PD-1/PD-L1 pathway and resistance mechanisms provide a rationale for sensitizing the resistant patients. Based on the limited therapeutic effect of anti-PD-1/PD-L1 as monotherapy, it is urgent to explore effective combinatorial approaches to overcome anti-PD-1/PD-L1 therapy’s resistance and provide insights into clinical applications. Combined therapies of PD-1/PD-L1 blockade with adjunctive strategies have demonstrated its potential in improving the probability, duration, and potency of clinical activity. We are evaluating the therapeutic potential of combination therapy of LAE005 in combination with AKT inhibitor LAE002 for the treatment of TNBC to demonstrate its efficacy profile.

Currently, there are seven FDA-approved PD-1/L1 monoclonal antibodies. There are more than 30 drugs in clinical trials globally.

FDA Approved PD-1/L1 Monoclonal Antibodies

Company	Generic Name	Brand Name	FDA Approval Month	FDA Approval Indications
Merck	Pembrolizumab	KEYTRUDA®	2014.9	Melanoma, NSCLC, HNSCC, cHL, PMBCL, Urothelial Carcinoma, Gastric Cancer, Esophageal Cancer, Cervical Cancer, HCC, MCC, RCC, MSI-H/dMMR Cancer, MSI-H/dMMR CRC, Endometrial Carcinoma, TMB-H Cancer, cSCC, TNBC
BMS	Nivolumab	OPDIVO®	2014.12	Unresectable or Metastatic Melanoma, NSCLC, Malignant Pleural Mesothelioma, Advanced RCC, cHL, HNSCC, Urothelial Carcinoma, MSI-H/dMMR CRC, HCC, Esophageal Cancer, Gastroesophageal Junction Cancer and Esophageal Adenocarcinoma
Regeneron/ Sanofi	Cemiplimab	LIBTAYO®	2018.9	NSCLC, BCC, Metastatic or Locally Advanced CSCC
GSK	Dostarlimab	JEMPERLI®	2021.4	dMMR Recurrent or Advanced Endometrial Cancer or Solid Tumors

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Company	Generic Name	Brand Name	FDA Approval Month	FDA Approval Indications
Roche	Atezolizumab	TECENTRIQ®	2016.5	Urothelial Carcinoma, NSCLC, SCLC, HCC, Melanoma, Alveolar Soft Part Sarcoma (ASPS)
Merck/Pfizer	Avelumab	BAVENCIO®	2017.3	Metastatic Merkel Cell Carcinoma, Locally Advanced or Metastatic Urothelial Carcinoma, Advanced RCC
AstraZeneca	Durvalumab	IMFINZI®	2017.5	NSCLC, ES-SCLC, Advanced Biliary Tract Cancer

Note: Information as of March 6, 2023.

Source: FDA, Literature Review, Frost & Sullivan analysis

In China, there are 10 PD-1 monoclonal antibodies and five PD-L1 monoclonal antibodies approved by the NMPA. There are more than 30 drugs in clinical trials in China.

NMPA Approved PD-1 Monoclonal Antibodies

INN	Trade Name	Company	Approval Date	Indications	Price (RMB)	Dosage	Injection Methods	2020 Revenue (\$ Million)	NRDL Status	Annual Cost after PAP or NRDL (Thousand RMB)
Nivolumab	Opdivo	BMS	Jun-2018	NSCLC, squamous cell carcinoma of the head and neck, adenocarcinoma of the stomach or gastroesophageal junction, pleural mesothelioma, esophageal cancer, urothelial cancer	100mg: 9,250RMB; 40mg: 4,587RMB	3mg/kg every 2 weeks	Intravenous	6,992.0 (Global)	NO	108.2'
Pembrolizumab	Keytruda	MSD	Jul-2018	Melanoma, NSCLC, esophageal squamous cell carcinoma, head and neck squamous cell carcinoma, colorectal cancer, liver cancer, TNBC	100mg: 17,918RMB	2mg/kg every 3 weeks	Intravenous	14,380.0 (Global)	NO	93.2'
Toripalimab	Tuoyi 拓益	Junshi (君實生物)	Dec-2018	Melanoma, nasopharyngeal carcinoma, urothelial carcinoma, esophageal cancer, NSCLC	80mg: 906RMB	3mg/kg every 2 weeks	Intravenous	160.5	Class B	57.4
Sintilimab	Daboshu 達伯舒	Innovent (信达生物)	Dec-2018	Classical Hodgkin lymphoma, NSCLC, HCC, esophageal cancer, gastric cancer, gastroesophageal cancer	100mg: 1080RMB	200mg every 3 weeks	Intravenous	359.7	Class B	36.7
Camrelizumab	Airuika 艾瑞卡	Hengrui (江蘇恒瑞)	May-2019	Classical Hodgkin lymphoma, HCC, NSCLC, Esophageal squamous cell carcinoma, NPC	200mg: 2,928RMB	200mg every 2 weeks	Intravenous	480.0	Class B	76.1
Tislelizumab	Baizean 百澤安	Beigene (百濟神州)	Dec-2019	Classical Hodgkin lymphoma, urothelial carcinoma, HCC, NSCLC, nasopharyngeal cancer, esophageal cancer	100mg: 1450RMB	200mg every 3 weeks	Intravenous	165.6	Class B	49.3
Penpulimab	Annike 安尼可	Chia Tai Tianqing (正大天晴)/ Akeso Biopharma (康方生物)	Aug-2021	Recurrent or refractory classical Hodgkin's lymphoma, NSCLC	100mg: 4875RMB	200mg every 2 weeks	Intravenous	NA	NO	19.5
Zimberelimab	Yutuo 譽妥	WuXi Biologics (藥明生物)/ GloriarBio (譽衡生物)	Aug-2021	Recurrent or refractory classical Hodgkin's lymphoma	120mg: 3300RMB	240mg every 2 weeks	Intravenous	NA	NO	171
Serplulimab	漢斯狀	Henlins (復宏漢霖)	Mar-2022	MSI-H solid tumors, NSCLC, SCLC	100mg: 5588RMB	3mg/kg every 2 weeks	Intravenous	NA	NO	285
Pucotenlimab	普佑恒	樂普生物	Jul-2022	MSI-H/dMMR solid tumors, advanced melanoma	NA	200mg every 3 weeks	Intravenous	NA	NO	-

Note: Information as of March 6, 2023.

Source: NMPA, Company Annual Report, Frost & Sullivan analysis

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NMPA Approved PD-L1 Monoclonal Antibodies

INN	Trade Name	Company	Approval Date	Indications	Price (RMB)	Dosage	Injection Methods	2020 Revenue (\$ Million)	NRDL Status	Annual Cost after PAP (Thousand RMB)
Atezolizumab	Tecentriq	Roche	Feb-2020	SCLC, HCC	1,200mg: 32,800RMB	1200mg every 3 weeks	Intravenous	2,965.0 (Global)	NO	295.2
Durvalumab	Imfinzi	AZ	Dec-2019	NSCLC	120mg: 6,066RMB; 500mg: 18,088RMB	10mg/kg, every 2 weeks	Intravenous	2,042.0 (Global)	NO	217.1
Envafolimab	恩維達	3D Medicines/ AI Phamab Oncology/ Simcere	Nov-2021	MSI-H/dMMR advanced solid tumor	200mg: 5,980RMB	400mg every 4 weeks	Subcutaneous	NA	NO	71.8
Sugemalimab	擇捷美	Cstone Pharma	Dec-2021	NSCLC	600mg: 12,375RMB	1200mg every 3 weeks	Intravenous	NA	NO	420
Adebrelimab	艾瑞利	Hengrui (江蘇恒瑞)	Mar-2023	SCLC	NA	NA	Intravenous	NA	NO	NA

Note: Information as of March 6, 2023.

Source: NMPA, Company Annual Report, Frost & Sullivan analysis

Licenses, Rights and Obligations

On February 4, 2020, we entered into a license agreement with Novartis. According to the license agreement, Novartis grants us an exclusive and sub-licensable license to practice Novartis’s and its affiliates’ interest in the licensed know-how and patents to research, develop and commercialize LAE005 worldwide. For more details, please see “– Collaboration and Licensing Arrangements – Collaboration with Novartis – LAE005 License Agreement” in this section.

Clinical Development Plan

When we in-licensed LAE005 from Novartis, LAE005 has been evaluated by Novartis in several Phase I studies for safety and efficacy in cancer treatment. LAE005 was also in a Phase I study as a single agent and in combination with PDR001 (spartalizumab, an anti-PD-1 monoclonal antibody developed by Novartis) in adult patients with advanced malignancies. We have initiated a Phase I/II trial in China for the treatment of TNBC in combination with LAE002 and nab-paclitaxel to continue to leverage the clinical value and explore AKT’s potential. We aim to obtain the preliminary clinical results in the first quarter of 2023. We plan to initiate the Phase II study in China in the first quarter of 2024 and complete the Phase II study in China in the fourth quarter of 2025. This study is planned to be expanded to a MRCT trial in China and the U.S. at the registrational stage.

We had not received any relevant regulatory agency’s concerns or objections to our clinical development plans as of the Latest Practicable Date, nor did any material unexpected or adverse changes had occurred since the date of issue of relevant regulatory approvals for LAE005.

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LAE003: A Potent ATP Competitive AKT Inhibitor

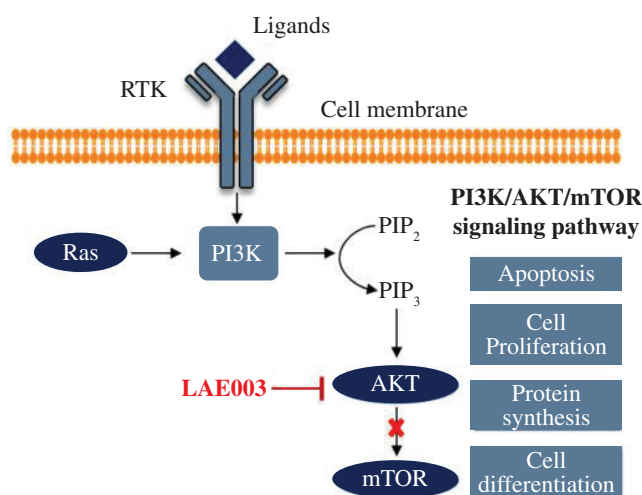
Overview

LAE003 is a potent ATP competitive AKT inhibitor. In the pre-clinical studies, LAE003 showed high potency and selectivity to AKT1, AKT2 and AKT3. LAE003 is currently at the clinical stage for cancer treatment and we are re-purposing it for the treatment of hereditary hemorrhagic telangiectasia and proteus syndrome. We expect LAE003 to be our lead drug candidate in the rare disease therapeutic area.

Mechanism of Action

AKT is a family of serine/threonine-specific protein kinase, which acts as a mediator in many biological processes like glucose metabolism, apoptosis, cell differentiation and transcription. Three members in the AKT family have been identified until now, namely AKT1, AKT2 and AKT3. While AKT2 is mostly involved in glucose transport and AKT3 is highly expressed in brain tissue, AKT1 plays a key role in cellular survival and metabolism mechanisms. LAE003 is a low nanomolar adenosine triphosphate competitive, AKT kinase inhibitor that inhibits baculovirus expressed, full-length human AKT1, 2 and 3 catalyzed phosphorylation of a synthetic peptide substrate.

The diagram below illustrates the mechanism of action of LAE003:



Glossary & abbreviation:

RTK: receptor tyrosine kinase; mTOR: mammalian target of rapamycin; PIP2: phosphatidylinositol(4,5)bisphosphate; PIP3: phosphatidylinositol-3,4,5-triphosphate

Source: Company data

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Advantage and Market Opportunity

LAE003 is a high potent and selective AKT inhibitor. To characterize the potency and selectivity of LAE003, the ability of LAE003 to inhibit baculovirus expressed full-length human AKT 1, 2 and 3 catalyzed phosphorylation of a synthetic peptide substrate was examined. The results showed that LAE003 inhibited AKT 1, 2 and 3 with IC₅₀ values of 2, 16 and 4 nM, respectively, which approached the nominal concentrations of enzymes used (20 nM) in the kinase assays. Ki* values were further determined in a filter binding assay using lower enzyme concentrations (0.1, 0.7, and 0.2 nM for human AKT 1, 2 and 3, respectively). Ki* values were 0.1, 1.4, and 1.5 nM in this more sensitive assay format for AKT 1, 2 and 3, respectively. To confirm the Ki* value against AKT1, the potency and binding kinetics of LAE003 for AKT1 were determined in a continuous fluorescence intensity assay using Sox-peptide (Sox-AKT-tide) and progress curve analysis. The results showed that LAE003 inhibited AKT1 with a Ki* value of 0.066 nM.

Hereditary hemorrhagic telangiectasia (HHT) is an autosomal dominant inherited disorder of blood vessel formation characterized by mucocutaneous and visceral vascular malformations resulting in direct communication between arterioles and venules. This process is thought to occur stepwise, starting with dilation of postcapillary venules, followed by arteriolar dilation and then loss of the intervening capillary bed. Because of abnormal vascular development, patients with HHT tend to form large vascular networks between the veins and arteries, including telangiectasia, arteriovenous malformation (AVM) and arteriovenous fistula. Although there is no cure for HHT, there are treatments for the symptoms of HHT. The cause of HHT is loss of function mutations in ALK1/ENG/SMAD. Studies have demonstrated that ALK1/ENG/SMAD mutation causes activation of the PI3K/AKT and VEGFR2 pathway in endothelial cells. Recent studies have revealed that PI3K-AKT signaling is over-activated in several HHT models and that its inhibition reduces the AVMs. As an AKT inhibitor, we believe LAE003 can reduce the AVMs to relieve the symptoms of HHT.

Proteus syndrome is a rare complex syndrome involving clinical presentation with atypical skeletal growth. The onset may involve any site of the body and typically occurs during infancy. Therapy for this disorder is limited to supportive care and surgical intervention. Genetic mosaicism, such as activating AKT1 mutations, has been suggested to be an important causes of Proteus syndrome. As LAE003 can potently inhibit these AKT mutations, we believe LAE003 exhibits the potential to be an effective therapy for Proteus syndrome.

Licenses, Rights and Obligations

On May 9, 2018, we entered into a license agreement with Novartis. According to the license agreement, Novartis grants us an exclusive, royalty-bearing, sub-licensable and assignable license regarding the licensed patent and data to develop, use, manufacture or have manufactured and/or commercialize LAE003 in any and all therapeutic, prophylactic and/or diagnostic uses in humans worldwide. For more details, please see “– Collaboration and Licensing Arrangements – Collaboration with Novartis – LAE002 and LAE003 License Agreement” in this section.

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Clinical Development Plan

When we in-licensed LAE003 from Novartis, LAE003 was in several Phase I, Phase II clinical trials for various cancer indications. We are re-purposing LAE003 for treating rare diseases such as hereditary hemorrhagic telangiectasia and Proteus syndrome. To further discover the therapeutic potential of our LAE003, we will continue to explore combination therapies that potentially may have better clinical outcomes than monotherapy. To that end, we are exploring potential opportunities to cooperate with global partners on the development of LAE003.

The differences between LAE002 and LAE003 include compound composition and inhibitory potency against AKT1, AKT2 and AKT3. In our commercial consideration to avoid LAE003 becoming a competitor to LAE002, based on their different compound composition and inhibitory potency against AKT, LAE002 is purposed for cancer treatment while LAE003 is repurposed for rare disease treatment. To avoid potential future competition, we plan to require the potential partners undertake not to engage, participate or assist in engaging or participating, directly or indirectly, in any development, manufacture and commercialization of LAE003 in the field of cancer therapy. Although LAE002 and LAE003 were licensed under the same license agreement, our post-licensing development and commercialization of LAE002 and LAE003 are independent.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET LAE003 SUCCESSFULLY.

PRE-CLINICAL-STAGE DRUG CANDIDATES

We have also developed a rich pipeline of pre-clinical drug candidates with strong pre-clinical validation and market potential. To leverage our knowledge in oncology and liver fibrosis and to build synergies between programs targeting both areas, we are focusing our research on immune cells important for cancer immune surveillance and liver fibrosis reversal. We are developing multiple monoclonal and bispecific antibodies against key regulatory pathways of NK cells and T cells, and bi-functional NK engagers targeting cancer cells and activated hepatic stellate cells (aHSC). These innovative molecules are in various stages of drug discovery, and we plan to have at least one molecule to enter the clinical stage each year on average, starting in 2023.

Oncology Drug Candidates

Although ICIs have been approved for a wide array of cancer indications worldwide, a large number of patients with solid tumors are not responsive to ICIs treatments or develop drug resistance ultimately. We are developing immuno-oncology agents that target the mechanisms for ICI-resistance. We are particularly interested in the inhibitory receptors expressed by cancer infiltrating lymphocytes (i.e., LAE102, LAE109, LAE111, LAE113 and LAE117) and ligands/receptors expressed on or produced by the cancer cells (i.e., LAE112). We believe that these inhibitory pathways represent targets for developing anticancer agents that could reverse resistance to ICIs.

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Our most advanced internally developed candidate is the activin receptor ActRIIA mAb, LAE102. As a member of the TGF β family, activin is attracting an increasing interest due to its multifunctional role in cancer development, particularly its immunomodulatory function. In several cancer types, high expression of activin is associated with shorter survival. LAE102 is a potent and selective ActRIIA mAb that shows anti-tumor activity in pre-clinical animal models. Furthermore, it increased the bodyweight of cancer-bearing animals.

Liver Fibrosis Drug Candidates

In addition to our pre-clinical-stage oncology drug candidates, we are also developing a series of pre-clinical drug candidates for liver fibrosis which represents another therapeutic area with huge unmet medical needs. We have designed and validated a TGF β inhibitor, LAE106, active only in fibrotic tissues. Liver fibrosis is the excessive accumulation of extracellular matrix proteins including collagen that occurs in chronic liver diseases. According to Frost & Sullivan, the global and China prevalence of liver fibrosis is expected to increase from 804.5 million and 139.3 million in 2021 to 966.5 million and 152.3 million in 2030, respectively. Control or cure of viral infection by patients after the removal or elimination of causative agent has shown that liver fibrosis is reversible, and recent evidence suggests that it can be reversed by regulating the immune system. Currently, there is no effective anti-liver fibrosis drug approved globally. Thus, there is unmet medical need for anti-fibrotic therapies to prevent liver disease progression.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR PRE-CLINICAL-STAGE DRUGS SUCCESSFULLY.

COLLABORATION AND LICENSING ARRANGEMENTS

Collaboration with Novartis

LAE001 License Agreement

On June 30, 2017, we entered into a license agreement (“**LAE001 License Agreement**”) with Novartis, a subsidiary of Novartis AG (NYSE: NVS), a multinational group of companies specializing in the research, development, manufacturing and marketing of healthcare products led by innovative pharmaceuticals and also including high-quality generic pharmaceuticals. Its major therapeutic focus includes cancer, cardiovascular, renal & metabolism diseases, immunology & dermatology, ophthalmology, neuroscience, and respiratory diseases. Its principal place of business locates in Basel, Switzerland. Novartis is one of our shareholders.

Novartis is the sole and exclusive owner of the intellectual property rights of LAE001. According to the LAE001 License Agreement, Novartis grants to us an exclusive, royalty-bearing, sub-licensable and assignable license regarding the licensed patents and data to develop, use, manufacture or have manufactured and/or commercialize LAE001 in any and all therapeutic, prophylactic and/or diagnostic uses in humans (“**LAE001 Field**”) worldwide. Novartis grants to us a non-exclusive, sublicensable, assignable license regarding the

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manufacturing technology to manufacture or have manufactured the LAE001 for development or commercialization of LAE001 in the LAE001 Field worldwide. The non-exclusive license of manufacturing technology of LAE001 granted by Novartis is in line with market practice and Novartis utilizes the same manufacturing technology for many of the products it manufactures. No other company has the legal right to manufacture LAE001 as we have the sole and exclusive manufacturing rights to the compounds of LAE001.

Novartis shall transfer to us all the data and information related to LAE001 and/or drug product manufactured therefrom for use in the LAE001 Field worldwide owned or controlled by Novartis or its affiliates and available in the global databases and archives, including relevant know-how related to the manufacturing of the LAE001 and/or drug products manufactured therefrom. As of the Latest Practicable Date, all such information, including know-how, had been transferred to us. We will be the sole owner of any inventions, know-how or similar IP rights conceived, created, reduced to practice or/and developed by us arising from our activities under the agreement.

In consideration of the licenses and rights granted to us, the upfront payment and the maximum milestone payments payable by us amount to US\$33.5 million in the aggregate, which includes US\$1.0 million non-refundable upfront payment and US\$32.5 million milestone payments, consisting of development milestone payments divided into individual payments between US\$5.0 million to US\$10.0 million upon (a) receipt of regulatory approval for two different indications in China, (b) receipt of regulatory approval for the use in the LAE001 Field in the U.S, (c) receipt of regulatory approval for the use in the LAE001 Field in one or more major EU markets, and (d) receipt of regulatory approval in Japan. We are also obligated to pay tiered royalties ranging from a single-digit percentage to a low teen percentage of annual net sales of LAE001. As of December 31, 2022, we have paid US\$1.0 million under the LAE001 License Agreement.

Unless terminated earlier, the LAE001 License Agreement shall continue in full force and effect in perpetuity. Novartis and we may terminate the LAE001 License Agreement upon a written mutual agreement. All rights and licenses granted to us under the LAE001 License Agreement will immediately terminate upon termination by either party. Novartis has the right to terminate the agreement by serving written notice on us only upon the occurrence of events including (i) we fail to pay the undisputed amount of upfront, milestone and royalty fees, and we fail to remedy such failure within 30 days of receipt of a written notice from Novartis specifying such failure; (ii) we fail to comply or are incompliant with the 2017 Shareholders Agreement, according to which, (a) we should issue 3,288 shares to Novartis AG so that Novartis AG can indirectly hold 5% equity interest in Laekna Therapeutics upon closing of the LAE001 License Agreement and (b) Novartis AG's ultimate beneficial interest in Laekna Therapeutics shall be maintained at 5% until the valuation of Laekna Therapeutics reaches US\$70 million, above which, Novartis AG's ultimate beneficial interest in Laekna Therapeutics shall be diluted on a pro rata basis. The valuation of Laekna Therapeutics was determined at each round of [REDACTED] Investment, taking into account its business prospects and the research and development of our drug candidates at the time of investment; (iii) we change our organizational structure without Novartis' prior written consent in a way

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that our Company, Laekna HK and Laekna Therapeutics are no longer affiliates; (iv) occurrence of an “Insolvency Event”, which means, in relation to a party (Novartis or our Company), any occurrence of the following: (a) a party is the subject of voluntary or involuntary bankruptcy proceedings instituted on behalf of or against Laekna, Inc., except for involuntary bankruptcy proceedings which are dismissed within 120 days, (b) an administrative receiver, receiver and manager, interim receiver, custodian, sequestrator or similar officer is appointed for substantially all of the assets of a party, (c) a resolution to wind up our Company shall have been passed other than a resolution of the solvent reconstruction or reorganization of a party, or (d) a resolution passed by a party’s board of directors to make an application for an administration order or to appoint an administrator for substantially all of the assets of such party; or (v) it has been adjudicated by a court with competent jurisdiction that we have materially breached our obligation to use commercially reasonable efforts to develop, manufacture and commercialize LAE001 in the LAE001 Field worldwide and fails to cure such breach within a period of 60 days after such court adjudication. We also have the right to terminate the license agreement by serving written notice on Novartis only upon the occurrence of the events including (a) Novartis has materially breached its obligation under the LAE001 License Agreement and fail to cure such breach, (b) an Insolvency Event occurred, and (c) upon 45 days’ written notice for material scientific, technical or medical reasons. We granted 776,437 ordinary shares to Novartis AG and Novartis to fulfill our obligations under the 2017 Shareholders Agreement, including (i) the issuance of 3,288 shares to Novartis AG in July 2017 to fulfill the share subscription obligation after signing the LAE001 License Agreement, and on April 4, 2018, Novartis AG transferred all its beneficial interest in Laekna Therapeutics to Novartis, (ii) the issuance of 563,315 shares to Novartis in April 2018 to fulfill the anti-dilution obligation resulting from the dilution due to Series Seed financing of our Company, and (iii) the issuance of 209,834 shares to Novartis in May 2018 to fulfill the anti-dilution obligation resulting from the dilution due to Series A financing of our Company. The 2017 Shareholders Agreement had been superseded by the 2018 Shareholders Agreement.

Under the LAE001 License Agreement, we will use commercially reasonable efforts to develop, manufacture and commercialize LAE001 at our own costs and expenses and conduct the development activities. According to the LAE001 License Agreement, our commercially reasonable efforts with respect to the development of LAE001 include (i) development activities in relation to prostate cancer, and (ii) that we may pursue another indication besides prostate cancer such as estrogen dependent endometrial cancer. Under the LAE001 License Agreement, we shall provide Novartis with written summary report periodically summarizing our R&D activities performed and anticipated R&D plans.

Our Directors are of the view that we have been using commercially reasonable efforts in the development of LAE001 and the associated risk of the LAE001 License Agreement with Novartis being terminated is low, on the following basis: (i) we have completed a Phase I clinical trial of a Phase I/II study of LAE001 for mCRPC and initiated the Phase II clinical trial, which is in line with the R&D plan required under the LAE001 License Agreement. For more details on the post-licensing R&D activities of LAE001, please see “– Clinical Stage Candidates – Core Product LAE001: A dual CYP17A1/CYP11B2 inhibitor – Post-licensing R&D activities”. Actual R&D expenses attributable to LAE001 during the Track Record Period

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were RMB54.1 million; (ii) our plans for registration and commercialization of LAE001 have been approved by Novartis; (iii) we expect to continue our commercially reasonable efforts in the development and commercialization of LAE001. For example, we plan to continue our development and commercialization of LAE005 and LAE002, and they are intended to be used for LAE001 as combination therapies, respectively, among other applications. For more details on the development plan of LAE001, see “– Clinical Stage Candidates – Core Product LAE001: A dual CYP17A1/CYP11B2 inhibitor – Clinical Development Plan”; (iv) we plan to use a portion of the net [REDACTED] from the [REDACTED] for the development and commercialization of LAE001. See “Future Plans and Use of [REDACTED]” in this document for further details; and (v) during the Track Record Period and up to the Latest Practicable Date, we provided Novartis with written summary report periodically summarizing our R&D activities performed and anticipated R&D plans for LAE001, and Novartis had not raised any concerns on our clinical progress or questioned on the commercial reasonableness of our efforts.

As of the Latest Practicable Date, we had no intention or plan to out-license LAE001 in the domestic or overseas markets.

LAE002 and LAE003 License Agreement

On May 9, 2018, we entered into a license agreement (“**LAE002 and LAE003 License Agreement**”) with Novartis. Novartis is the sole and exclusive owner of the intellectual property rights of LAE002 and LAE003. The rights and details of LAE002 under the LAE002 and LAE003 License Agreement are the same as those of LAE003. According to the LAE002 and LAE003 License Agreement, Novartis grants to us a royalty-bearing, sub-licensable and assignable exclusive license to develop, use, manufacture or have manufactured and/or commercialize LAE002 and LAE003 in any and all therapeutic, prophylactic and/or diagnostic uses in humans (the “**LAE002 and LAE003 Field**”) worldwide. Novartis grants to us a non-exclusive, sublicensable, assignable license regarding the manufacturing technology to manufacture or have manufactured the LAE002 and LAE003 for development or commercialization of LAE002 and LAE003 in the LAE002 and LAE003 Field worldwide. The non-exclusive license of manufacturing technology of LAE002 and LAE003 granted by Novartis is in line with market practice and Novartis utilizes the same manufacturing technology for many of the products it manufactures. No other company has the legal right to manufacture LAE002 and LAE003 as we have the sole and exclusive manufacturing rights to the compounds of LAE002 and LAE003.

Novartis shall transfer to us all the data and information related to LAE002 and LAE003 and/or drug product manufactured therefrom for use in the LAE002 and LAE003 Field worldwide owned or controlled by Novartis or its affiliates and available in the global databases and archives, including relevant IP and know-how related to the manufacturing of LAE002 and LAE003. As of the Latest Practicable Date, all such information, including know-how, had been transferred to us. We will be the sole owner of any improvements to the licensed patents and data and IP rights that are discovered, generated, developed, invented or created solely by us, our affiliates or third parties acting on us or our behalf while conducting

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activities in connection with the development, manufacture and/or commercialization of LAE002 and LAE003, and will retain all of its rights, title and interest. We will use commercially reasonable efforts to develop, manufacture and commercialize LAE002 and LAE003 at our own costs and expenses and to conduct the development activities. "Commercially reasonable efforts" in the LAE002 and LAE003 license agreements has the same definition as in the LAE001 license agreement.

In consideration of the licenses under the agreement granted to us, we are required to pay the non-refundable upfront payment of US\$5.0 million, US\$242.5 million in milestone payments, consisting of (i) development milestone payments of up to US\$57.5 million divided into individual payments between US\$2.5 million to US\$10.0 million upon either LAE002 or LAE003 (a) dosing of the first patient in the first visit in the first Phase III registrational clinical trial, (b) the first NDA acceptance; (c) receipt of regulatory approval for three different indications in China, (d) receipt of regulatory approval for three different indications in the U.S., (e) receipt of regulatory approval for three different indications in one or more EU markets; and (ii) sales milestone payments of up to US\$185.0 million divided into individual payments upon achieving four different sales targets. Each milestone shall be deemed earned as of the first achievement of the respective milestone event and is payable one-time only. We are also obligated to pay tiered royalties ranging from a single-digit percentage to a low teen percentage of total annual net sales of LAE002 and LAE003. As of December 31, 2022, we have paid US\$5.0 million under the LAE002 and LAE003 License Agreement.

Unless terminated earlier, the LAE002 and LAE003 License Agreement shall continue in full force and effect in perpetuity. Novartis and we may terminate the LAE002 and LAE003 License Agreement upon a written mutual agreement. All rights and licenses granted to us under the LAE002 and LAE003 License Agreement will immediately terminate upon termination by either party. Novartis has the right to terminate the agreement by serving written notice on us only upon the occurrence of events including (i) we fail to pay the undisputed amount of upfront, milestone and royalty fees, and we fail to remedy such failure within 30 days of receipt of a written notice from Novartis specifying such failure; (ii) we fail to comply or are incompliant with the 2018 Shareholders Agreement, according to which, (a) we should issue 165,200 shares to Novartis so that Novartis can hold 6% equity interest in Laekna Therapeutics upon closing of the LAE002 and LAE003 License Agreement and (b) Novartis' ultimate beneficial interest in Laekna Therapeutics shall be maintained at 6% until the valuation of Laekna Therapeutics reaches US\$70 million, above which, Novartis' ultimate beneficial interest in Laekna Therapeutics shall be diluted on a pro rata basis. The valuation of Laekna Therapeutics was determined at each round of [REDACTED] Investment, taking into account its business prospects and the research and development of our drug candidates at the time of investment; (iii) we change our organizational structure without Novartis' prior written consent in a way that our Company, Laekna HK and Laekna Therapeutics are no longer affiliates; (iv) Insolvency Events, which has the same definition as in the LAE001 license agreement; or (v) it has been adjudicated by a court with competent jurisdiction that we have materially breached our obligation to use commercially reasonable efforts to develop, manufacture and commercialize LAE002 and LAE003 in the LAE002 and LAE003 Field worldwide and fails to cure such breach within a period of 60 days after such court

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adjudication. We also have the right to terminate the license agreement by serving written notice on Novartis only upon the occurrence of the events including (i) Novartis has materially breached its obligation under this agreement, (ii) Insolvency Events occurred, and (iii) upon 45 days’ written notice for material scientific, technical or medical reasons. We granted 165,200 ordinary shares after signing the LAE002 and LAE003 License Agreement in May 2018 to Novartis to fulfill the anti-dilution obligation under the 2018 Shareholders Agreement. Since the date of the Series B financing, Laekna Therapeutics has been valued at over US\$70 million. We are not obligated to issue additional shares to Novartis in the future to maintain the agreed equity interest percentage should the valuation of Laekna Therapeutics subsequently fall below US\$70 million as the 2017 Shareholders Agreement had been superseded by the 2018 Shareholders Agreement, which had then been superseded by the Series D Shareholders Agreement. The Series D Shareholders Agreement does not contain such anti-dilution mechanism.

Under the LAE002 and LAE003 License Agreement, our commercially reasonable efforts with respect to the development of LAE002 include (i) we will build on Novartis’ Phase I/II LAE002 study “an open-label Phase I/II study of LAE002 in combination with carboplatin and paclitaxel in subjects with PROC”, advance LAE002 to a global Phase III registrational trial study, initially focusing on market approval in the U.S., EU and China; (ii) we will conduct pre-clinical and clinical trials to evaluate if LAE002 alone or combine with LAE001 and prednisone have benefits in mCRPC patients relapsed after abiraterone or enzalutamide; (iii) we will conduct both pre-clinical and clinical study to evaluate whether LAE002 and LAE001 combining with endocrine therapies will be effective to treat the relapsed breast cancer carrying PTEN mutation by controlling both ER/PR and AKT activities; (iv) we will seek a partner to combine immune-oncology therapy for expanding the indications of LAE002; (v) we will explore other oncology indications such as gastric cancer, TNBC, liver cancer and esophageal cancer carrying PTEN mutation. If a proof-of-concept is achieved, we will initiate registration studies for NDA approval. Our commercially reasonable efforts with respect to the manufacturing of LAE002 allow us to initially work with CMOs on the manufacturing of LAE002 and LAE003 for clinical uses. In the long term, we may consider to transfer the manufacture technology to a CMO in China based on quality and economics considerations.

To demonstrate our “commercially reasonable efforts”, we shall provide Novartis with a written summary report periodically summarizing our R&D activities performed and anticipated R&D plans.

Our Directors are of the view that we have been using commercially reasonable efforts in the development of LAE002 and the associated risk of the LAE002 and LAE003 License Agreement with Novartis being terminated is low, on the following basis: (i) our current clinical studies for LAE002 are in line with the R&D plans required by Novartis. For more details on the post-licensing R&D activities of LAE002, please see “– Clinical Stage Candidates – Core Product LAE002: An ATP competitive AKT inhibitor – Post-licensing R&D activities”. Actual R&D expenses attributable to LAE002 during the Track Record Period were RMB271.7 million; (ii) our registration and commercialization plans for LAE002 have been approved by Novartis; (iii) we expect to continue our commercially reasonable efforts in the development and commercialization of LAE002. For example, we plan to continue our

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development and commercialization of LAE005 and LAE001, and they are intended to be used for the LAE002 as combination therapies, respectively, among other applications. For more details on the development plan of LAE002, see “– Core Product LAE002: An ATP competitive AKT inhibitor – Clinical Development Plan”; (iv) we plan to use a portion of the net [REDACTED] from the [REDACTED] for the development and commercialization of LAE002. See “Future Plans and Use of [REDACTED]” in this document for further details; and (v) during the Track Record Period and up to the Latest Practicable Date, we provided Novartis with written summary report periodically summarizing our R&D activities performed and anticipated R&D plans for LAE002, and Novartis had not raised any concerns on our clinical progress or questioned on the commercially reasonableness of our efforts.

As of the Latest Practicable Date, we had no intention or plan to out-license LAE002 in the domestic or overseas markets.

LAE005 License Agreement

On February 4, 2020, we entered into a license agreement (“**LAE005 License Agreement**”) with Novartis. According to the LAE005 License Agreement, Novartis grants to us an exclusive and sub-licensable license to practice Novartis’ and its affiliates’ interest in the licensed know-how and patents to research, develop and commercialize LAE005 worldwide. The manufacturing technology of LAE005 is not licensed to us and we can use our own manufacturing process for LAE005. As the manufacturing of LAE005 is not exclusively dependent on Novartis’ manufacturing technology and Novartis has transferred the analytical manufacturing method to us, we cooperated with CDMOs on the manufacturing of LAE005 during the Track Record Period. As of the Latest Practicable Date, we had not experienced any obstacles in the manufacturing of LAE005. We may sublicense (through multiple tiers) the license at any time at our sole discretion to our affiliates, CROs, CDMOs, local and regional distributors, or other similar fee-for-service providers without notice to Novartis. As of the Latest Practicable Date, we had no sublicensing plan for LAE005.

Novartis is the sole and exclusive owner of the intellectual property rights of LAE005, save as one patent family that is jointly owned by President & Fellow of Harvard College, Dana Farber Cancer Inst. Inc. and Novartis AG. For details, see “– Intellectual Property” below in this section. President & Fellow of Harvard College and Dana Farber Cancer Inst. Inc. agreed for Novartis to license their jointly owned patent of LAE005 to us. Novartis shall transfer to us all the data and information relating to the LAE005. As of the Latest Practicable Date, all such information, including know-how, had been transferred to us. All know-how and patent rights that are created, conceived of, or reduced to practice by or on behalf of us, our affiliates or our agents and the practice of the licenses granted thereafter will be owned by us.

Novartis should continue funding and managing a LAE005 related clinical study identified as a study of LAE005 single agent and in combination with PDR001 (spartalizumab, an anti-PD-1 monoclonal antibody developed by Novartis) in patients with advanced malignancies (NCT02936102) (“**Ongoing Clinical Trial**”) until they are completed in the ordinary course of Novartis’ operations. No IND or clinical trial applications (“**CTA**”) will be transferred to us. Nevertheless, we have the right to use the data and information in all Ongoing

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Clinical Trial related regulatory filings, and establish and file all necessary documentation with regulatory authorities to support our own IND or CTA and further development of the LAE005. Other than for the Ongoing Clinical Trial, we will be solely responsible for all regulatory matters relating to the development of the LAE005 at our own costs and expenses. By ourselves or through our affiliates or sublicensees, we will use commercially reasonable efforts to develop the LAE005 and obtain regulatory approvals in at least one of the following markets, the U.S., one of the major EU countries, either Japan or China. “Commercially reasonable efforts” in the LAE005 license agreements has the same definition as in the LAE001 license agreement.

In consideration of the licenses and rights granted to us, the upfront payment and the maximum milestone payments payable by us amount to US\$128.0 million in the aggregate, which consist of US\$10.0 million in non-refundable upfront payment, and US\$118.0 million in milestone payments, consisting of (i) development milestone payments of up to US\$28.0 million divided into individual payments between US\$2.0 million to US\$10.0 million upon (a) the first visit of the first patient to the first registrational trial, (b) acceptance of a biologic license application in any jurisdiction or application for the authorization to market the product in any country or group of countries outside the U.S., (c) regulatory approval for three different indications; and (ii) sales milestone payments of up to US\$90.0 million divided into individual payments upon achieving three different sales targets. We are also obligated to pay tiered royalties calculated ranging from a single-digit percentage to a low teen percentage of annual net sales of LAE005. As of December 31, 2022, we have paid US\$10.0 million under the LAE005 License Agreement.

Suppose either Novartis or us is in material breach of any material obligation, the non-breaching party may give written notice to the breaching party specifying the claimed particulars of such breach, and in the event, such material breach is not cured within 90 days after such notice, the non-breaching party will have the right to terminate the agreement immediately by giving written notice to the breaching party to such effect. If any Insolvency Events occurs, which has the same definition as in the LAE001 license agreement, we will give immediate notice to Novartis of such occurrence, and Novartis will have the right to terminate this agreement by written notice immediately. We may also terminate the agreement without cause at any time on 90 days’ prior written notice. All rights and licenses granted to us under the LAE005 License Agreement will immediately terminate upon termination by either party.

After we in-licensed LAE005, we designed a clinical trial to explore the therapeutic potential of the combination therapy of LAE002 and LAE005 in patients with TNBC. We conducted post-licensing R&D activities, including (i) preparing the clinical trial design/framework and protocol; (ii) coordinating with the FDA for the review and approval of our clinical trial, (iii) coordinating all post-licensing clinical development activities, (iv) designing and coordinating the selection process for qualified CROs to assist in engaging clinical sites and coordinating clinical studies once commenced; and (v) supervising the clinical studies. Actual R&D expenses attributable to LAE005 during the Track Record Period were RMB32.0 million. We plan to use a portion of the net [REDACTED] from the [REDACTED] for the R&D of LAE005. See “Future Plans and Use of [REDACTED]” in this document for further details.

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Collaboration with Innovent

On July 6, 2021, we entered into a collaboration agreement (“**Innovent Collaboration Agreement**”) with Innovent Biologics (Suzhou) Co. Ltd. (“**Innovent**”), a subsidiary of Innovent Biologics, Inc. (HK: 1801), a Hong Kong-listed Chinese biopharmaceutical company. Innovent is an Independent Third Party to us.

According to the Innovent Collaboration Agreement, Innovent and we will collaborate in a clinical combination trial to evaluate the safety, pharmacokinetics, pharmacodynamics and preliminary efficacy of the concomitant and sequenced administration of LAE002 and sintilimab injection in subjects with solid tumors (“**Study**”). Innovent will supply the sintilimab injection for free for our use in the combination therapy study. Innovent will remain as the sole owner of all know-how and patents of sintilimab injection controlled by Innovent that are necessary for sintilimab injection’s development. All know-how that is created, conceived or reduced to practice by us or Innovent, in the performance of the development activities under the Innovent Collaboration Agreement, and all patent rights claiming such know-how (other than these that solely relates to sintilimab injection or LAE002), shall be jointly owned by us and Innovent.

According to Frost & Sullivan, sintilimab is a marketed anti-PD-1 monoclonal antibody in China, and Innovent plans to commercialize sintilimab in the U.S. as well. It has been approved for six indications, all have been included in the National Reimbursement Drug List (NRDL), and those six indications include: (i) the treatment of relapsed or refractory classic Hodgkin’s lymphoma after systemic chemotherapy; (ii) in combination with pemetrexed and platinum chemotherapy as the first-line treatment of non-squamous non-small cell lung cancer lacking EGFR or ALK driver mutations; (iii) in combination with gemcitabine and platinum chemotherapy as the first-line treatment of squamous non-small cell lung cancer; (iv) in combination with Byvasda (bevacizumab biosimilar injection) as the first-line treatment of unresectable or advanced hepatocellular carcinoma; (v) in combination with cisplatin plus paclitaxel or cisplatin plus 5-fluorouracil as the first-line treatment of esophageal squamous cell carcinoma; and (vi) in combination with chemotherapy as the first-line treatment of unresectable, locally advanced, recurrent or metastatic gastric or gastroesophageal junction adenocarcinoma. Additionally, Innovent currently has one regulatory submission for sintilimab in combination with bevacizumab biosimilar and chemotherapy for the treatment of EGFR mutated non-squamous NSCLC following EGFR-TKI treatment under review of the NMPA. As of the Latest Practicable Date, sintilimab had met their primary endpoints in a Phase II study as a second-line treatment of esophageal squamous cell carcinoma and another Phase III study as a second-line treatment for squamous NSCLC with disease progression following platinum-based chemotherapy. Sintilimab plus platinum-based chemotherapy conferred better anti-tumor efficacy and clinical benefits compared to chemotherapy alone, which led to FDA’s acceptance for review of biological license application of sintilimab in the U.S. However, in March 2022, the FDA issued a complete response letter (CRL) indicating it cannot approve the biologics license application for sintilimab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of advanced NSCLC. The FDA had concluded that the supporting data from the Phase III clinical trial, which had been conducted entirely in China, could not be applied to a U.S. population. They noted that the study population was younger,

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predominantly male, and included higher rates of smokers than are generally found in the U.S. The CRL also included a recommendation for an additional clinical study, specifically a multiregional clinical trial comparing the first line standard of care therapy for metastatic NSCLC to sintilimab with chemotherapy utilizing a non-inferiority design with an overall survival as the endpoint. As of the Latest Practicable Date, sintilimab was not an approved product in the U.S.

We believe that the CRL issued by the FDA for sintilimab will not have a material impact on the Study, on the basis that: (i) the combination study will be conducted in China and as of the Latest Practicable Date, we did not have any plan to conduct a combination study of LAE002 and sintilimab overseas in collaboration with Innovent, (ii) despite the CRL, sintilimab may still be approved in the future if the issues in the CRL were addressed, (iii) there are a few alternative FDA approved anti-PD-1 monoclonal antibodies other than sintilimab that can be used for combination therapies with LAE002, and (iv) although we have not formulated a Phase III clinical trial design using sintilimab with Innovent overseas, if in the future we do plan to develop the combination use of LAE002 and sintilimab outside of China, our Phase III clinical trial could also be designed as a MRCT that includes adequate enrollment of U.S. patients to mitigate the concerns in the CRL.

We will be the sponsor of the Study and be responsible for obtaining all necessary approvals and clearances, including regulatory and institutional review board (IRB) approvals and customs clearances, for the conduct of the Study, including filing the IND to the NMPA. Innovent will reasonably cooperate with us to provide us any information for the sintilimab injection that is reasonably necessary to allow us to fulfill our obligations as the sponsor of the Study. We would conduct the Study and lead the development activities and shall use or retain personnel with sufficient skills and experiences as are required to accomplish efficiently and expeditiously the Study in a good scientific manner. We have the decision-making authority and are solely responsible for the daily operational activities.

Each party shall be solely responsible for its internal costs and expenses in connection with its conduct or support of any development activities. We shall be fully responsible for all the costs and expenses in connection with the conduct of the development activities for the Study and other activities required for the Study except for the cost of sintilimab injection, which Innovent shall provide for free.

Each party agrees that we and Innovent shall jointly own all joint collaboration technology. Each party has the right to use and exploit such joint collaboration technology both within and outside the scope of the Study, without the consent of the other party and without any accounting to the other party. For those countries where a specific license is required for a joint owner of a joint collaboration technology to exploit such joint collaboration technology in such countries, each party grants to the other party a perpetual, irrevocable, non-exclusive, worldwide, royalty-free, fully paid-up, transferrable and sub-licensable license, under such party's right, title and interest in and to all joint collaboration technology to exploit such joint collaboration technology. As between the parties, title to all collaboration technology that solely relates to LAE002 shall be owned by us, and title to all collaboration technology that solely relates to the sintilimab injection shall be owned by Innovent.

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Our collaboration is non-exclusive other than that, during the term of the Innovent Collaboration Agreement, (i) we, including through our affiliates, shall not collaborate with any third-party to conduct any clinical trial of combination therapy of LAE002 and any anti-PD-1 antibody in mainland China and (ii) Innovent, including through its affiliates, shall not collaborate with any third party to conduct clinical trial of combination therapy of sintilimab injection and any AKT inhibitor in mainland China.

OUR PLATFORM

We believe that fully-integrated in-house R&D capabilities are critical to our success. We have built a biopharmaceutical platform to identify drug candidates against evidence-based and novel targets, increasing the efficiency and likelihood of success while reducing the cost of development. Our platform facilitates collaboration among different functional groups and feeds into early discovery and research to cultivate targets with clinical and commercial potential. Our platform integrates all the necessary capabilities to streamline our target-to-market timeline. Our platform spans research and development, CMC, quality assurance and control, regulatory affairs to commercialization.

Research and Development

We believe research and development are critical to our future growth and our ability to remain competitive in the global biopharmaceutical market. Leveraging our global reach, we have been able to stay at the forefront of global biology and pharmaceutical research, source attractive business development opportunities, execute and closely monitor complex MRCTs. In the foreseeable future, with global rights attached to all our product candidates, we aim to penetrate both the China and overseas market and reap the geographically diversified economic rewards.

We are dedicated to enhancing our pipeline by leveraging our strong in-house R&D capabilities, from early stage drug discovery to clinical development. As of the Latest Practicable Date, our R&D team consisted of approximately 60 employees. We also work with CROs to support our pre-clinical and clinical studies in China and other regions. Our R&D team members have extensive pre-clinical and clinical development experience, focusing on oncology and liver diseases. In 2021 and 2022, our R&D expenses were RMB173.3 million and RMB313.4 million, respectively.

Our R&D team is generally responsible for the global development of our Core Products and other pipeline products. For our internally discovered and developed drug candidates, we conducted clinical activities including: (i) coordinating all clinical development activities; (ii) designing the key aspects of the clinical study; (iii) designing and coordinating the selection process for qualified CROs to assist in engaging clinical sites and coordinating clinical studies once commenced; (iv) supervising the clinical studies; and (v) overseeing extensive regulatory outreach and coordination in China and the U.S. For our in-licensed Core Products, we are responsible for developing the candidates in our licensed territories. We promptly commenced research and development activities after in-licensing drug candidates from our licensing

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partners. We have devoted a considerable amount of time and resources to the R&D of in-licensed drug candidates, and such efforts include but are not limited to: (i) the design of the clinical trials to be implemented in our licensed territories and proactive communication with relevant regulatory authorities to obtain the approvals; (ii) the preparation of clinical trials, including the selection of clinical CROs and clinical sites; and (iii) the manufacturing of clinical samples through our cooperation with CDMOs. Our drug discovery and pre-clinical R&D, clinical development, CMC and regulatory affairs teams have been working on the development of Core Products during the post-licensing period.

Drug Discovery and Pre-clinical Development

Our drug discovery and pre-clinical development team is led by Dr. Justin Gu, who has over 20 years of experience in early-stage drug discovery. The primary goal of our discovery team is to identify new targets and novel drug candidates in the oncology and liver fibrosis disease areas; and the key activities span from target discovery, hit to lead generation, PCC selection, IND enabling studies to IND filing. In addition, our team also conducts pre-clinical translational research to support the clinical development of our drug candidates. To complement our internal capabilities, the team worked closely with the local CROs which have significantly increased the speed and efficiency of our internal discovery effort. Except for LAE002, LAE001, LAE005 and LAE003, all other product candidates have been discovered and developed by our R&D team. Our key R&D personnel remained employed during Track Record Period and up to the Latest Practicable Date.

As of the Latest Practicable Date, among our drug discovery and pre-clinical R&D team members, over 40% obtained a post-graduate degree with over 50% of them holding a Ph.D. degree. Our R&D team has made contributions to dozens of discovery programs. For our self-developed pipeline products, during the drug discovery stage, our drug discovery and pre-clinical R&D team explores new chemical properties, structure-activity-relationship (SAR) analysis based on the biological understanding of the disease, and carries out synthesis and structure optimization of the target molecules for potential drug candidates. During the drug evaluation stage, our drug discovery and pre-clinical R&D team coordinates and accomplishes pre-clinical R&D activities to evaluate product candidates' pharmacology, pharmacokinetics and toxicology. With our R&D platform, we are able to conduct a full range of pre-clinical R&D activities including product activity screening, studies of cellular functions of product candidates, product biochemical studies, biomolecule detection and others. Below are some of the highlights of our drug discovery and pre-clinical development capacities:

- We conduct extensive bioinformatics data mining to identify target and mechanism of action for oncology and liver fibrosis diseases. We design and implement detailed biochemical, cellular, and animal studies to identify the signaling pathway of the target and to validate its role in disease. We try to build synergies between oncology and liver fibrosis disease area by focusing on the regulatory pathways of the immune cells, and on targets that are selectively expressed on cancer cells or activated hepatic stellate cells.

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- Leveraging our internal antibody discovery expertise platform and our cooperation with CROs, we conduct extensive screenings to identify novel, potent and selective mAbs against the selected targets. Then we build bispecific or bifunctional antibodies based on our deep knowledge in disease biology and experience in antibody engineering.
- We conduct extensive *in vitro* functional characterization of our molecules, e.g. their effect in regulating the immune cell function and immune cell-mediated killing of cancer cells and aHSC cells. For this purpose, we established a comprehensive aHSC-depletion platform that enabled us to quickly and comprehensively evaluate the effect of our molecules on aHSC *in vitro*.
- We perform extensive pre-clinical proof-of-mechanism studies in animal models to build PK/PD relationship and to evaluate the antitumor or anti-fibrosis efficiency of our drug candidates. For this purpose, we use a wide variety of different models based on the mechanism of action of our drug candidates. Xenograft models in immune deficient mice are typically used for evaluating anti-tumor drug candidates. Syngeneic models in immune competent mice are the common choice for characterizing immune oncology drug candidates. For antifibrosis drug candidates, we use chemical- or diet-induced fibrosis models.
- After a drug candidate shows the desired activities in the proof-of-mechanism animal models and meet all the other criteria for a pre-clinical candidate (PCC), we will then move the candidate into CMC and pre-IND tox studies. Large quantity of our drug candidates will be manufactured by our CMC team in collaboration with our CRO partners. PK and long-term toxicity studies will be conducted in animals before filing for IND.

Clinical Development

Clinical Development Team

Our clinical development team is led by Dr. Yong Yue, who has over 20 years of experience in cancer treatment, especially in liver cancers. The clinical development team covers most of the key functions that enable us to execute well, from clinical development strategy, clinical development planning, setting up quality assurance and control system, to clinical trial design, trial operations, safety monitoring, data management, data analysis and programming, clinical supply, procurement, etc.

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Clinical Trial Design and Implementation

Our clinical development team is responsible for our trial design and execution and manages the procedures of our clinical trials with the assistance of CROs and SMOs. Our rapid trial advancements are driven by our (i) extensive clinical development experience, (ii) well-designed trial protocols, (iii) multi-center trial strategy in close collaboration with trial sites (i.e., hospitals) and corresponding principal investigators (PIs), and (iv) efficient and effective trial execution.

For the Core Products and other pipeline products, as the sponsor of our clinical trials, our clinical development team is responsible for initiating and funding the trials, formulating trial protocols, managing the trial implementation throughout the whole process and across multiple clinical sites following the trial protocols and GCP. Our clinical development team designs and formulates trial protocols and prepares investigators’ brochures based on the differentiated profile and target patient population of our drug candidates and clinical practice in China and the U.S. to maximize our drug candidates’ clinical potential and to accelerate the regulatory approval process. Trial protocols usually include background and basic information, trial objectives and purpose, trial design and implementation approach.

Our clinical development team is also responsible for the selection of trial sites. We select trial sites based on multiple factors. We have entered into a cooperative relationship with numerous trial sites (i.e., hospitals) and PIs to support our clinical trials at different stages. We believe that these institutions’ size and geographic diversity provide us with a significant advantage in implementing large-scale clinical trials and enable us to conduct multiple clinical trials concurrently.

In 2021 and 2022, we cooperated with seven and seven leading PIs, respectively, to conduct the clinical trials of our drug candidates. To the best of our knowledge, none of them has any past or present relationships with our Group, our Directors, shareholders, senior management or any of their respective associates. As the sponsor of our clinical trials, we take primary responsibility for the design and execution of the entire trial. Our clinical trial team formulates trial protocols and selects and engages trial sites and PIs to conduct clinical trials. The PIs are primarily responsible for conducting site-level clinical research activities according to our trial protocols and in accordance with laws, regulations, and the GCP Guideline, a quality standard for the overall conduct of the clinical trial. The PIs regularly communicate with us on the trial progress and observations to evaluate the efficacy and safety of our drug candidates. Each trial has a leading PI with primary responsibility to ensure compliance with trial protocol and good clinical practice over the entire trial. Through the trial process and with the assistance of CROs or SMOs, we closely monitor the trial activities, perform site audits, conduct an ongoing risk assessment and safety evaluation, review protocol deviated cases, and review clinical data to protect the safety of subjects and ensure the integrity of trial results. We collect and analyze trial data after the last subject completes the last visit to prepare documentation for regulatory approvals of our drug candidates. The roles and responsibilities of the PIs in our clinical trials are in line with the common industry practices. In accordance with the laws and regulations, we enter into agreements with the hospitals that

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the PIs belong to and settle the fees and expenses with those hospitals. To avoid any potential conflict of interests, we do not have any agreements with or make any payment to the PIs directly. We conduct our clinical trials in accordance with the relevant laws and regulations in China in line with the common industry practice.

The following table sets forth the background of leading PIs of our clinical trials during the Track Record Period:

Background

PI A	He is a director of the Multi-disciplinary Team for GU cancer and president of the Chinese Anti-Cancer Association-Genitourinary Oncology Committee.
Dr. Thomas Herzog	He is a deputy director of the University of Cincinnati Cancer Institute and professor of Obstetrics and Gynecology at the UC College of Medicine.
Dr. William Edenfield	He is a hematology and oncology specialist based in Greenville, Carolina and has approximately 30 years of experience in the medical field. He graduated from the University of Miami Miller School of Medicine in 1992.
Dr. Lingying Wu (吳令英)	She is the director of the Department of Gynecologic Oncology of Cancer Hospital of Chinese Academy of Medical Sciences, the executive standing committee member of the Clinical Oncology Collaborative Center of Chinese Anti-Cancer Association and a member of the Gynecologic Oncology Specialty Committee.
Dr. Lin Shen (沈琳)	She is the director of the Department of Gastrointestinal Oncology of Peking University Cancer Hospital.
PI B	He is a member of the Chinese Academy of Engineering, the director of the National Clinical Research Center for New Drugs (Anti-tumor), and the 6th Academic Committee of the National Cancer Center.
Dr. Sneha Phadke	She is a clinical associate professor of internal medicine-hematology, oncology, and blood and marrow transplantation in the University of Iowa Health Center.

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Translational Research

We conduct pre-clinical and clinical translational research to assess the effects of our drug candidates in specific group of patients. The patients can often be defined as presence or absence of a biomarker, or progressed after certain drug treatment. This translational research can greatly help our clinical trial design and make the best uses of a drug on patients who will receive the most benefits. These insights help further guide us toward new directions in drug discovery and efficiently obtain proof of concept results. We also maintain extensive collaboration with physicians, scientists and key opinion leaders, and further develop products based on their clinical feedback to our drug candidates, whether in terms of indications or potential treatment combinations. We have established a rich network of top-tier CROs, SMOs, research institutions and hospitals so that our drug candidates can be quickly moved to the clinical stage.

Collaboration with CRO Partners (including both CROs and SMOs)

We collaborate with CRO partners (including both CROs and SMOs) to conduct and support our pre-clinical and clinical studies in line with industry practice. We select our CRO partners by weighing various factors, such as their qualifications, academic and professional experience, industry reputation and service fees. To the best of our Company’s knowledge, none of them has any past or present relationships with our Group, our Directors, shareholders, senior management or any of their respective associates.

The pre-clinical CRO partners mainly provide us with services related to pre-clinical toxicity and safety evaluations, such as animal studies, of our drug candidates in accordance with our study design and under our supervision. The clinical CRO partners provide us with an array of services necessary for complex clinical trials in accordance with our trial design and under our supervision. CRO partners generally provide a comprehensive suite of services to assist us with implementing and managing clinical trials, including trial preparation, source data verification, clinical safety management, data management, and report preparation. We choose to engage a CRO partner based on the complexity and workload of a specific trial. We closely monitor the work of our CRO partners and provide specific directions to ensure the quality and efficiency of the trial execution. This approach allows us to leverage the experience of our in-house team to better focus on critical clinical trial elements, such as trial design, data analysis and decision making. All studies of our drug candidates on humans are conducted in compliance with the applicable laws, regulations and in line with the industry standards. We believe our ability to conduct and work closely with CRO partners to conduct pre-clinical studies and clinical trials enables us to shorten the time required for drug development by generating the requisite data reliably and efficiently.

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The following table sets forth background of our major CRO partners and expenses attributable thereto during the Track Record Period:

	Background	For the Year Ended		Total Amount during the Track Record Period
		December 31, 2021	2022	
		RMB'000	RMB'000	RMB'000
CRO Partners				
CRO A	It is headquartered in the U.S. and was founded in 2014. It conducts clinical trials on behalf of its pharmaceutical clients to expedite the drug approval process.	20,533	19,465	39,998
GOG Foundation, Inc.	It is headquartered in the U.S. and was founded in 1970. It is an organization that provides services in clinical trials and research in the field of gynecologic malignancies.	7,769	24,250	32,019
CRO B	It is headquartered in the U.S. and was founded in 1982. It provides biopharmaceutical development and commercial outsourcing services, focused primarily on Phase I-IV clinical trials and associated laboratory and analytical services. It is a company listed on the New York Stock Exchange.	15,227	12,767	27,994
CRO C	It is headquartered in Shanghai and was founded in 2010. It provides non-clinical safety evaluation, non-clinical pharmacokinetic studies, preclinical and clinical biomarker analysis and drug application consulting services.	–	15,648	15,648
CRO D	It is headquartered in Shanghai and was founded in 2016. It is a clinical development partner, committed to enable customers to accelerate the delivery of innovative solutions to patients worldwide.	6,125	3,520	9,645
Total		49,654	75,650	125,304

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In 2021 and 2022, the expenses related to CRO partners included in our research and development expenses were RMB76.5 million and RMB121.0 million, respectively. We mainly determine the service fees related to the CRO partners in accordance with the then prevailing market prices of similar services, the number of enrolled patients, the duration of the clinical trials, the number of service cycles, the number of centers monitored and the quality and contents of the services provided.

Chemistry, Manufacture & Controls and Manufacturing

CMC Team

Our chemistry, manufacture and control (CMC) team is led by Dr. Tao Feng, who is experienced in drug development and manufacturing for various products. As of the Latest Practicable Date, our CMC team consists of six professionals with established experience in process development, production and quality management from well-known biopharmaceutical and pharmaceutical companies. Our CMC team is responsible for (i) process development, scale-up, optimization, characterization and validation; (ii) analytical method development and validation; and (iii) clinical drug manufacturing and commercial product launching.

Collaboration with CDMO Partners (including both CMOs and CDMOs)

We collaborate with our CDMO partners (including both CMOs and CDMOs) to manufacture a portion of our drug candidates to supply for pre-clinical studies, clinical trials and potentially for the commercial-scale production of large molecule drugs. Our CDMO partners are usually companies that primarily engage in the development and manufacturing of drugs. We select our CDMO partners based on their operating history, market reputation, relevant expertise, internal quality control system, production technology, cGMP certification, production capacity, and pricing. To the best of our Company’s knowledge, none of them has any past or present relationships with our Group, our Directors, shareholders, senior management or any of their respective associates, and the CMOs and CDMOs engaged by us are Independent Third Parties. We did not experience material product quality issues in respect of the products manufactured by our CDMO partners during the Track Record Period. We believe that other alternative CDMO partners can meet our quality standards at comparable prices.

Under our agreement with our CDMO partners, they are required to perform services according to the prescribed time frame as set out in the agreement. Usually, we pay the CDMO partners in a lump sum with a short credit period. Our CDMO partner is responsible for manufacturing our required products in accordance with certain product specifications, in compliance with cGMP requirements and our quality standards. We retain all the intellectual property rights and grant our CDMO partner the right to use our intellectual property rights for such manufacturing and packaging activities during the contract period. We are entitled to inspect and audit our CDMO partner’s manufacturing process. Our CDMO partner is also required to acquire and maintain all relevant permits and certificates. If our CDMO partner fails to deliver products or comply with substantial obligations under the relevant agreement, we are entitled to terminate the agreement or reduce our order amount. Our CDMO partner receives processing fees from us according to a price schedule in the agreement, which sets per unit fees for respective production volumes.

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The following table sets forth background of CDMO partners and expenses attributable thereto during the Track Record Period:

	Background	For the Year Ended		Total Amount during the Track Record Period
		December 31, 2021	2022	
		RMB'000	RMB'000	RMB'000
CDMO Partners				
CDMO A	It is headquartered in Jiangsu and was founded in 2000. It provides a broad portfolio of R&D and manufacturing services that enable its pharmaceutical and healthcare industry clients to advance discoveries and deliver treatments to patients. It is a company listed on the Hong Kong Stock Exchange and the Shanghai Stock Exchange.	27,721	80,430	108,151
HALO PHARMACEUTICAL, INC. D/B/A CAMBREX WHIPPANY	It is headquartered in the U.S. and was founded in 1981. This leading small molecule CDMO provides drug substance, drug product, and analytical services across the entire drug lifecycle.	7,475	8,325	15,800
CDMO B	It is headquartered in Shanghai and was founded in 2014. It is a cloud supply chain platform for pharmaceutical R&D industry with SaaS-based e-commerce services, consumables and instruments procurement integration. Its service scope covers the whole life cycle of pharmaceutical research and development.	1,927	3,721	5,648
CDMO C	It is headquartered in the U.S. and was founded in 2007. It is the global leader in enabling pharma, biotech, and consumer health partners to optimize product development, launch, and full life-cycle supply for patients around the world.	1,046	994	2,040
CDMO D	It is headquartered in Italy and was founded in 2006. It is one of the leading CDMOs focused on development, clinical and commercial production and fully dedicated to anticancer drugs.	-	1,434	1,434
Total		38,169	94,904	133,073

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In 2021 and 2022, the expenses related to CDMO partners included in our research and development expenses were RMB42.6 million and RMB98.3 million, respectively. We mainly determine the service fees related to the CDMO partners in accordance with the then prevailing market prices of similar services, the number of enrolled patients, the duration of the clinical trials, the number of products manufactured, and the quality and contents of the services provided.

Manufacturing Facilities

To support future commercial manufacturing of our small molecule products, we plan to construct a new oral solid dosage manufacturing facility in eastern China. Our site is designed to comply with the cGMP requirements of the NMPA, EMA and FDA. Our manufacturing capacity and production lines will be inter-changeable among the products. We expect that the completed manufacturing facility will be able to support our commercialization needs in China and overseas for the next three years. In the future, we may expand or add additional manufacturing facilities to meet our commercial needs.

LAE002, the drug candidate that we expect to first commercialize, will be initially manufactured by CDMOs upon marketing approval and later transferred to our own manufacturing facility upon approval by competent regulatory authority.

Quality Assurance and Control

As of the Latest Practicable Date, our quality assurance and control team had two members with an average of approximately 15 years of industrial experience. Our quality assurance team ensures that our suppliers deliver products in accordance with our product quality requirements and current GMP regulations through protocols specifying quality guarantees, manufacturing site monitoring and regular supplier evaluations.

Regulatory Affairs

Our regulatory affairs team is responsible for the regulatory approval process of our drug candidates, including assembling application dossiers for IND and NDA, addressing inquiries from relevant authorities and monitoring our R&D projects to ensure their compliance with relevant regulations. Our regulatory affairs team manages the regulatory submission process for our drug candidates, which requires filings to be made to and approved by the relevant authorities before clinical trials and commercialization can be initiated. The regulatory affairs team prepares and manages regulatory filings by drafting filing dossiers, addressing regulatory questions and conducting CMC and GMP readiness assessments for our drug candidates. We possess extensive knowledge and experience with regard to regulatory filings in China and the U.S. With our presence and expertise in both the U.S. and China, we can design our clinical trials to maximize operational efficiency.

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Commercialization

We plan to adopt localized commercialization strategies for both domestic and overseas markets. As of the Latest Practicable Date, we had 95 employees in total, including 85 employees in China and 10 employees in the U.S. For the domestic market, we plan to partner with principal investigators with substantial industry influence and expertise, publish our clinical trial results in academic conferences and journals for physician education, recruit market analysts and product promotion specialists to tailor commercializing strategies for each of our Core Products, engage distributors that have broad hospital coverage, and assemble a full-fledged in-house commercialization team with expertise in medical, sales and marketing, regulatory and supply chain areas. In particular, considering the fierce competition in China's oncology drug market, we plan to work with competent local partners for commercialization, and leverage their sales channels for marketing. We also plan to adopt a tiered provincial market-entry approach with the goal of achieving nationwide coverage in the medium term. Our priority is to initially focus on top tier provinces that have favorable reimbursement coverage and high patient volume. As we expand into tier two and lower tier provinces, we plan to continue to invest in building our on-the-ground presence and coverage. We will 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. We believe these marketing and business development strategies will help us obtain market shares in the indications that we focus on. For the overseas market, we plan to partner with local pharmaceutical companies to utilize their local sales networks and other resources to achieve mutually beneficial results and maximize the commercial value of our Core Products.

Pricing, Tendering and Reimbursement Strategies

During the Track Record Period and up to the Latest Practicable Date, we had not commercialized any of our Core Products. We have not yet formulated any definitive pricing policy for our Core Products. When our Core Products progress to commercialization in the future, we will determine their prices based on various factors such as our Core Products' advantages, costs, the prices of competing products, and if they are to be included into the National Reimbursement Drug List (NRDL), the NRDL's reference price. We plan to conduct extensive market research with KOLs, hospitals, physicians and patients as well as regulatory agencies before pricing our Core Products, and intend to take into account various factors such as feedback collected from these parties, our production costs, the differences in safety and efficacy profiles, the estimated demand for our Core Products, and the clinical value we bring to the patients to price our Core Products.

In order to gain market share against existing and future branded and generic competitors, we will also consider seeking inclusion of our Core Products into the NRDL and other reimbursement programs. Inclusion into the NRDL is evaluated and determined by the relevant government authorities and we may face significant competition for successful inclusion. While products included in the NRDL or the PRDL are typically generic and essential drugs, many innovative drugs have been included in the NRDL in the past. Although we believe that the Core Products are eligible for inclusion upon commercialization and meeting NRDL's criteria, if we fail to have our Core Products included in the NRDL after commercialization, our sales channels may be limited and our revenue from commercial sales will be highly

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dependent on patient self-payments, which could make our products less competitive. We may need to seek alternatives such as commercial private insurance coverage of LAE001 and LAE002 and need to expand our sales channels and explore new collaboration partnerships, such as engaging distribution partners in China, to maximize the sales potential of our products and enhance our commercialization capability, especially on customer reach. We also plan to expand our sales network by closely communicating with physicians, especially KOLs in renowned comprehensive hospitals through clinical trial cooperation and other academic activities. As we expand our portfolio, we believe we will be well-positioned to leverage our existing sales network to rapidly launch and commercialize our new products.

We have built an extensive patent portfolio to protect each of our drug candidates, including in relation to their structure, treating method/use, combination and others. Although patents related to composition of matter of LAE002 or LAE003 may expire in 2028, we plan to apply patent term extension for LAE002 or LAE003 to extend the patent term in China, the U.S. and other jurisdictions. Additionally, other patents relating to the drug candidate or product at issue such as methodology, usage or formulation patents may continue to protect our exclusivity in developing and commercializing them. Although generic competitors of LAE002 and LAE003 are currently not available, upon the expiration of relevant patents, we may face fierce competition from generic or biosimilar products, including from the ATK inhibitors in generic or biosimilar form of LAE002 and LAE003, which may have a negative impact on the commercialization of LAE002 and LAE003 and our financial position. In addition to the above commercialization strategy efforts, we may seek to optimize our profits by introducing our own generic drugs before the relevant patents expire.

Additionally, we plan to build a dedicated in-house sales and marketing team to cover the market in China. Our initial target is to create, at the time of the commercialization of LAE002, a sales team of approximately 60 people to cover approximately 50 of the top hospitals in China, which are equipped with the technology and physicians to administer our LAE002. In particular, we plan to set up sales and operations teams at the target hospitals to facilitate the use of our products. These teams will ensure our LAE002 are administered in accordance with the applicable standards and provide advice to the hospital staff. As our business grows over the next three years, we anticipate expanding our sales force to approximately 100 people in order to support the administration of our LAE002 across the top 100 oncology hospitals in China. For the commercialization of LAE003, we plan to collaborate with partners for its development and commercialization overseas.

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To support our long-term business strategy and to fulfill the potential of our company's assets, our corporate and business development group advances a holistic approach to continuously assess partnering opportunities with various global and regional stakeholders in the biopharmaceutical and biotech industry. These opportunities may include co-developments of new treatment modalities for our existing clinical stage pipeline in order to deliver additional solutions for patients. Additionally, as part of our core strategy to develop innovative drugs to market, we continue to seek research partnerships, in the pursuit to bring in house cutting edge science and technologies in the field of drug development for cancer and liver diseases.

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Our R&D team collaborates closely with our corporate and business development group to evaluate business opportunities to optimize our pipeline structure in accordance with our product development strategy and innovative R&D principles. Leveraging our understanding and scientific insights into cancer disease biology, especially the PI3K/AKT/mTOR pathway, we have successfully acquired from Novartis four clinically validated assets with strong combinatorial potential in solid tumors, spearheaded by LAE002 and LAE001.

We have a proven track record of success partnering with global pharmaceutical and biotechnology companies across our pipeline, and we continue to manage those alliances and transform them into success stories. We understand the importance of the network we have built to drive our strategic focus forward. Therefore, we continue to engage with external resources for innovation and growth that will transform our efforts to a commercial success.

INTELLECTUAL PROPERTY

Intellectual property rights are central to the success of our business. Our commercial future will depend, in part, on our ability to acquire and protect our intellectual property rights for commercially significant technologies, inventions and know-how. This includes acquisition of new patents, defense of existing patents, and protection of our trade secrets. We will also have to operate without infringing, misappropriating, or otherwise violating third parties’ valid, enforceable intellectual property rights.

As of the Latest Practicable Date, we hold 163 patents and patent applications (including in-licensed patents and patent applications with global rights), among which 136 patents and patent applications of our drug candidates were in-licensed from Novartis AG. The following table sets forth an overview of our material granted patents and filed patent applications in connection with our clinical and pre-clinical drug candidates as of the Latest Practicable Date:

Product	Subject Matter of Patent Family ⁽¹⁾	Jurisdiction	Status	Applicant/Assignee	Expected Patent Expiration ⁽²⁾	Market Commercial Rights of the Company
LAE002/LAE003	Composition of matter	U.S.	issued	Novartis AG	2031	exclusive license rights
		Argentina, Australia, Brazil, Canada, mainland China, EPO (Austria, Belgium, Denmark, France, Germany, Greece, Hong Kong, Ireland, Italy, Netherlands, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, UK), India, Israel, Japan, South Korea, Mexico, Singapore, South Africa	issued	Novartis AG	2028	exclusive license rights

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Product	Subject Matter of Patent Family ⁽¹⁾	Jurisdiction	Status	Applicant/Assignee	Expected Patent Expiration ⁽²⁾	Market Commercial Rights of the Company
	Combinations for treating cancer and use thereof	Japan	issued	Novartis AG	2034	exclusive license rights
		U.S., mainland China, EPO, Hong Kong, Japan	pending	Novartis AG	2034	exclusive license rights
		Mainland China, EPO (France, Germany, UK), Japan	issued	Novartis AG	2034	exclusive license rights
LAE002	Crystalline N-((1)-2-amino-1-[(3-fluorophenyl)methyl]ethyl)-5-chloro-4-(4-chloro-1-methyl-1h-pyrazol-5-yl)-2-thiophenecarboxamide hydrochloride	U.S.	issued	Novartis AG	2031	exclusive license rights
		Australia, Brazil, Canada, mainland China, Israel, Japan, South Korea, Mexico, Singapore, South Africa	issued	Novartis AG	2030	exclusive license rights
		EPO, Hong Kong	pending	Novartis AG	2030	exclusive license rights
		U.S., mainland China, EPO (France, Germany, UK), Japan	issued	Novartis AG	2032	exclusive license rights
LAE001	Composition of matter	U.S.	issued	Novartis AG	2031	exclusive license rights
		Australia, Brazil, Canada, mainland China, EPO (Austria, Belgium, France, Germany, Greece, Italy, Netherlands, Poland, Portugal, Spain, Switzerland, Turkey, UK), India, Japan, South Korea, Mexico	issued	Novartis AG	2030	exclusive license rights
LAE005	Antibody molecules to PD-L1 and uses thereof	U.S.	issued	President & Fellows of Harvard College; Dana Farber Cancer Inst. Inc.; Novartis AG	2036	exclusive license rights
		Australia, mainland China, Israel, Japan, Mexico, Eurasia, Macao	issued	President & Fellows of Harvard College; Dana Farber Cancer Inst. Inc.; Novartis AG	2035	exclusive license rights

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Product	Subject Matter of Patent Family ⁽¹⁾	Jurisdiction	Status	Applicant/Assignee	Expected Patent Expiration ⁽²⁾	Market Commercial Rights of the Company
		U.S., Brazil, Canada, mainland China, EPO, Hong Kong, India, Japan, South Korea, Singapore, South Africa	pending	President & Fellows of Harvard College; Dana Farber Cancer Inst. Inc.; Novartis AG	2035	exclusive license rights
	Dosage regimens for anti-PD-L1 antibodies and uses thereof	U.S., mainland China, EPO, Japan, Hong Kong	pending	Novartis AG	2039	exclusive license rights
Combination of LAE002 and LAE001	Method of treating cancer	U.S., Australia, Brazil, Canada, mainland China, Eurasia, EPO, Israel, Japan, South Korea, Mexico, Singapore, South Africa	pending	Our Company	2040	ownership
Combination of LAE002 and LAE005	Combination of afuresertib and an anti-PD-L1 mAb	PCT	pending	Our company	2043	ownership
LAE104/LAE105	Depletion of activated hepatic stellate cells (HSCs)	PCT	pending	Our Company	2042	ownership
LAE102	Anti-ACVR2A antibodies and uses thereof	PCT	pending	Our Company	2042	ownership
LAE111	Anti-il1rb1 and/or anti-il1rb2 antibodies and uses thereof	PCT	pending	Our Company	2044	ownership
LAE119	Fused multicyclic compounds and their use as PARP1 inhibitors	PCT	pending	Our Company	2043	ownership
LAE120	Fused bicyclic compounds and their use as USP1 inhibitors	PCT	pending	Our Company	2043	ownership
	Heteroaromatic compounds and their use as USP1 inhibitors	PCT	pending	Our Company	2044	ownership

Abbreviations: EPO = European Patent Office; UK = United Kingdom; U.S. = United States; PCT = Patent Cooperation Treaty.

Notes:

- (1) Unless otherwise indicated, the patent for applications within the same family is the same and is therefore disclosed once.
- (2) The expected patent expiration date is estimated based on current filing status on the assumption that a patent is granted to a pending application, without taking into account any possible patent term adjustments or extensions except as noted for the U.S. patents, the expiration date of which takes into account the patent term adjustments and terminal disclaimers as shown in the U.S. Patent and Trademark Office database, assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

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The term of individual patents may vary based on the countries in which they are obtained. In most countries and regions in which we file patent applications, the term of an issued patent is generally 20 years from the filing date of the formal patent application on which the patent is based in the applicable country or region. In the U.S., a patent's term may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for administrative delays by the United States Patent and Trademark Office (USPTO), in excess of a patent applicant's delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly owned patent having an earlier expiration date.

The actual protection provided by a patent varies on a claim-by-claim and country-by-country basis and depends upon various factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country or region, and the validity and enforceability of the patent. We cannot provide any assurance that patents will be issued with respect to any of our owned or licensed pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our product candidates and methods of manufacturing the same.

We have not obtained patent protections for some early-stage drug candidates because (i) more efforts are needed to complete the design of molecular structure of the drug candidates and to evaluate the characteristics, functions and effects of the drug candidates; and (ii) the submitted patent applications are currently in prosecution of patent office. As of the Latest Practicable Date, amongst our non-patented drug candidates, LAE102, LAE104, LAE105, LAE111, LAE119 and LAE120 patent applications have been submitted to patent offices in major markets, and have been accepted for prosecution. For LAE106, LAE109, LAE113, LAE117, and LAE112, once we have determined the molecular structure for the final drug candidates to the clinical studies, we will file patent applications in China, U.S. and other relevant jurisdictions promptly. We also plan to set up patent portfolios to provide extensive patent protections.

We may rely, in some circumstances, on trade secrets and confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements and non-competition agreements with our senior management, certain key members of our R&D team, and other employees who have access to trade secrets or confidential information about our business. Our standard employment contract, which we use to employ each employee, contains an assignment clause. We own all the rights to all inventions, technology, know-how, and trade secrets derived during such employees' employment.

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These agreements may not sufficiently protect our trade secrets and confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secrets and confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and confidential information may become known or be independently developed by a third party or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or obtain or use information that we regard as proprietary without our consent. As a result, we may not sufficiently protect our trade secrets and proprietary information.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining the physical security of our premises and the physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. See “Risk Factors – Risks Relating to Our Intellectual Property Rights” to describe risks related to our intellectual property.

We conduct our business under the brand name “LAEKNA”. As of the Latest Practicable Date, we had registered 15 trademarks and two trademark applications in mainland China and Hong Kong. We are also the registered owner of three domain names.

As of the Latest Practicable Date, we had not been involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent.

SUPPLIERS

During the Track Record Period, we primarily procured services and raw materials to develop our drug candidates from highly reputable manufacturers and suppliers. Our purchases mainly include third-party contracting services for pre-clinical evaluation and clinical trials of our drug candidates, raw materials, and consumables. Our purchases from our five largest suppliers in the aggregate in each period during the Track Record Period amounted to RMB78.7 million and RMB152.6 million, representing 63.4% and 67.2% of our total purchases (excluding value-added tax), respectively. Our purchases from our largest supplier in each period during the Track Record Period amounted to RMB27.7 million and RMB80.4 million, representing 22.3% and 35.4% of our total purchases (excluding value-added tax), respectively.

To the best of our knowledge, all of our five largest suppliers during the Track Record Period are Independent Third Parties. None of our Directors, their respective associates or any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers during the Track Record Period.

In addition, we believe that adequate alternative sources for such supplies exist, and we have developed alternative sourcing strategies for these supplies. We will establish necessary relationships with alternative sources based on supply continuity risk assessment. We generally have credit periods of 30 days.

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Below is a summary of the key terms of a typical agreement with our CROs, SMOs and CDMOs.

- *Services.* The CRO, SMO, or CDMO provides us with services such as implementing a clinical research project, manufacturing products as specified in the master agreement or work order.
- *Term.* The CRO, SMO or CDMO is required to perform its services according to the prescribed timeframe set out in the master agreement or a work order.
- *Payment.* We are required to make payments to the CRO, SMO, or CDMO according to the payment schedule agreed by the parties.
- *Confidentiality.* We and the CRO, SMO or CDMO agree to keep confidential any information in relation to the performance of the master agreement.
- *Intellectual Property.* We own all intellectual property derived from the clinical research project, and we are entitled to apply patent for such intellectual properties.

The tables below set forth certain information about our five largest suppliers in terms of total purchases during the Track Record Period:

For the Year Ended December 31, 2021

Supplier	Years of Relationship	Credit Term	Product or Service Supplied	Purchase Amount (RMB'000)	Percentage of Total Purchases
Supplier A (CDMO A)	Since 2018	30 days	CDMO service, pre-clinical research service, clinical research coordinator service	27,721	22.3%
Supplier B (CRO A)	Since 2019	30 days	CRO service	20,533	16.5%
Supplier C (CRO B)	Since 2018	30 days	CRO service	15,227	12.3%
Supplier D	Since 2019	30 days	Clinical research service	7,769	6.3%
Supplier E	Since 2019	N/A	CDMO service	7,475	6.0%

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For the Year Ended December 31, 2022

Supplier	Years of Relationship	Credit Term	Product or Service Supplied	Purchase Amount <i>(RMB'000)</i>	Percentage of Total Purchases
Supplier A (CDMO A)	Since 2018	30 days	CDMO service, pre-clinical research service, clinical research coordinator service	80,430	35.4%
Supplier D	Since 2019	30 days	Clinical research service	24,250	10.7%
Supplier B (CRO A)	Since 2019	30 days	CRO service	19,465	8.6%
Supplier F (CRO C)	Since 2021	30 days	Pre-clinical research service	15,648	6.9%
Supplier C (CRO B)	Since 2018	30 days	CRO service	12,767	5.6%

COMPETITIONS

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, competition and a strong emphasis on proprietary drugs. While we believe our pipeline of clinical and pre-clinical stage proprietary assets, leading R&D capability, biopharmaceutical platform and seasoned management team provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, and public and private research institutions.

We primarily focus on the research and development of small molecule targeted oncology therapies, in particular, our Core Products, LAE001 (anti-CYP17A1 androgen synthesis inhibitor) and LAE002 (AKT inhibitor). Although no AKT inhibitor has been approved for commercialization yet, seven AKT inhibitors are under clinical development globally, focusing on the treatment of a variety of solid tumors such as ovarian cancer and breast cancer. For anti-androgen drugs, there are seven anti-androgen drugs approved for commercialization globally (ex-China) and seven anti-androgen drugs approved in China. There are 11 anti-androgen drugs in clinical trials globally and five anti-androgen drugs in clinical trials in China.

We also face potential competition from existing drug products and drug product candidates under development even though they may be of different classes as well as conventional treatment therapies in the entire oncology market. Although the field of cancer treatment has developed significantly in the past decade, conventional treatment methods such

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as surgery, radiotherapy and chemotherapy are still been widely used to treat cancer. Alternative treatments such as targeted oncology and immuno-oncology are generally used only if other therapy options are not suitable or effective on patients. See “Industry Overview” for more details on the competitive landscape of the various markets in which we compete.

GOVERNMENT GRANTS, AWARDS AND RECOGNITIONS

We have received a wealth of grants and awards. Major government grants that we had received as of the Latest Practicable Date are set forth in the table below.

Year	Grant Type	Project Name	Project Level
2021	Subsidies for science and technology projects	Shanghai Science and Technology Commission Innovative Product Tackling Project (上海市科學技術委員會創新產品攻關項目)	Provincial
2020	Subsidies for science and technology projects	Zhangjiang High-Tech Park Support for innovation and entrepreneurship environment (張江科學城支持創新創業環境細則政策)	Provincial

The following table sets forth some of the important accreditations and awards we had received from the relevant authorities and organizations in China as of the Latest Practicable Date in recognition of our research and development capabilities:

Year	Accreditation/Award	Accreditation Organization
2022	2022 China Pharmaceutical Seed Enterprise Innovation Top 100 (2022中國醫藥種子企業創新100強)	Healthcare Executive (E藥經理人)
2022	2022 Pioneers: The Scientists (科學家創業先鋒榜)	www.chinastarmarket.cn (科創版日報)
2022	China Future 50 – Biotech (中國生物科技創新50企業)	KPMG (畢馬威)
2021	2021 China CSR Cloud Summit “Excellent Case of Social Responsibility” (2021中國企業社會責任雲峰會“社會責任優秀案例”)	www.xinhuanet.com (新華網)

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Year	Accreditation/Award	Accreditation Organization
2021	2021 China Sci-Tech Good Company Biomedical Pioneer-10 (2021中國科創好公司,生物醫療Pioneer-10)	www.chinastarmarket.cn (科創版日報)
2021	2021 China Pharmaceutical Seed Enterprise Innovation Top 100 (2021中國醫藥種子企業創新100強)	Healthcare Executive (E藥經理人)
2021	2021 R&D Frontier Award (2021年度研發前沿獎)	Pharma DJ (研發客)
2021	Top 100 Most Powerful Companies with Technology Top 50 Most Powerful Innovative Companies with Technology (最具科技力量百強企業榜,最具科技力量創新企業TOP50)	Frost & Sullivan
2020	The First Tumor Treatment High Technology Conference – and Annual Top 20 of Tumor Treatment High Technology (首屆腫瘤診療黑科技大會-暨腫瘤診療黑科技年度TOP20)	Liangyihui (良醫匯) and CSCO Foundation (北京市希思科臨床腫瘤學研究基金會)
2019	China Medical Health Industry Investment and Financing Glory List – Top 20 Best Newcomer Award in Medical Health Industry (中國醫療大健康產業投融資榮耀榜-醫療健康產業最佳新銳獎TOP20)	CHC Consultant (CHC醫療傳媒) and CITIC Securities (中信證券)
2018	Insight Zhangjiang Top 100 (洞見張江TOP100)	Zhangjiang Venture (張江科投) and JingData (鯨準)

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our principal insurance policies cover employee benefits liability and adverse events in clinical trials. We currently do not maintain insurance for environmental liability or property loss. Please refer to the section headed “Risk Factors – Risks Relating to our Operations – We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources” in this document.

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We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made or been the subject of any material insurance claims.

EMPLOYEES

As of the Latest Practicable Date, we had 95 employees in total. Among the 95 employees, 74 are stationed in our headquarters in Shanghai. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Function	Number	Percentage of Total
Research and Development	60	63.2%
CMC and Quality	8	8.4%
Business Development	2	2.1%
Operations	25	26.3%
Total	95	100%

We enter into individual employment contracts with our employees covering salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause and grounds for termination. We also enter into separate confidentiality and non-competition agreements with our senior management, certain key members of our R&D team, and other employees who have access to trade secrets or confidential information about our business.

To maintain our workforce’s quality, knowledge, and skill levels, we provide continuing education and training programs, including internal training, to improve their technical, professional or management skills. We also provide training programs to our employees from time to time to ensure their awareness and compliance with our policies and procedures in various aspects. Furthermore, we provide various incentives and benefits to our employees, including competitive salaries, bonuses and share-based compensation, particularly our key employees.

Our employees’ remuneration comprises salaries, bonuses, provident funds, social security contributions, and other welfare payments. We have made contributions to our employees’ social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds pursuant to applicable laws and regulations. We have complied with all statutory social security insurance fund and housing fund obligations applicable to us under the laws and regulations in China in all material aspects during the Track Record Period and as of the Latest Practicable Date. Please refer to the section headed “Risk Factors – Risks Relating to Doing Business in China – Failure to comply with relevant regulations relating to social insurance and housing provident fund may subject us to penalty” in this document.

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LAND AND PROPERTIES

As of the Latest Practicable Date, we do not own any real property. As of the Latest Practicable Date, we leased four properties in China with an aggregate GFA of approximately 5,493.3 sq.m. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms to meet our future needs. We do not anticipate undue difficulty in renewing our leases upon their expiration.

The following table sets forth the details of our leased properties as of the Latest Practicable Date:

Usage	Location	GFA (sq.m)	Lease Term
Office and laboratory	Shanghai	1,261.1	September 16, 2021 to September 15, 2027
Office	Beijing	60	September 1, 2022 to August 31, 2023
R&D	Shanghai	4,042.2	August 10, 2021 to November 30, 2030
Office	Shanghai	130	March 28, 2022 to March 31, 2023; (Renewed) April 1, 2023 to March 31, 2024
Office	Los Angeles, United States	N/A*	December 1, 2022 to November 30, 2023

Note:

* In the U.S., we entered into a membership agreement with 10250 Constellation Tenant LLC (“WeWork”) for the capacity of five memberships for our office operation.

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ENVIRONMENTAL, SOCIAL, AND GOVERNANCE

Governance

We acknowledge our environmental protection and social responsibilities and are aware of the climate-related issues that may impact our Group’s business operation. We are committed to complying with environmental, social and governance (“ESG”) reporting requirements upon [REDACTED].

We have established a set of ESG policies covered under relevant international standards. We endeavor to reduce negative impacts on the environment through our commitment to energy saving and sustainable development. For environmental matters, we have adopted policies related to (i) reduction of greenhouse gas emissions, (ii) treatment of exhaust gas and solid waste, (iii) adoption of materials that cause minimum environmental concerns to the extent possible, and (iv) conservation of energy, among other aspects. We continue to promote work-life balance and create a positive workplace for all of our employees. For social matters, we have adopted policies related to (i) product quality, (ii) employee health, promotion, compensation and benefits, (iii) employee training, wellness and professional and personal development, and (iv) employee complaint handling, among other aspects.

Our ESG policies also sets out different parties’ respective responsibilities and authority in managing the ESG matters. Our Board has overall responsibility for overseeing and determining our Group’s environmental, social, and climate-related risks and opportunities impacting our Group, establishing and adopting the ESG policy and targets of our Group, and reviewing our Group’s performance annually against the ESG targets and revising the ESG strategies as appropriate if significant variance from the target is identified.

Our Company [has established] an ESG committee, see “Directors and Senior Management – Corporate Governance – ESG Committee” for details.

Potential Impacts of ESG-Related Risks

We do not conduct manufacturing activities, thus generate no direct emissions and industrial wastes. However, we are subject to various ESG related laws and regulations in China, and our operations are regularly inspected by local government authorities. For further details, please refer to “Regulatory Overview – Regulations on Environmental Protection and Fire Prevention” in this document.

During the Track Record Period and up to the Latest Practicable Date, we have not received any fines or penalties associated with the breach of any environmental laws or regulations. To the best knowledge and belief of our Directors, we are not subject to material environmental liability risk and will not incur material compliance costs in the future.

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In view of the nature of our business, to the best knowledge of our Directors, the climate change will not have any major impact on our business operation. In the case of extreme natural weather, we will actively respond to the relevant policies of local government, make contingency plans in addition to the life insurance contributed by our Group to ensure the safety of our staff. In the case of acute physical risks such as direct damage to assets and indirect impacts from supply chain disruption as a result of extreme weather events, we will make corresponding contingency and disaster preparedness plans, and we believe that we have the ability to deal with climate crisis. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material impact on our business operations, strategies or financial performance as a result of environmental, social and climate-related issues.

Potential transition risk may result from a lower-carbon economy, which entails climate-related regulations and policy change and reputational risk. Currently, the National Development and Reform Commission and the Ministry of Ecology and Environment have jointly issued the Opinions on Further Strengthening the Cleanup of Plastic Pollution, laying out a five-year roadmap to restrict the use, production and sale of plastic products by 2020, 2022, and 2025, respectively. Our Group will work with the suppliers to comply with such regulations, and we will monitor the scope to ensure our works meet the expectations of the regulators.

	Risks	Potential Impacts
Short term (current annual reporting period)	<ul style="list-style-type: none"> • Extreme weather conditions such as flooding and storms • Sustained elevated temperature 	<ul style="list-style-type: none"> • Reduced revenue from damage to assets, disruption to third-party logistic providers or third-party manufacturers
Medium term (one to three year)		<ul style="list-style-type: none"> • Increased operating expenses
Long term (four to ten years)	<ul style="list-style-type: none"> • Change in climate-related regulations • Shifts in customer preferences 	<ul style="list-style-type: none"> • Reduced demand for goods and services

Strategies in Addressing ESG-Related Risks

We have adopted various measures in managing the air emissions and greenhouse gas (“GHG”) emissions during our operations, including but not limited to:

- requiring employees to turn off lights, equipment, and other electronic devices when the devices are not in operation and before they leave the premises;

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- using more energy-efficient lighting products, such as LED lighting;
- setting and keeping the air conditioners to a default temperature of around 24 to 26 degrees; and
- conducting regular inspection and maintenance of vehicles and equipment.

Our total cost of compliance with environmental protection and health and safety laws and regulations in 2021 and 2022 was RMB95,000 and RMB90,000, respectively. We do not expect our costs of complying with current and future environmental protection and health and safety laws to increase significantly going forwards.

We will adopt various strategies and measures to identify, assess, manage and mitigate environmental, social and climate-related risks, including but not limited to:

- reviewing and assessing the ESG reports of similar companies in the industry to ensure that all relevant ESG-related risks are identified on a timely basis.
- discussing among management from time to time to ensure all the material ESG areas are recognized and reported.
- discussing with key stakeholders on key ESG principles and practices to ensure that the significant aspects are covered.
- organizing a specific ESG risk management process to identify and consider ESG risks and opportunities separate from other business risks and opportunities.
- setting targets for environment KPIs, including with regard to emission, pollution and other impact on the environment aimed at reducing emissions and natural resource consumption.
- collecting adverse events of drugs from clinical trials, including following the relevant regulations on the collection of adverse events once our drugs are approved and monitoring adverse events of drugs from literature, social media and reports.

We will adopt comprehensive measures to mitigate environmental impact from our business, strategy and financial performance in the near, medium and long term, as summarized below:

Focus areas	Key measures
Exhaust gas management	<ul style="list-style-type: none">• Adopt exhaust gas treatment system and install active carbon filters
Greenhouse gas management	<ul style="list-style-type: none">• Increase the use of clean energy

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Focus areas	Key measures
	<ul style="list-style-type: none">• Use energy efficient equipment
Sewage management	<ul style="list-style-type: none">• Install sewage treatment system
Solid waste management	<ul style="list-style-type: none">• Require proper handling and disposal of solid waste• Set up hazardous waste storage sites in accordance with relevant standards and establish standardized hazardous waste management system• Engage qualified third-party suppliers for solid waste disposal
Energy and resource conservation	<ul style="list-style-type: none">• Improve energy-saving features such as energy-saving transformers• Conserve water by recycling rain water and installing low-flow valves

Our Group will conduct an enterprise risk assessment at least once a year to cover the current and potential risks faced by our Group, including, but not limited to, the risks arising from the ESG aspects and strategic risk around disruptive forces such as climate change. Our Board will assess or engage an external expert to evaluate the risks and review our Group’s existing strategy, target and internal controls, and necessary improvement will be implemented to mitigate the risks. Our Board, Audit Committee, and the ESG Committee will maintain oversight of our Group’s approach to risk management, including climate-related risks and risks monitored as part of the standard operating processes to ensure the appropriate mitigations are in place of the regular management reviews.

The decision to mitigate, transfer, accept or control risk is influenced by various factors such as government regulation, transportation network and public perception. Our Group will incorporate climate-related issues, including physical and transition risk analysis, into our risk assessment processes and risk appetite setting. If the risk and opportunities are considered material, our Group will make reference to them in the course of the strategy and financial planning process. Upon annual review of the environmental, social and climate-related risks and our Group’s performance in addressing the risks, we may revise and adjust the ESG strategies as appropriate.

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Metrics and Targets

We have monitored the following metrics to assess and manage the environmental and climate-related risks arising from our business and manufacturing operations since 2021:

Resource Consumption

- *Electricity consumption.* We have monitored our electricity consumption levels and implement measures to improve energy efficiency since 2021. In 2021 and 2022, our electricity consumption levels were 0.2 million kWh and 0.2 million kWh, respectively. We intend to reduce the level of our per capita electricity consumption by approximately 10% per thousand dollars of R&D expense by 2023 through (i) installing energy efficient lighting in future decoration and ensuring lights are switched off when not in use either manually or through automatic sensors, and (ii) switching off certain IT equipment or setting up automatic power shutdown for certain systems and devices when not in use.
- *Water consumption.* We have monitored our water consumption levels and implement measures to promote water conservation since 2021. In 2021 and 2022, our water consumption levels were 323 tons and 281 tons, respectively. We intend to reduce the level of our per capita water consumption by approximately 10% per thousand dollars of R&D expense by 2023 through (i) selecting, installing and maintaining water-saving devices and appliances to avoid waste, and (ii) posting slogans on saving water in our office, encouraging employees to save water in their daily life, including when working in the office.

Discharge Management

- *Greenhouse gas discharge.* We have monitored our GHG discharge levels on a periodic basis since 2021. In 2021 and 2022, our GHG emissions were approximately 117.86 tons and 126.43 tons, respectively. We intend to reduce the level of our per capita GHG discharge by approximately 10% per thousand dollars of R&D expense by 2023 through (i) putting forward strict environmental protection requirements in the process of selecting suppliers of raw materials and consumables, (ii) reducing the use of air conditioners in our laboratories to the extent possible, especially in winter, and (iii) limiting business air travels and replacing long-journey in-person meetings with virtual conferences where possible.
- *Hazardous waste discharge.* We have monitored our hazardous waste discharge levels on a periodic basis since 2021. In 2021 and 2022, our hazardous waste discharge levels were approximately 2.12 tons and 1.97 tons, respectively, and such waste was disposed by qualified third parties. We intend to reduce the level of our per capita hazardous waste discharge by approximately 10% per thousand dollars of R&D expense by 2023 through (i) reducing discharge of sewage from our laboratories, and (ii) discharging sewage into urban sewage systems with the aim to cause little pollution to the environment.

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Our Board will set targets for each material KPIs at the beginning of each financial year in accordance with the disclosure requirements of Appendix 27 to the Listing Rules and other relevant rules and regulations upon [REDACTED]. The relevant targets on material KPI will be reviewed on an annual basis to ensure that they remain appropriate to the needs of our Group. In setting targets for the ESG-related KPIs, we have taken into account our respective historical consumption or discharge levels during the Track Record Period, and have considered our future business expansion in a thorough and prudent manner with a view of balancing business growth and environmental protection to achieve sustainable development.

Workplace Safety

We have adopted and maintained a series of rules, standard operating procedures, and measures to maintain our employees’ healthy and safe environment. We implement safety guidelines to set out information about potential safety hazards and procedures for operating in the manufacturing facilities. We require new employees to participate in safety training to familiarize themselves with the relevant safety rules and procedures. In particular, we conduct training sessions on fire control safety and regularly perform emergency evacuation drills to reduce risks associated with potential fire accidents. Also, we have policies in place and have adopted relevant measures to ensure the hygiene of our work environment and the health of our employees.

We provide company-level and department-level training for all new hires so that our employees are effectively familiarized with each other’s responsibilities. We provide training in systematic management theory, technology and application skills for middle and senior management. Staff in specialized departments, such as finance and R&D, receive basic training in their field and gain up-to-date business knowledge. We have established an employee performance management system that provides regular reviews of compensation and development for high-performing employees. We provide benefits such as an improved health insurance plan to bring a better welfare experience to our employees. We use equity incentives as a long-term incentive plan to encourage employees to start and grow with the company.

Our PRC Legal Adviser has confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had not been subject to any material claim or penalty in relation to health, work safety, social and environmental protection, and had been in compliance with the relevant laws and regulations in China in all material aspects.

PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, our PRC Legal Adviser confirmed we had obtained requisite licenses, approvals and permits from relevant Chinese authorities that are material to our operations in China, and such licenses, permits and certifications all remain in full effect. For more details regarding the laws and regulations to which we are subject, please see the section headed “Regulatory Overview” in this document. We had not experienced any material difficulty in renewing such licenses, permits, approvals and certificates during the Track Record Period and up to the Latest Practicable Date, and we currently do not expect to have

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any material difficulty in renewing them when they expire, if applicable. There is no material legal impediment in renewing such licenses, permits, approvals and certificates as they expire in the future as long as we are in compliance with applicable laws, regulations and rules. During the Track Record Period and up to the Latest Practicable Date, we had not been penalized by any government authorities for any material non-compliance relating to maintenance and renewal of our material licenses, permits, approvals and certificates.

LEGAL PROCEEDINGS AND COMPLIANCE

Legal Proceedings

During the Track Record Period and up to the Latest Practicable Date, we were not a party to any actual or threatened legal or administrative proceedings. We are committed to maintaining the standards of compliance with the laws and regulations applicable to our business. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business.

Legal Compliance

Our PRC Legal Adviser confirmed that during the Track Record Period and up to the Latest Practicable Date, we had complied with applicable laws and regulations in China in all material aspects. Our Directors confirmed that we were not involved in any material or systematic non-compliance incidents.

Our compliance team is responsible for building, developing and improving our compliance management system to ensure our compliance culture is embedded into everyday workflow. The team conducts compliance training for target groups and identifies, assesses, and reports compliance risks and expectations in a timely manner. For example, we provide formal and comprehensive company-level legal seminars to our employees, followed by on-the-job training to efficiently get them familiarized with their responsibilities and our compliance requirements. Our compliance team will also work with the senior management team to monitor and evaluate the effectiveness of our compliance function and structure to ensure that we comply with the applicable laws and regulations. For example, we will periodically conduct compliance and performance reviews on our employees against our internal compliance standards to ensure their compliance awareness meets our requirements.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are exposed to various risks in our business operations, and we believe that risk management is important to our success. For details, see “Risk Factors – Risks Relating to Our Operations”. Our Directors oversee and manage the overall risks associated with our

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operations. We have prepared written terms of reference in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code and Corporate Governance Report as set out in Appendix 14 to the Listing Rules.

To monitor the ongoing implementation of our risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following risk management measures:

- establish an Audit Committee to review and supervise our financial reporting process and internal control system;
- adopt various policies to ensure compliance with the Listing Rules, including but not limited to aspects related to risk management, connected transactions and information disclosure;
- provide anti-corruption and anti-bribery compliance training periodically to our senior management and employees to enhance their knowledge and compliance with applicable laws and regulations; and
- attend training sessions by our Directors and senior management in respect of the relevant requirements of the Listing Rules and duties of directors of companies listed in Hong Kong.

Internal Control

We have engaged an independent internal control consultant to assess our internal control system in connection with the [REDACTED]. The internal control consultant has conducted a review procedure on our internal control system in certain aspects, including financial reporting and disclosure controls, corporate level controls, information system control management and other procedures for our operations. The internal control consultant has not identified any material deficiencies in our internal system.

We have also appointed external legal counsels to advise us on compliance matters, such as compliance with the regulatory requirements on clinical research and development, which is also monitored by our regulatory and quality assurance team. We have also established anti-bribery guidelines and compliance requirements in our employee handbook. After considering the remedial actions we have taken, our Directors are of the view that our internal control system is adequate and effective for our current operations.

We plan to provide our Directors, senior management, and relevant employees with continuous training programs and updates regarding the relevant laws and regulations in China and the U.S. regularly to proactively identify any concerns and issues relating to any potential non-compliance.

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Anti-Bribery

We maintain strict anti-corruption policies among our employees. We believe we will be less affected by the increasingly stringent measures taken by the Chinese government to correct corruptive practices in the pharmaceutical industry. We strictly prohibit bribery or other improper payments in our business operations. This prohibition applies to all business activities, anywhere globally, whether involving government officials or healthcare professionals. Improper payments prohibited by this policy include bribes, kickbacks, excessive gifts or entertainment, or any other payment made or offered to obtain an undue business advantage. We keep accurate books and records that reflect transactions and asset dispositions in reasonable detail. Requests for false invoices or payment of unusual, excessive or inadequately described expenses are rejected and promptly reported. Misleading, incomplete or false entries in our books and records are never acceptable. We will also ensure that future commercialization team personnel comply with applicable promotion and advertising requirements, including restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

Data Privacy Protection

We have established procedures to protect the confidentiality of patients’ data. We maintain policies requiring our personnel to be trained to collect and safeguard personal information and require our CROs to have data protection clauses in our agreements with them. They are responsible for safeguarding data in their possession. According to the GCP and relevant regulations, access to clinical trial data has been strictly limited to authorized personnel.

Additionally, we require external parties and internal employees involved in clinical trials to comply with confidentiality requirements. Data are to be used only for the intended use, as agreed by the patients and consistent with the Informed Consent Form (the “ICF”). We will obtain consent from patients if any use of data falls outside the scope of ICF.

We have a number of ongoing or planned clinical studies in China and the U.S. Any transfer of clinical trial data in connection with our product development efforts and regulatory communications is subject to the applicable local data and privacy protection laws, including those in China and the U.S. Together with our CROs and other collaborators, we have implemented controls and arrangements designed to ensure a data management and transfer plan is developed and implemented to govern the transfer of all clinical trial data or other potentially sensitive information. Related measures include, as applicable, ensuring that the cross-border transfer of this clinical data and information is permitted, any requisite approvals are properly obtained, and applicable filings are made, in each case, with the competent authorities and in accordance with relevant laws and regulations (particularly in the case of any transfer between China and the U.S.). Although the laws and regulations in this area and the nature of our potential clinical studies are evolving, to date, we have not experienced any material difficulty in data transfer, and we believe our transfer of relevant clinical trial data and information between China and the U.S. is in line with market practice.

DIRECTORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board of Directors consists of nine Directors, comprising three executive Directors, three non-executive Directors and three independent non-executive Directors. The table below sets forth certain information in respect of the members of the Board:

Name	Age	Time of Joining our Group	Time of Appointment as Director	Position	Roles and Responsibilities
Dr. LU Chris Xiangyang	[59]	July 2016	July 2016	Chairman Executive Director Chief Executive Officer	Responsible for overseeing the overall business strategy, R&D activities, business planning and operational management
Ms. XIE Ling (謝玲)	[51]	April 2017	May 2018	Executive Director Senior vice president	Responsible for overseeing our global operations, including administrative, human resources, finance, legal, IT and compliance matters
Dr. GU Xiang Ju Justin	[57]	January 2020	May 2022	Executive Director Chief Scientific Officer	Responsible for overseeing our pre-clinical discovery research works
Dr. WANG David Guwei	[61]	July 2019	July 2019	Non-executive Director	Responsible for providing professional advice to the Board
Ms. JI Dongmei (吉冬梅)	[49]	April 2022	April 2022	Non-executive Director	Responsible for providing professional advice to the Board
Mr. SUN Yuan (孫淵)	[34]	April 2022	April 2022	Non-executive Director	Responsible for providing professional advice to the Board
Dr. YIN Xudong	[56]	Date of this document	Date of this document	Independent non-executive Director	Responsible for providing independent opinion and judgment to the Board

DIRECTORS AND SENIOR MANAGEMENT

Name	Age	Time of Joining our Group	Time of Appointment as Director	Position	Roles and Responsibilities
Mr. CHAU Kwok Keung (鄒國強)	[46]	Date of this document	Date of this document	Independent non-executive Director	Responsible for providing independent opinion and judgment to the Board
Dr. LI Min	[60]	Date of this document	Date of this document	Independent non-executive Director	Responsible for providing independent opinion and judgment to the Board

Executive Directors

Dr. LU Chris Xiangyang, aged [59], is our Chairman, executive Director and Chief Executive Officer. Dr. Lu is the founder of our Group and is responsible for overseeing the overall business strategy, R&D activities, business planning and operational management. Dr. Lu was appointed as a Director in July 2016 and re-designated as an executive Director in May 2022.

Dr. Lu has over 20 years of drug discovery and development experience in the biotechnology and pharmaceutical industry. Dr. Lu had worked in Ontogeny, Inc., a biotechnology company, in 1998. From November 2001 to September 2003, he worked at Wyeth Research, a U.S. based pharmaceutical company as the principal scientist and had led multiple drug discovery projects. From September 2003 to March 2016, he worked at Novartis Institutes for BioMedical Research (“NIBR”) and China Novartis Institutes for BioMedical Research Co., Ltd. (諾華(中國)生物醫學研究有限公司) (“CNIBR”). He was bestowed Novartis VIVA Award with “Novartis Leading Scientist” honorary title in November 2012. His last position there was Executive Director and was responsible for leading the drug discovery platform and multiple disease research programs. NIBR and CNIBR are under Novartis AG. He then joined Frontline Bioventures (通和資本), a venture capital firm focusing on investment in healthcare industry, in 2016 as a venture partner, responsible for providing general professional advice from biotechnology perspective to the investment portfolio of Frontline Bioventures on a part-time basis. Dr. Lu had ceased to be a venture partner in Frontline Bioventures since April 2017. After the incorporation of the Company and before Dr. Lu left Frontline Bioventures, Dr. Lu was not involved in any investment of Frontline Bioventures which competed or was likely to compete, directly or indirectly, with the Group’s business.

Dr. Lu received his Bachelor of science degree and Master of science degree in biology department from Nankai University (南開大學) in China in July 1985 and June 1988, respectively. Dr. Lu obtained the Doctor of Philosophy degree from the School of Medicine of the University of North Carolina at Chapel Hill in the United States in August 1995. Dr. Lu was a postdoctoral fellow at Harvard University in the United States from 1995.

Dr. Lu is a director of Laekna HK and Laekna Therapeutics.

DIRECTORS AND SENIOR MANAGEMENT

Ms. XIE Ling (謝玲), aged [51], is our executive Director and senior vice president, and is responsible for overseeing our global operations, including administrative, human resources, finance, legal, IT and compliance matters. Ms. Xie joined our Company in April 2017 as a vice president of head of operation and has been a senior vice president of head of operation since April 2019. She was appointed as a Director in May 2018 and re-designated as an executive Director in May 2022.

From August 2002 to September 2004, Ms. Xie was an executive assistant at Boehringer Ingelheim Shanghai Pharmaceuticals Co., Ltd. (上海勃林格殷格翰藥業有限公司). From January 2008 to March 2017, Ms. Xie served as an executive assistant at CNIBR under Novartis AG, and was responsible for administrative support. Ms. Xie was accredited as national second-level psychological counselor (國家二級心理諮詢師) by Ministry of Human Resources and Social Security of the PRC (人力資源和社會保障部) in March 2011, and she was certified as Myers-Briggs Type Indicator (MBTI) practitioner by Center for Applications of Psychological Type in the United States in March 2012.

Ms. Xie received her Bachelor’s degree in law from East China University of Political Science and Law (華東政法大學) in China in July 2003.

Ms. Xie is a director of Laekna Therapeutics and Laekna Pharmaceutical.

Dr. GU Xiang Ju Justin, aged [57], is our executive Director and Chief Scientific Officer, and is responsible for overseeing our pre-clinical discovery research works. Dr. Gu joined our Group in January 2020 as our Chief Scientific Officer and was appointed as a Director and re-designated as an executive Director in May 2022.

Dr. Gu has over 20 years of experience in the biotechnology and pharmaceutical industry. From April 2001 to October 2008, he first served as a scientist and then as a group leader at Genomics Institute of the Novartis Research Foundation. From November 2008 to April 2019, he worked at CNIBR in Shanghai, with his last position as the director of lead discovery. Before joining our Group, Dr. Gu was a venture partner at GP Healthcare Capital Co., Ltd. (上海金浦醫療健康股權投資基金管理有限公司) from April 2019 to December 2019.

Dr. Gu received his Bachelor’s degree in biology from Nankai University (南開大學) in China in 1985; Master’s degree from the Institute of Botany, The Chinese Academy of Sciences (中國科學院植物研究所) in China in 1988; and the Doctor of Philosophy degree in biochemistry from the Ohio State University in the United States in March 1997. Dr. Gu was a postdoctoral fellow at Massachusetts Institute of Technology in the United States from January 1997 to August 2000.

Dr. Gu is a director of Laekna Therapeutics.

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Non-executive Directors

Dr. WANG David Guowei, aged [61], is our non-executive Director, and is responsible for providing professional advice to the Board. Dr. Wang was appointed as a Director in July 2019 and re-designated as a non-executive Director in May 2022.

Dr. Wang has over 20 years of experience in the medical industry. Dr. Wang is a partner and senior managing director of Asia at OrbiMed Advisors LLC, an investment fund with a focus on healthcare industry, where he has worked since August 2011. Since March 2020, Dr. Wang has been a director of Gracell Biotechnologies Inc. (a company listed on NASDAQ Global Market, stock code: GRCL). He has also served as a director of Sichuan Biokin Pharmaceutical Co., Ltd (四川百利天恒藥業股份有限公司) (a company listed on Shanghai Stock Exchange, stock code: 688506) since September 2017. Further, since February 2016, he has been a non-executive director of AK Medical Holdings Limited (愛康醫療控股有限公司) (a company listed on the Stock Exchange, stock code: 1789), and since December 2017, he has been a non-executive director of Gaush Meditech Ltd (高視醫療科技有限公司) (a company listed on the Stock Exchange, stock code: 2407). From April 2006 to July 2011, he served as managing director at WI Harper Group. From March 2010 to July 2012, he served on the board of directors of Edan Instruments, Inc. (深圳市理邦精密儀器股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 300206), a provider of advanced electronic medical equipment, where he also served on both the audit committee and strategic committee. He was a director of Suzhou Medical System Technology Co., Ltd. (蘇州麥迪斯頓醫療科技股份有限公司) (a company listed on the Shanghai Stock Exchange, stock code: 603990) from October 2012 to May 2019, a non-executive director of EC Healthcare (醫思健康) (formerly known as Union Medical Healthcare Limited (香港醫思醫療集團有限公司)) (a company listed on the Stock Exchange, stock code: 2138) from August 2018 to April 2020 and a director of Amoy Diagnostics Co., Ltd. (廈門艾德生物醫藥科技股份有限公司) (a company listed on the Shenzhen Stock Exchange, stock code: 300685) from June 2015 to August 2021.

Dr. Wang received his Bachelor’s degree in medicine from Beijing Medical University (北京醫科大學) (currently known as Peking University Health Science Center (北京大學醫學部)) in China in July 1986. He received his Doctor of Philosophy degree in developmental biology from California Institute of Technology in the United States in June 1995.

Dr. Wang is a director of Laekna Therapeutics.

Ms. JI Dongmei (吉冬梅), aged [49], is our non-executive Director, and is responsible for providing professional advice to the Board. Ms. Ji was appointed as a Director in April 2022 and re-designated as a non-executive Director in May 2022.

Ms. Ji has over 20 years of experience in equity investment industry and in financial institutions. She joined Haitong-Fortis Private Equity Fund Management Co., Ltd. (海富產業投資基金管理有限公司) as an investment manager in 2004, primarily responsible for project management and investment management and she left the company in 2013. From May 2013 to July 2015, she served as the managing director and member of the investment committee of GP Capital Co., Ltd. (金浦產業投資基金管理有限公司), primarily responsible for project

DIRECTORS AND SENIOR MANAGEMENT

management and investment management. Since August 2015, she has been a president, founding managing partner and chairwoman of the investment committee of GP Healthcare Capital Co., Ltd. (上海金浦醫療健康股權投資基金管理有限公司), responsible for managing the overall operation of the company and the fund.

Ms. Ji received her Bachelor’s degree in microbiology and Master’s degree in genetics from Fudan University (復旦大學) in China in July 1996 and in July 1999, respectively.

Ms. Ji is a director of Laekna Therapeutics.

Mr. SUN Yuan (孫淵), aged [34], is our non-executive Director, and is responsible for providing professional advice to the Board. Mr. Sun was appointed as a Director in April 2022 and re-designated as a non-executive Director in May 2022.

Mr. Sun has over 8 years of experience in investment management industry. He joined SDIC Fund Management Co., Ltd. (國投創新投資管理有限公司) in September 2013. He then joined CS Capital (Nanjing) Co., Ltd. (國投招商(南京)投資管理有限公司) in January 2022, a wholly-owned subsidiary of CS Capital Co., Ltd. (國投招商投資管理有限公司), and is currently its director. CS Capital Co., Ltd. is the general partner of Future Industry Investment Fund II (先進製造產業投資基金二期(有限合夥)), one of our [REDACTED] Investors. He obtained the Chartered Financial Analyst qualification in November 2017.

Mr. Sun received his Bachelor’s degree in computer science and technology from Tsinghua University (清華大學) in China in July 2010. He received his Master’s degree in finance from Washington University in St. Louis in the United States in December 2012.

Mr. Sun is a director of Laekna Therapeutics.

Independent Non-executive Directors

Dr. YIN Xudong, aged [56], was appointed as our independent non-executive Director with effect from the date of this document, and is responsible for providing independent opinion and judgment to the Board.

Dr. Yin has over 22 years of experience in biotechnology industry. He once worked at Clontech Laboratories Inc. (currently known as Becton, Dickinson and Company) (a global medical technology company listed on the New York Stock Exchange, stock code: BDX). During his employment with Boston Consulting (Shanghai) Co., Ltd. (a global business management and consulting firm), he served as a director manager from April 2000 to February 2004. He then worked at AstraZeneca Plc, a multinational pharmaceutical and biotechnology company listed on the London Stock Exchange (stock code: AZN), NASDAQ Global Market (stock code: AZN) and the NASDAQ Stockholm (stock code: AZN) in China from February 2004 to January 2011 with his last position as the president, AstraZeneca China. From January 2011 to December 2021, he served as head of the Asia Pacific, Middle East and Africa regions of Novartis Pharmaceuticals Corporation and president of Novartis Group in China.

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Dr. Yin received his Bachelor of Sciences degree in biochemistry from Peking University (北京大學) in China in 1987. He further obtained his Doctor of Philosophy degree in biological science from Stanford University in the United States in June 1995. In addition, he received his Master of Business Administration degree from Harvard University in the United States in June 1998.

Mr. CHAU Kwok Keung (鄒國強), aged [46], was appointed as our independent non-executive Director with effect from the date of this document, and is responsible for providing independent opinion and judgment to the Board.

Mr. Chau has over 20 years of experience in accounting and financial management. Mr. Chau was employed by Arthur Andersen & Co. initially as a staff accountant and he was subsequently promoted to be a senior consultant in the Global Corporate Finance Solution Segment of Arthur Andersen & Co. in March 2002. He was the financial controller of Shanghai Hawei New Materials and Technology Company Limited from June 2002 to August 2003 and the deputy group financial controller of China South City Holdings Limited (華南城控股有限公司) (a company listed on the Stock Exchange, stock code: 1668) from August 2003 to April 2005. Mr. Chau has also held various positions at China.com Inc. (中華網科技公司) (currently known as Sino Splendid Holdings Limited (中國華泰瑞銀控股有限公司)) (a company listed on the Stock Exchange, stock code: 8006) from October 2005 to October 2007, including qualified accountant, chief financial officer, company secretary and authorized representative. Mr. Chau has served as the chief financial officer of Comtec Solar Systems Group Limited (卡姆丹克太陽能系統集團有限公司) (a company listed on the Stock Exchange, stock code: 712) from November 2007 to January 2020 and served as its executive director from June 2008 to January 2020. He has also been an independent director of Bank of Zhangjiakou Co., Ltd. (張家口銀行股份有限公司) since April 2020. Mr. Chau joined BetterLife Holding Limited (百得利控股有限公司) (“**BetterLife Holding**”) (a company listed on the Stock Exchange, stock code: 6909) as chief financial officer in September 2020 and was appointed as an executive director in December 2020. He is responsible for overall financial planning and management, company secretarial affairs, coordination of investor relations and administrative work of BetterLife Holding.

Mr. Chau had also served as (i) a member of the supervisory board of RIB Software AG (currently known as RIB Software SE), a software company in Germany which was listed on the Frankfurt Stock Exchange (stock code: RIB) from February 2011 to June 2013; (ii) an independent non-executive director and the chairman of the audit committee of Qingdao Port International Co., Ltd. (青島港國際股份有限公司) (a company dual-listed on the Stock Exchange (stock code: 6198) and the Shanghai Stock Exchange (stock code: 601298)) from May 2014 to May 2019; (iii) an independent non-executive director and the chairman of the audit committee of Forward Fashion (International) Holdings Company Limited (尚晉(國際)控股有限公司) (a company listed on the Stock Exchange, stock code: 2528) from December 2019 to August 2021; and (iv) an independent non-executive director and the chairman of the audit committee of China Xinhua Education Group Ltd. (中國新華教育集團有限公司) (a company listed on the Stock Exchange, stock code: 2779) from October 2017 to November 2022.

DIRECTORS AND SENIOR MANAGEMENT

He has been serving as (i) an independent director of The9 Limited (第九城市) (a company listed on NASDAQ Global Market, stock code: NCTY) since October 2015; (ii) an independent non-executive director of China Tobacco International (HK) Company Limited (中煙國際(香港)有限公司) (a company listed on the Stock Exchange, stock code: 6055) since December 2018; (iii) an independent non-executive director and the chairman of the audit committee of Suzhou Basecare Medical Corporation Limited (蘇州貝康醫療股份有限公司) (a company listed on the Stock Exchange, stock code: 2170) since October 2021; and (iv) an independent non-executive director and the chairman of the audit committee and remuneration committee of China Infrastructure & Logistics Group Ltd. (中國通商集團有限公司) (a company listed on the Stock Exchange, stock code: 1719) since May 2022.

Mr. Chau has been a member of the Association of Chartered Certified Accountants since June 2002, a Chartered Financial Analyst since September 2003 and a member of the Hong Kong Institute of Certified Public Accountants since July 2005. Mr. Chau also obtained a certificate of Qualified Independent Director from the Shanghai Stock Exchange since August 2017, and was certified by China Banking and Insurance Regulatory Commission Zhangjiakou Supervision Branch (中國銀行保險監督管理委員會張家口監管分局) as qualified director of banking institutions in China since March 2020. Mr. Chau has been a fellow member of the Institute of Public Accountants of Australia and Institute of Financial Accountants since June 2020.

Mr. Chau received a Bachelor’s degree in Business Administration from the Chinese University of Hong Kong in December 1998.

Although Mr. Chau currently serves as a director in various companies, including listed companies in Hong Kong and the U.S. (the “**Relevant Companies**”), our Directors believe that it will not result in Mr. Chau not having sufficient time to act as our independent non-executive Director or not properly discharging his fiduciary duties as an independent non-executive Director. having considered the following factors:

- (i) as advised and confirmed by Mr. Chau, save and except for serving as an executive director and chief financial officer of BetterLife Holding, (a) he does not hold any senior management role in the Relevant Companies which would require him to devote substantial time and attention as is required from senior management members of listed companies, and (b) his roles in the Relevant Companies are non-executive in nature which do not require his full-time involvement and he does not participate in the day-to-day operations of the Relevant Companies;
- (ii) as advised and confirmed by Mr. Chau, he has not found difficulties in devoting to and managing his time for the Relevant Companies and he is confident that with his experience in being responsible for multiple roles, he will be able to properly discharge his duties to our Company;

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- (iii) as advised and confirmed by Mr. Chau, none of the Relevant Companies of which he is a director has questioned or complained about his time devoted to such companies;
- (iv) as advised and confirmed by Mr. Chau, he had a 100% attendance rate for the general meetings, board meetings and board committee meetings (as the case may be) of the Relevant Companies in respect of the most recent three financial years; and
- (v) in discharging his responsibilities within our Group, as advised and confirmed by Mr. Chau, he is sufficiently supported by our senior management and other staff members of our Group.

Dr. LI Min, aged [60], was appointed as our independent non-executive Director with effect from the date of this document, and is responsible for providing independent opinion and judgment to the Board.

Dr. Li has over 30 years of experience in academia and the biomedical and pharmaceutical industries. From January 2014 to March 2019, he served as a senior vice president and global head of neuroscience R&D at GlaxoSmithKline plc., a renowned science-led global healthcare company listed on the London Stock Exchange (stock code: GSK) and the New York Stock Exchange (stock code: GSK). During his employment with GlaxoSmithKline plc., he also served as the general manager of GSK R&D China. From January 2019 to January 2020, he served as the venture partner of Lilly Asia Ventures, a biomedical venture capital firm focused on healthcare investments. Dr. Li founded SciNeuro Pharmaceuticals in January 2020, a biotechnology company to develop innovative therapeutics for central nervous system diseases, and he has been serving as its chief executive officer and director since February 2020. Dr. Li has been serving as an independent director of Adagene Inc. (a company listed on NASDAQ Global Market, stock code: ADAG) since February 2021.

Dr. Li was a post-doctorate fellow at University of California San Francisco and also admitted as a Helen Hay Whitney Fellow. He was appointed as an assistant Professor of Physiology at Johns Hopkins University School of Medicine in March 1993 and had served as a tenured Professor of Neuroscience at Johns Hopkins University School of Medicine until 2013. Dr. Li has been a Fellow of the American Association for the Advancement of Science since November 2011.

Dr. Li received his Bachelor of Science degree in biochemistry from Wuhan University in China in July 1984. He further obtained his Doctor of Philosophy degree from Johns Hopkins University School of Medicine in the United States in May 1991.

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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	Time of Joining our Group	Position	Roles and Responsibilities
Dr. LU Chris Xiangyang	[59]	July 2016	Chief Executive Officer	Responsible for overseeing the overall business strategy, R&D activities, business planning and operational management
Ms. XIE Ling (謝玲)	[51]	April 2017	Senior vice president	Responsible for overseeing our global operations, including administrative, human resources, finance, legal, IT and compliance matters
Dr. GU Xiang Ju Justin	[57]	January 2020	Chief Scientific Officer	Responsible for overseeing our pre-clinical discovery research works
Dr. YUE Yong	[62]	July 2018	Chief Medical Officer	Responsible for overseeing our medical strategy and clinical development
Ms. WANG Liqing (王黎青)	[52]	August 2019	Vice president	Responsible for overseeing our corporate finance and procurement matters

DIRECTORS AND SENIOR MANAGEMENT

Dr. LU Chris Xiangyang, aged [59], is our Chairman, executive Director and Chief Executive Officer. For details of his biography, please see the sub-section headed “– Board of Directors – Executive Directors” in this section.

Ms. XIE Ling (謝玲), aged [51], is our executive Director and senior vice president. For details of her biography, please see the sub-section headed “– Board of Directors – Executive Directors” in this section.

Dr. GU Xiang Ju Justin, aged [57], is our executive Director and Chief Scientific Officer. For details of his biography, please see the sub-section headed “– Board of Directors – Executive Directors” in this section.

Dr. YUE Yong, aged [62], is our Chief Medical Officer, and is responsible for overseeing our medical strategy and clinical development. Dr. Yue joined our Group in July 2018 as our Chief Medical Officer.

Dr. Yue has over 20 years of experience in the pharmaceutical industry. In 2002, he worked at Sanofi, a global healthcare company listed on the Euronext Paris (ticker symbol: SAN) and NASDAQ Global Market (stock code: SNY), and had accumulated experience in the area of multiple sclerosis and immunology. Dr. Yue was a surgical resident at Brigham and Women’s Hospital of Harvard Medical School in the United States from July 2006 to July 2008 and received the US Medical License in the state of Massachusetts in the United States. From June 2008 to 2013, he worked at GlaxoSmithKline plc., a renowned science-led global healthcare company listed on the London Stock Exchange (stock code: GSK) and the New York Stock Exchange (stock code: GSK). He had worked as a principal clinical research scientist at GlaxoSmithKline consumer healthcare and had involved in a number of research and studies in clinical development for Analgesics (a pain relief medication). Before joining our Group, he worked at Janssen, the pharmaceutical company of Johnson & Johnson (a company listed on NASDAQ Global Market, stock code: JNJ) from 2013 to July 2018, and had involved in a number of research and studies in medical affairs and clinical development.

Before working in the United States, Dr. Yue was a surgical oncologist with ample clinical experience in China and Switzerland. Prior to joining the pharmaceutical industry, Dr. Yue was a doctoral student of University of Geneva Medical School (graduated in December 1993) and a physician to performing post-graduate in Surgical Critical Care Medicine (from December 1992 to December 1993) with the Department APSIC at University Hospitals of Geneva in Switzerland. He was a physician of the Department of Neurosurgery at Tianjin Medical University General Hospital (天津醫科大學總醫院) in China from 1987 to 1995. He was a postdoctoral research fellow at Lab for Cancer Research, Ernest Mario School of Pharmacy, Rutgers University in the United States with multiple publications from January 1996 to 1999.

In September 1980, Dr. Yue was admitted in an eight-year medical education program consisting of three years of pre-medicine study at Nankai University (南開大學) in China and five years of medicine study at Tianjin Medical University (天津醫科大學). He obtained a Master of Medicine degree from Tianjin Medical University (天津醫科大學) in China in July

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1988. Dr. Yue obtained the Educational Commission for Foreign Medical Graduates Certification from the US Educational Commission for Foreign Medical Graduates in December 2005. In December 1993, Dr. Yue obtained the Doctor of Medical Science degree from the University of Geneva in Switzerland.

Ms. Wang Liqing (王黎青), aged [52], is our vice president, and is responsible for overseeing our corporate finance and procurement matters. Ms. Wang joined our Group in August 2019 as a vice president.

Ms. Wang has over 20 years of experience in finance matters. She once worked as an accounting supervisor in Shanghai Lever Co., Ltd. (上海利華有限公司), a joint venture company of Unilever engaged in the manufacturing and sales of fast moving consumer products. She then joined Johnson & Johnson (China) Co., Ltd. (強生(中國)有限公司) in 1998. From March 2005 to December 2010, she worked in Dumex Infant Food Co., Ltd. (多美滋嬰幼兒食品有限公司) as a financial controller, a member of the Danone Group, a multinational enterprise focusing on food, where she was responsible for the management of accounting and reporting, taxation and treasury related matters. From January 2011 to September 2018, she worked in Cargill Investment (China) Co., Ltd. (嘉吉投資(中國)有限公司) with her last position as GCK accounting and finance lead in finance department. Prior to joining our Group, in September 2018, Ms. Wang joined Shanghai Yitu Network Technology Co., Ltd. (上海依圖網絡科技有限公司) as the financial vice president, a company principally engaged in artificial intelligence technology development, and was responsible for overseeing the financial management of the company.

Ms. Wang graduated in Accountancy from Shanghai Lixin University of Accounting and Finance (上海立信會計金融學院) (formerly known as Lixin College of Higher Education in Accounting (立信會計高等專科學校)) in China in July 1991. She obtained a Master of Business Administration degree jointly offered by Shanghai University of Finance and Economics (上海財經大學) in China and Webster University in the United States in November 2003.

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 as disclosed in “C. Further Information about our Directors” in Appendix IV, none of our Directors held any interest in the securities within the meaning of Part XV of the SFO. As of the Latest Practicable Date, none of our Directors or senior management is related to other Directors or senior management of our Company.

DIRECTORS AND SENIOR MANAGEMENT

JOINT COMPANY SECRETARIES

Mr. KE Chenyu (柯晨煜) was appointed as a joint company secretary of our Company in May 2022. Mr. Ke joined our Group in August 2021 as our head of legal, responsible for overseeing legal, regulatory and compliance matters of our Company.

Prior to joining our Group, Mr. Ke worked at Kaye Scholer LLP from August 2011 to July 2013. He served as an associate at Benesch, Friedlander, Coplan & Aronoff LLP from September 2013 to July 2014. From August 2015 to August 2021, he served as the legal general manager of Shanghai Fosun High Technology (Group) Co., Limited (上海復星高科技(集團)有限公司), a wholly-owned subsidiary of Fosun International Limited (復星國際有限公司) (a company listed on the Stock Exchange, stock code: 656), and was responsible for the legal and compliance in healthcare sector.

Mr. Ke obtained his Bachelor’s degree in law from East China University of Political Science and Law (華東政法大學) in China in July 2007. He obtained his Master’s degree in law from Georgetown University Law Center in the United States in May 2015.

Ms. TANG Wing Shan Winza (鄧穎珊) was appointed as a joint company secretary of our Company in November 2022.

Ms. Tang serves as the assistant vice president of governance services of Computershare Hong Kong Investor Services Limited. She has more than 15 years of experience in company secretarial services.

Ms. Tang obtained a Bachelor’s degree in laws from City University of Hong Kong and a Master’s degree in corporate governance from London South Bank University. She is an associate member of the Hong Kong Chartered Governance Institute and the Chartered Governance Institute.

Our Company [was granted] a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules such that Mr. Ke may be appointed as a joint company secretary of our Company, on the condition that the waiver can be revoked if there are material breaches of the Listing Rules by our Company. For details, see “Waivers and Exemptions – Waiver in respect of joint company secretaries”.

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 executive Directors 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 conditions of the service

DIRECTORS AND SENIOR MANAGEMENT

contract or by either party giving to the other not less than three months’ prior notice. 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 service contracts and appointment letters, see “Statutory and General Information – C. Further Information about our Directors – 1. Particulars of Directors’ Service Contracts and Appointment Letters” in Appendix IV.

For more information on the Directors’ remuneration during the Track Record Period as well as information on the highest paid individuals, please see Notes 7 and 8 of the Accountants’ Report set out in Appendix I.

Save as disclosed above in this section and the sections headed “Financial Information”, “Accountants’ Report” in Appendix I and “Statutory and General Information” in Appendix IV, 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 and one non-executive Director, namely, Mr. CHAU Kwok Keung (鄒國強), Dr. WANG David Guowei and Dr. LI Min. Mr. CHAU Kwok Keung (鄒國強), 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 executive Director, namely, Ms. Xie, and two independent non-executive Directors, namely, Dr. YIN Xudong and Mr. CHAU Kwok Keung (鄒國強). Dr. YIN Xudong 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

DIRECTORS AND SENIOR MANAGEMENT

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.

Nomination and Corporate Governance Committee

Our Company has established the Nomination and Corporate Governance Committee with written terms of reference in compliance with Rule 3.27A of the Listing Rules and the Corporate Governance Code. The Nomination and Corporate Governance Committee consists of one executive Director, namely, Dr. Lu, and two independent non-executive Directors, namely, Dr. YIN Xudong and Dr. LI Min. Dr. Lu 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.

ESG Committee

Our Company [has established] an ESG committee (the “**ESG Committee**”) at our Board level that comprises three members, including our senior vice president, head of legal department and head of communication and public affairs. The ESG Committee will have a specific focus on environmental matters, such as energy consumption, pollutants, greenhouse gas emissions and reporting, as well as waste management and recycling efforts. The ESG Committee serves as a supportive role to our Board in implementing the agreed ESG Policy, targets and strategies; identifying and assessing ESG-related matters, including climate-related risks, by taking into consideration the metrics and targets stipulated in Appendix 27 to the Listing Rules and applicable laws, regulations and industry standards; managing how our Group adapts its business in light of climate change; collecting ESG data from different parties while preparing for the ESG report; and continuous monitoring of the implementation of measures to address our Group’s ESG-related risks. The ESG Committee has to report to our Board on a periodic basis on the ESG performance of our Group and the effectiveness of the ESG systems.

DIRECTORS AND SENIOR MANAGEMENT

Corporate Governance Code

Pursuant to 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. Lu has served as our Chairman since May 2018 and Chief Executive Officer since April 2017. Dr. Lu is the founder of our 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. Lu 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 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.

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 drug discovery and development, medical, equity investment and accounting and finance. They obtained degrees in various areas including genetic science, law, medicine, microbiology and microbial engineering, biochemistry and business administration. Our board diversity policy is well implemented as evidenced by the fact that there are both male and female Directors ranging from [34] years old to [61] years old with different nationalities and experience from different industries and sectors.

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.

DIRECTORS AND SENIOR MANAGEMENT

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.

Anti-corruption and Whistle Blowing Policies

We are committed to acting with integrity, honesty, fairness, impartiality, and ethical business practices. We have adopted an anti-corruption policy to promote an ethical culture within our Group and have zero-tolerance for bribery and any act of corruption. Our Board and senior management also strive to promote an ethical culture within our Group. We have also adopted a whistle blowing policy that serves the purpose of establishing whistleblowing procedures for employees and other relevant external parties of our Group, in order to report and escalate any suspicious misconducts. In accordance with the policy, we protect all whistleblowers from any kind of retaliation. All the information provided by the whistleblowers will be kept strictly confidential.

Compliance Adviser

We have appointed Huajin Corporate Finance (International) 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].

DIRECTORS AND SENIOR MANAGEMENT

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 and independent 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.

RELATIONSHIP BETWEEN OUR EXECUTIVE DIRECTORS AND NOVARTIS

Several members of our senior management team also previously worked for Novartis’ affiliates. Dr. Lu, our Chairman, executive Director and Chief Executive Officer, worked at Novartis Institutes for BioMedical Research and China Novartis Institutes for BioMedical Research Co., Ltd. from 2003 to 2016 with the last position as an Executive Director. Ms. Xie, our executive Director and senior vice president, worked at China Novartis Institutes for BioMedical Research Co., Ltd. as an executive assistant from 2008 to 2017. Dr. Gu, our executive Director and Chief Scientific Officer, served first as a scientist and then as a group leader at Genomics Institute of the Novartis Research Foundation from 2001 to 2008. Although our three executive Directors were all employed by Novartis’ affiliates previously and have known each other well since then, they have made and will make decisions independently and not in concert.

SUBSTANTIAL SHAREHOLDERS

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the Conversion and [REDACTED], 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 interests in our Company as of the Latest Practicable Date	Approximate percentage of interests in our Company upon the completion of the [REDACTED] (assuming the [REDACTED] is not exercised)	Approximate percentage of interests in our Company upon the completion of the [REDACTED] (assuming the [REDACTED] is fully exercised)
Dr. Lu ⁽²⁾	Beneficial interest	2,960,387	[9.07]%	[REDACTED]	[REDACTED]
	Founder of a discretionary trust	2,000,000	[6.13]%	[REDACTED]	[REDACTED]
Ms. Xie ⁽³⁾⁽⁴⁾	Interest in controlled corporation	750,000	[2.30]%	[REDACTED]	[REDACTED]
	Interest in controlled corporations	[3,411,877]	[10.45]%	[REDACTED]	[REDACTED]
OrbiMed Asia Partners III, L.P. ⁽⁵⁾	Beneficial interest	5,787,973	[17.73]%	[REDACTED]	[REDACTED]
OrbiMed Asia GP III, L.P. ⁽⁵⁾	Interest in controlled corporation	5,787,973	[17.73]%	[REDACTED]	[REDACTED]
OrbiMed Advisors III Limited ⁽⁵⁾	Interest in controlled corporation	5,787,973	[17.73]%	[REDACTED]	[REDACTED]
GP Healthcare Capital, Inc. ⁽⁶⁾	Beneficial interest	3,303,988	[10.12]%	[REDACTED]	[REDACTED]
GP Healthcare Capital Co., Ltd. ⁽⁶⁾	Interest in controlled corporation	4,090,980	[12.53]%	[REDACTED]	[REDACTED]

SUBSTANTIAL SHAREHOLDERS

Notes:

- (1) The number of shares held assuming that (i) [3,411,877] ordinary shares have been issued to the ESOP Trusts, and (ii) 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 [REDACTED].
- (2) Dr. Lu beneficially holds 2,960,387 ordinary shares under his own name. Moreover, 2,000,000 ordinary shares of our Company are held by the Family Trust, which is in turn wholly-owned by The Bryn Mawr Trust Company of Delaware as trustee of the Family Trust, which Dr. Lu is the settlor. Accordingly, Dr. Lu is deemed to be interested in the ordinary shares held by the Family Trust under the SFO. Further, pursuant to the [REDACTED] Share Option Scheme, Dr. Lu was granted Share Options to subscribe for 263,552 ordinary shares.
- (3) Ms. Xie is interested in 750,000 ordinary shares through Linbell Technology Holdings Limited, a limited liability company incorporated in the BVI and is wholly-owned by Ms. Xie. Accordingly, Ms. Xie is deemed to be interested in the ordinary shares held by Linbell Technology Holdings Limited under the SFO. Further, pursuant to the [REDACTED] Share Option Scheme, Ms. Xie was granted Share Options to subscribe for 248,275 ordinary shares.
- (4) Includes Shares held by the ESOP Trusts. Pursuant to the trust deed dated [●], Futu Trustee Limited (the trustee of the ESOP Trusts) will exercise their voting rights in accordance with the instructions of Ms. Xie. Accordingly, Ms. Xie is deemed to be interested in the ordinary shares held by the ESOP Trusts under the SFO.
- (5) OrbiMed Asia Partners III, L.P. is a venture capital fund operated by OrbiMed and registered as exempted limited partnerships in the Cayman Islands. The general partner of OrbiMed Asia Partners III, L.P., is OrbiMed Asia GP III, L.P., whose general partner is OrbiMed Advisors III Limited. Accordingly, each of OrbiMed Asia GP III, L.P. and OrbiMed Advisors III Limited is deemed to be interested in the shares held by OrbiMed Asia Partners III, L.P. under the SFO.
- (6) GP Healthcare Capital, Inc. is interested in 3,303,988 ordinary shares as of the Latest Practicable Date. GP Healthcare Capital, Inc. is an exempted company incorporated in the Cayman Islands and its sole shareholder is Shanghai GP Healthcare Equity Investment Enterprise (Limited Partnership) (上海金浦醫療健康股權投資合夥企業(有限合夥)), whose general partner is GP Healthcare Capital Co., Ltd. (上海金浦醫療健康股權投資基金管理有限公司).

Further, Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership) is interested in 786,992 ordinary shares as of the Latest Practicable Date. Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership) is a limited liability partnership established in the PRC and its general partner is GP Healthcare Capital Co., Ltd.. As such, GP Healthcare Capital Co., Ltd. is deemed to be interested in the shares held by GP Healthcare Capital, Inc. and Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership).

Except as disclosed above, our Directors are not aware of any other person who will, immediately following the completion of the [REDACTED] (assuming the [REDACTED] 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 10% or more of the nominal value of any class of our share capital carrying rights to vote in all circumstances at general meetings of our Company. 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 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].

Before the [REDACTED]

As of the Latest Practicable Date, our authorized share capital was US\$50,000 divided into 500,000,000 shares of a par value of US\$0.0001 each, of which (i) 472,582,465 are designated as ordinary shares; (ii) 2,029,640 are designated as Series Seed Preferred Shares; (iii) 3,986,840 are designated as Series A Preferred Shares; (iv) 4,542,984 are designated as Series B Preferred Shares; (v) 6,858,071 are designated as Series C Preferred Shares; and (vi) 10,000,000 are designated as Series D Preferred Shares.

As of the Latest Practicable Date, our issued share capital was US\$[2,922.5358], comprising [29,225,358] shares of a par value of US\$0.0001 each (without taking into account [3,411,877] ordinary shares which shall be issued to the ESOP Trusts), of which (i) [7,941,637] are designated as ordinary shares; (ii) 2,029,640 are designated as Series Seed Preferred Shares; (iii) 3,986,840 are designated as Series A Preferred Shares; (iv) 4,542,984 are designated as Series B Preferred Shares; (v) 6,858,071 are designated as Series C Preferred Shares; and (vi) 3,866,186 are designated as Series D Preferred Shares.

Upon completion of the [REDACTED]

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 a par value of US\$[0.00001] each. The Preferred Shares will be converted into ordinary Shares of our Company on a one-to-one basis by way of re-designation immediately before the completion of the [REDACTED], and our authorized share capital will be US\$50,000 divided into [5,000,000,000] Shares of par value of US\$[0.00001] each.

Assuming the [REDACTED] are not exercised, the share capital of our Company immediately following completion of the [REDACTED], Conversion and [REDACTED] will be as follows:

Description of Shares	Number of Shares	Aggregate par value of Shares (US\$)
Shares in issue (including the Shares which shall be issued to the ESOP Trusts and the Shares upon re-designation of the Preferred Shares)	[326,372,350]	[3,263.7235]
Shares to be issued under the [REDACTED]	<u>[REDACTED]</u>	<u>[REDACTED]</u>
Total	<u>[REDACTED]</u>	<u>[REDACTED]</u>

SHARE CAPITAL

Assuming the [REDACTED] is exercised in full, the share capital of our Company immediately following completion of the [REDACTED], Conversion and [REDACTED] will be as follows:

Description of Shares	Number of Shares	Aggregate par value of Shares (US\$)
Shares in issue (including the Shares which shall be issued to the ESOP Trusts and the Shares upon re-designation of the Preferred Shares)	[326,372,350]	[3,263.7235]
Shares to be issued under the [REDACTED]	<u>[REDACTED]</u>	<u>[REDACTED]</u>
Total	<u><u>[REDACTED]</u></u>	<u><u>[REDACTED]</u></u>

ASSUMPTIONS

The above tables assume that the [REDACTED] becomes unconditional, that Shares are issued pursuant to the [REDACTED], and that the Preferred Shares are converted into 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; (iv) cancel any Shares which have not been taken or agreed to be taken; (v) make provision for the allotment and issue of Shares which do not carry any voting rights; (vi) change the currency of denomination of its share capital; and (vii) reduce its share premium account in any manner authorized, and subject to any conditions prescribed by law. In addition, our Company may, subject to the provisions of the Cayman Companies Act, reduce its share capital or capital redemption reserve by its Shareholders passing a special resolution. See “Appendix III – Summary of the Constitution of our Company and Cayman Companies Act – 2. Articles of Association – 2.1 Shares - (c) Alteration of Capital.”

SHARE CAPITAL

[REDACTED] SHARE OPTION SCHEME

We adopted the [REDACTED] Share Option Scheme. For further details, see “Statutory and General Information – D. [REDACTED] Share Option Scheme” in Appendix IV.

[REDACTED] SHARE OPTION SCHEME

We adopted the [REDACTED] Share Option Scheme. For further details, see “Statutory and General Information – E. [REDACTED] Share Option Scheme” in Appendix IV.

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 of not more than the sum of:

- 20% of the aggregate number of issued Shares immediately following completion of the [REDACTED]; and
- the aggregate number of the Shares repurchased by us under the authority referred to in the paragraph 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 “Statutory and General Information – A. Further Information about our Group – 5. Resolutions of our Shareholders” in Appendix IV 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 of up to 10% of the aggregate number of our Shares in issue immediately following completion of 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 [REDACTED] (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 “Statutory and General Information – A. Further Information about our Group – 6. Repurchase of our own securities” in Appendix IV.

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.

For further details of the general mandate to repurchase Shares, see “Statutory and General Information – A. Further Information about our Group – 5. Resolutions of our Shareholders” in Appendix IV.

FINANCIAL INFORMATION

You should read the following discussion and analysis with our audited historical financial information, including the notes thereto, included in the Accountants’ Report in Appendix I to this document. Our historical financial information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”), 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 2021 and 2022 refer to our financial year ended December 31 of such years. Unless the context otherwise requires, financial information described in this section is described on a consolidated basis.

OVERVIEW

Founded in 2016, we are a science-driven, clinical-stage biotechnology company. We have two Core Products: Core Product LAE002 is an adenosine triphosphate (ATP) competitive AKT inhibitor for the treatment of ovarian cancer, prostate cancer, breast cancer and PD-1/PD-L1 drug-resistant solid tumors. The other Core Product LAE001 is an androgen synthesis inhibitor that simultaneously inhibits cytochrome P450 family 17 subfamily A member 1 (CYP17A1) and cytochrome P450 family 11 subfamily B member 2 (CYP11B2) for the treatment of prostate cancer. Our infrastructure has already enabled the rapid development of 15 innovative product candidates, including one registrational clinical trial and another five clinical trials for our Core Products. Among these six clinical trials, three are multi-regional clinical trials (MRCTs) designed to address global medical needs in the standard of care (SOC)-resistant cancers.

We currently have no products approved for commercial sale and have not generated any revenue from product sales. We were not profitable and incurred operating losses during the Track Record Period. For the years ended December 31, 2021 and 2022, we incurred loss of RMB749.0 million and RMB781.6 million, respectively. We recorded losses as a result of significant research and development expenses, administrative expenses and fair value changes on financial instruments issued to investors.

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We expect to incur significant amount of expenses and operating losses for at least the next several years as we further our pre-clinical research efforts, continue the clinical development of, and seek regulatory approvals for our drug candidates before commercializing any approved products. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a [REDACTED] company. We expect that our financial performance will fluctuate from period to period due to the development status of our drug candidates, regulatory approval timeline and commercialization of our future approved drugs.

BASIS OF PRESENTATION AND PREPARATION

We recorded net liabilities of RMB1,111.2 million and RMB1,905.1 million as of December 31, 2021 and 2022, respectively, and incurred recurring losses from operations since incorporation. Our historical financial information has been prepared on a going concern basis as the directors of the Company believe that the Preferred Shares will not be redeemed within the next twelve months from December 31, 2022. The directors of the Company are satisfied that the Group will have sufficient financial resources to meet its financial obligations as they fall due and to sustain its operations for the foreseeable future, after reviewing the Group’s cash flow projection and taking into account the expected working capital requirements covering the next twelve months from December 31, 2022.

Our historical financial information has been prepared in accordance with applicable International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board (“IASB”). All IFRSs effective for the accounting period commencing from January 1, 2021, together with the relevant transitional provisions, have been adopted by us in the preparation of the consolidated financial information. The consolidated financial information has been prepared under the historical cost convention, except for financial assets and liabilities at fair value through profit or loss which have been measured at fair value, as explained in the respective accounting policies in the Accountants’ Report in Appendix I to this document. Our consolidated financial information is presented in RMB and all values are rounded to the nearest thousand except as otherwise indicated. The preparation of the consolidated financial information in conformity with IFRSs requires the use of certain critical accounting estimates. It also requires our management to exercise its judgment in the process of applying our accounting policies.

Our consolidated statements of profit or loss and other comprehensive income, consolidated statements of changes in equity and consolidated statements of cash flows for the years ended December 31, 2021 and 2022 and our consolidated statements of financial position as of December 31, 2021 and 2022 have been derived from the Accountants’ Report included in Appendix I to this document.

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CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles that conform with IFRSs issued by the IASB. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, income and expenses. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

We set forth below certain 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 historical financial information. 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 and 3 to the Accountants’ Report in Appendix I to this document.

Significant Accounting Policies

Intangible Assets

Research and Development Expenditures

We incur significant costs and efforts on research and development activities, which include expenditures on drug products. Research expenditures are charged to profit or loss as an expense in the period the expenditures are incurred. Development costs are recognized as assets if they can be directly attributable to a newly developed drug product and all the following can be demonstrated:

- (i) the technical feasibility of completing the development project so that it will be available for use or sale;
- (ii) our intention to complete the development project to use or sell it;
- (iii) our ability to use or sell the development project;
- (iv) how the development project will generate probable future economic benefits for us;
- (v) our availability of adequate technical, financial and other resources to complete the development and to use or sell the development project; and
- (vi) the ability to measure reliably the expenditures attributable to the development project.

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The cost of an internally generated intangible asset is the sum of the expenditures incurred from the date the asset meets the recognition criteria above to the date when it is available for use. The costs capitalized in connection with the intangible asset include costs of materials and services used or consumed, employee costs incurred in the creation of the asset and an appropriate portion of relevant overheads. We generally consider capitalization criteria for internally generated intangible assets is met when regulatory approval of a new drug license is obtained.

Capitalized development expenditures are amortized using the straight-line method over the life of the related drug products. Amortization shall begin when the asset is available for commercial use. Subsequent to initial recognition, internally generated intangible assets are reported as cost less accumulated amortization and accumulated impairment losses. Please see Note 2(h)(ii) to the Accountants' Report in Appendix I to this document for further discussions on impairment of other non-current assets.

Development expenditures not satisfying the above criteria are recognized in the profit or loss as incurred, and development expenditures previously recognized as an expense are not recognized as an asset in a subsequent period.

In-licenses

Intangible assets acquired separately are measured at cost on initial recognition.

Certain intangible assets are for licenses of intellectual properties in development, with non-refundable upfront payments, milestone payments and royalty payments. Upfront payments are capitalized when paid. Milestone payments are capitalized as intangible assets when incurred and enhanced the expected future economic benefits of the intangible assets, unless the payments are for outsourced research and development work which would follow the capitalization policy in Note 2(f)(i) to the Accountants' Report in Appendix I to this document. Royalty payments would be accrued for in line with the underlying sales and recognized as a cost of sales.

The intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortized when ready for commercial use and over the economic useful life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least at the end of each reporting period. Intangible assets with indefinite useful lives or not ready for commercial use will not be amortized but tested for impairment annually either individually or at the cash generating unit level. The impairment test would compare the recoverable amount of the in-licensed asset to its carrying value. The useful life of an intangible asset with an indefinite life is reviewed annually to determine whether the indefinite life assessment continues to be supportable. If not, the change in the useful life assessment from indefinite to finite is accounted for on a prospective basis.

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Software

Computer software is recognized at historical cost and subsequently carried at cost less accumulated amortization and accumulated impairment losses (see Note 2(h)(ii) to the Accountants' Report in Appendix I to this document). We amortized on a straight-line basis over their estimated useful lives of five years based on the current functionalities and the daily operation needs of the software.

Both the period and method of amortization are reviewed annually.

Leased Assets

At the inception of a contract, we assess whether the 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. Control is conveyed where the customer has both the rights to direct the use of the identified asset and to obtain substantially all of the economic benefits from that use.

Where the contract contains lease component(s) and non-lease component(s), we have elected not to separate non-lease components and accounts for each lease component and any associated non-lease component as a single lease component for all leases.

At the lease commencement date, we recognize a right-of-use asset and a lease liability, except for short-term leases that have a lease term of 12 months or less and leases of low-value assets. When we enter into a lease in respect of a low-value asset, we decide whether to capitalize the lease on a lease-by-lease basis. The lease payments associated with those leases which are not capitalized are recognized as an expense on a systematic basis over the lease term.

Where a lease is capitalized, the lease liability is initially recognized at the present value of the lease payments payable over the lease term, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, using a relevant incremental borrowing rate. After initial recognition, the lease liability is measured at amortized cost and interest expense is calculated using the effective interest method. Variable lease payments that do not depend on an index or rate are not included in the measurement of the lease liability and hence are charged to profit or loss in the accounting period in which they are incurred.

The right-of-use asset recognized, when a lease is capitalized, is initially measured at cost, which comprises the initial amount of the lease liability plus any lease payments made at or before the commencement date, and any initial direct costs incurred. Where applicable, the cost of the right-of-use assets also includes an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, discounted to their present value, less any lease incentives received. The right-of-use asset is subsequently stated at cost less accumulated depreciation and impairment losses (see Notes 2(h)(ii) to the Accountants' Report in Appendix I to this document for further details).

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The lease liability is remeasured when there is a change in future lease payments arising from a change in an index or rate, or there is a change in our estimate of the amount expected to be payable under a residual value guarantee, or there is a change arising from the reassessment of whether we will be reasonably certain to exercise a purchase, extension or termination option. When the lease liability is remeasured in this way, a corresponding adjustment is made to the carrying amount of the right-of-use asset, or is recorded in profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

The lease liability is also remeasured when there is a change in the scope of a lease or the consideration for a lease that is not originally provided for in the lease contract (“lease modification”) that is not accounted for as a separate lease. In this case the lease liability is remeasured based on the revised lease payments and lease term using a revised discount rate at the effective date of the modification. The only exceptions are rent concessions that occurred as a direct consequence of the COVID-19 pandemic and met the conditions set out in paragraph 46B of IFRS 16 Leases. In such cases, we have taken advantage of the practical expedient not to assess whether the rent concessions are lease modifications, and recognized the change in consideration as negative variable lease payments in profit or loss in the period in which the event or condition that triggers the rent concessions occurred.

Credit Losses and Impairment of Assets

Credit losses from financial instruments

The Group recognizes a loss allowance for expected credit losses (ECLs) on financial assets measured at amortized cost (including cash and cash equivalents and other receivables). Other financial assets measured at fair value are not subject to the ECL assessment.

Measurement of ECLs

ECLs are a probability-weighted estimate of credit losses. Credit losses are measured as the present value of all expected cash shortfalls (i.e. the difference between the cash flows due to the Group or the Company in accordance with the contract and the cash flows that the Group or the Company expects to receive).

The expected cash shortfalls are discounted using the following discount rates where the effect of discounting is material:

- fix-rate financial assets and other receivables: effective interest rate determined at initial recognition or an approximation thereof; and
- variable-rate financial assets: current effective interest rate.

The maximum period considered when estimating ECLs is the maximum contractual period over which the Group is exposed to credit risk.

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In measuring ECLs, the Group or the Company takes into account reasonable and supportable information that is available without undue cost or effort. This includes information about past events, current conditions and forecasts of future economic conditions.

ECLs are measured on either of the following bases:

- 12-month ECLs: these are losses that are expected to result from possible default events within the 12 months after the reporting date; and
- lifetime ECLs: these are losses that are expected to result from all possible default events over the expected lives of the items to which the ECL model applies.

For all financial assets, the Group recognizes a loss allowance equal to 12-month ECLs unless there has been a significant increase in credit risk of the financial instrument since initial recognition, in which case the loss allowance is measured at an amount equal to lifetime ECLs.

Financial Instruments Issued to Investors

Financial instruments issued to investors consist of preferred shares and a warrant for purchase of ordinary shares and preferred shares.

(i) Preferred shares

A preferred share is classified as a financial liability if the Company is required to be liquidated upon events beyond its control and the preferred share is not in the most subordinated class of instruments issued by the Company. The financial liability is mandatorily measured at fair value through profit or loss, if any embedded derivative required to be separated cannot be measured reliably; otherwise, the embedded derivatives are measured at fair value through profit or loss and the host debt is initially measured at fair value and subsequently at amortized cost.

(ii) Warrant

During the Track Record Period, the Company issued a warrant under which the holder has the right to subscribe for the Company’s ordinary shares and preferred shares at a predetermined price during a specific period.

A warrant is classified as a financial liability if it will not be settled only by the Company exchanging a fixed number of cash or another financial asset for a fixed number of its own equity instruments. A warrant liability is initially recognized at fair value on the date a warrant contract is entered into and is subsequently re-measured to its fair value at the end of each reporting period. Changes in fair value are recognized in profit or loss.

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The preferred shares and the warrant were valued by the directors of the Company with reference to valuation reports carried out by an independent qualified professional valuer which has appropriate qualifications and experience in valuation of similar instruments. The Company used the back-solve method and income approach to determine the underlying share value of the Company and performed an equity allocation based on a hybrid method of Binomial Option Pricing model (OPM model) and Probability Weighted Expected Return method (PWERM method) to arrive the fair value of the preferred shares and the warrant as at the dates of issuance and at the end of each reporting period. Should any of the key valuation assumptions used to determine the fair value of these financial instruments issued to investors changed, it may lead to a change in the fair value of financial instruments issued to investors. The fair value of the preferred shares and the warrant of the Group are set out in Notes 21 and 24(e) to the Accountants' Report in Appendix I to this document.

Share-based Payments

The fair value of share options granted to employee is recognized as an employee cost with a corresponding increase in a capital reserve within equity. The fair value is measured at grant date using the binomial lattice model, taking into account the terms and conditions upon which the options were granted. Where the employees have to meet vesting conditions before becoming unconditionally entitled to the options, the total estimated fair value of the options is spread over the vesting period, taking into account the probability that the options will vest.

During the vesting period, the number of share options that is expected to vest is reviewed. Any resulting adjustment to the cumulative fair value recognized in prior years is charged/credited to the profit or loss for the year of the review, unless the original employee expenses qualify for recognition as an asset, with a corresponding adjustment to the capital reserve. On vesting date, the amount recognized as an expense is adjusted to reflect the actual number of options that vested (with a corresponding adjustment to the capital reserve) except for forfeitures due to failures to meet vesting conditions relating to the market price of the Company's shares. The equity amount is recognized in the capital reserve until either the option is exercised (when it is included in the amount recognized in share capital for the shares issued) or the option expires (when it is released directly to retained profits).

The grant by the Company of options over its equity instruments to the employees of subsidiaries undertakings in the Group is treated as a capital contribution. The fair value of employee services received, measured by reference to the grant date fair value, is recognized over the vesting period as an increase to investment in subsidiary undertakings, with a corresponding credit to equity in separate financial statements of the Company.

Government Grants

Government grants are recognized in the statement of financial position initially when there is reasonable assurance that they will be received and that we will comply with the conditions attaching to them. Grants that compensate us for expenses incurred are recognized as income in profit or loss on a systematic basis in the same periods in which the expenses are incurred. Grants that compensate us for the cost of an asset are presented in the consolidated statements of financial position by setting up the grant as deferred income and consequently are effectively recognized in profit or loss on a systematic basis over the useful life of the asset.

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Critical Accounting Judgments and Estimates

Research and Development Expenses

Development expenses incurred on our pipeline are capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, our intention to complete and our ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure the reliably of expenditure during the development. Development expenses which do not meet these criteria are expensed when incurred. Management will assess the progress of each of the research and development projects and determine the criteria met for capitalization. All development expenses were expensed when incurred during the Track Record Period.

Recognition of Deferred Tax Assets

Deferred tax assets are recognized for deductible temporary differences and cumulative tax losses. As those deferred tax assets can only be recognized to the extent that it is probable that future taxable profit will be available against which they can be utilized, management’s judgment is required to assess the probability of future taxable profits. Management’s assessment is reviewed from time to time and additional deferred tax assets are recognized if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered.

Impairment of Intangible Assets Not Ready For Commercial Use

Intangible assets not ready for commercial use are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. We obtained in-licenses through acquisition for the purpose of continuing the research and development work and commercialization of the products, which are classified as intangible assets not ready for use.

An impairment loss is recognized for the amount by which the intangible asset’s carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an intangible asset’s fair value less costs of disposal and value in use. For the purposes of assessing impairment, each in-license is recognized as a cash-generating unit.

SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations, financial condition and the period-to-period comparability of our financial results have been, and are expected to continue to be, principally 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 fair value changes in financial instruments issued to investors are mainly associated with the changes in our Company’s valuation. The financial instruments issued to investors will be converted into Shares upon the [REDACTED], which will result in a net asset position, and we will recognize no further loss or gain on fair values changes from such financial instruments issued to investors post [REDACTED].

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Our Ability to Successfully Develop Our Drug Candidates

Our business and results of operations depend on our ability to successfully develop our drug candidates. As of the Latest Practicable Date, we have strategically developed a pipeline of 15 innovative product candidates, including our Core Products LAE002 and LAE001. Our drug candidates are developed both as monotherapy and combination therapy with a focus on the treatment of cancers and liver fibrosis. Since our inception, we have obtained over eight IND approvals from the FDA and the NMPA and have initiated six clinical trials, including three MRCTs across China, the U.S. and other jurisdictions. For more information on the development status of our various drug candidates, see “Business – Drug Candidates.” 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.

Our Ability to Commercialize Our Products and Drug Candidates

All of our drug candidates are in either clinical or pre-clinical stage. Although we currently have no product approved for commercial sale and have not generated any revenue from product sales, we expect to commercialize one or more of our drug candidates over the coming years as they move towards the final stages of development. Our ability to generate revenue from our drug candidates is dependent on the degree of market acceptance, as well as our ability to establish manufacturing capabilities and sales channels, and undertake extensive sales and marketing efforts.

Funding for Our Operations

During the Track Record Period, we funded our operations primarily through equity financing. Going forward, in the event of the successful commercialization of one or more of our drug candidates, we expect to primarily fund our operations with revenue generated from sales of our commercialized drug products. However, with the continuing expansion of our business, we may require further funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. Any fluctuation in the funding for our operations will impact our cash flow and our results of operations.

Our Research and Development Expenses

We believe our ability to successfully develop drug candidates is the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high-quality drug candidates requires significant investments of financial resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. As a result of this commitment, our pipeline of pre-clinical and clinical stage drug candidates has been steadily advancing and expanding. Our operations have consumed substantial amounts of cash since inception. Net cash used in our operations was RMB198.0 million and RMB306.3 million in 2021 and 2022, respectively. We expect our expenditures to increase significantly in connection with our ongoing activities, particularly as

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we advance the clinical development of our clinical assets and continue research and development of our pre-clinical assets. In addition, we may from time to time initiate additional clinical trials of, and seek regulatory approvals for, our current pipeline products and future drug candidates. These expenditures may include the following, among others:

- expenses incurred for payments to CROs, SMOs and CDMOs, investigators and clinical trial sites that conduct our clinical studies;
- employee related expenses, including salaries, benefits and equity compensation expenses;
- licensing fees to collaboration partners, including milestone payment and royalty payment, whereas applicable;
- costs associated with pre-clinical activities;
- expenses associated with the construction and maintenance of our manufacturing facilities;
- costs of acquiring, developing, and manufacturing clinical study materials;
- facilities, depreciation, and other expenses, which include office leases and other overhead expenses; and
- expenses associated with operating as a [REDACTED] company.

Potential Competition Upon Commercialization

The development and commercialization of innovative drugs is highly competitive. We face competition from global and China-based pharmaceutical and biotechnology companies, in particular companies currently marketing products or expect to be marketing products that compete or may compete directly or indirectly with our drug candidates. There are a number of pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for indications for which we are developing our drug candidates. Please refer to “Market Opportunity and Competition” for details of our major competitors for each drug candidate and “Risk Factors – Risks Relating to Our Pre-clinical and Clinical Development of Our Drug Candidates – We face substantial competition and our competitors may discover, develop or commercialize competing drugs earlier or more successfully than we do.” for further details of the risks associated with potential competition. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel therapies that are more effective, safer or less costly than our current or future drug candidates, or obtain regulatory approvals or market penetration for their products more rapidly than we do for our drug candidates.

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DESCRIPTION OF SELECTED COMPONENTS OF CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

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

	For the Year Ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Other income	520	4,798
Other losses	(990)	(4,353)
Administrative expenses	(51,884)	(80,238)
Research and development expenses	(173,256)	(313,356)
Loss from operations	(225,610)	(393,149)
Finance costs	(922)	(1,389)
Fair value changes on financial instruments issued to investors	(522,432)	(387,056)
Loss before taxation	(748,964)	(781,594)
Income tax	—	—
Loss for the year	(748,964)	(781,594)
Other comprehensive income for the year		
(after tax and reclassification adjustments)		
<i>Items that will not be reclassified to profit or loss:</i>		
Exchange differences on translation of financial statements of the Company	10,781	(71,656)
<i>Item that may be reclassified subsequently to profit or loss:</i>		
Exchange differences on translation of financial statements of foreign subsidiaries	8,156	(48,947)
Total comprehensive loss for the year	(730,027)	(902,197)

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Other Income

Our other income primarily consists of interest income from bank deposits, realized gain on wealth management products, net gain on termination of leases and government grants. Government grants mainly represent subsidies received from local governments for the purpose of promoting research and clinical trial activities in the form of allowance for new drug development and talents. During the Track Record Period, most of the government grants were received from authorities in Shanghai, China. Net gain on termination of leases represents the gain we recognized based on the difference between the carrying amount of the right-of-use assets and the lease liabilities and deduction of estimated penalties in relation to a lease agreement on which we have delivered a termination notice to the lessor in 2022.

In 2021, we mainly used bank deposits to preserve our funds. As a result, there was no realized gain on wealth management products in 2021. In 2022, we purchased short-term wealth management products in order to generate reasonable low-risk returns. With regards to the purchase of wealth management products, we have formulated the investment policy of diversifying risks and generating steady returns on the premise of ensuring the safety of funds.

Our Chief Executive Officer and the finance department are mainly responsible for making, implementing and supervising our investment decisions. We have implemented the following treasury policies and internal authorization controls:

- We have formulated the internal control measures to control our process of investment in wealth management products;
- Our Board authorizes and supervises the Chief Financial Officer to approve through a strict review and decision-making process, and our Chief Executive Officer is responsible for the approval of our material investments in wealth management products;
- Our finance department is responsible for the analysis and research of investments in wealth management products, as well as the long-term routine management of such investments; and
- Investments in wealth management products could be made when we have surplus cash that is not required for our short-term working capital purposes and in no event beyond the amount authorized by our senior management team.

Prior to making an investment, we ensure that there remains sufficient working capital for our business needs, operating activities, research and development and capital expenditures even after purchasing such wealth management products. We adopt a prudent approach in investing wealth management products. Our investment decisions are made on a case-by-case basis and after due and careful consideration of a number of factors, such as the duration of the investment and the expected returns. To control our risk exposure, we have in the past sought, and may continue in the future to seek other low-risk wealth management products with terms not longer than twelve months and may continue to invest in similar wealth management products using our surplus cash. Our investments in wealth management products after the [REDACTED] will be subject to compliance with Chapter 14 of the Listing Rules.

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The following table sets forth a breakdown of our other income for the periods indicated.

	For the Year Ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Interest income from bank deposits	409	823
Realized gain on wealth management products	–	42
Net gain on termination of leases	–	3,653
Government grants	111	280
	<u>111</u>	<u>280</u>
Total	<u>520</u>	<u>4,798</u>

Other Losses

Our other losses primarily consist of net foreign exchange loss and impairment loss on property, plant and equipment. The following table sets forth a breakdown of our other losses for the periods indicated.

	For the Year Ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Net foreign exchange loss	989	3,544
Impairment loss on property, plant and equipment	–	807
Others	1	2
	<u>1</u>	<u>2</u>
Total	<u>990</u>	<u>4,353</u>

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Administrative Expenses

Our administrative expenses primarily consist of staff costs, equity settled share-based payments, rental expenses, office and utility expenses, depreciation and amortization expenses, professional service expenses, [REDACTED] expenses and others. The following table sets forth a breakdown of our administrative expenses for the periods indicated.

	For the Year Ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Staff costs	19,177	30,052
Equity settled share-based payments	6,004	10,069
Rental expenses	868	1,844
Office and utility expenses	1,882	1,626
Depreciation and amortization expenses	2,178	1,162
Professional service expenses	20,313	9,481
[REDACTED] expenses	[REDACTED]	[REDACTED]
Others	1,462	2,108
Total	51,884	80,238

Research and Development Expenses

Our research and development expenses primarily consist of staff costs, equity settled share-based payments, discovery research expenses, clinical development expenses, depreciation and amortization expenses and others. Our research and development expenses increased significantly during the Track Record Period primarily attributable to (i) increases in clinical development expenses and discovery research expenses incurred due to clinical trials for our Core Products and pre-clinical trials for our drug candidates such as LAE102 and (ii) an increase in staff costs incurred due to the expansion of our R&D team. The following table sets forth a breakdown of our research and development expenses for the periods indicated.

	For the Year Ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Staff costs	36,695	61,571
Equity settled share-based payments	6,023	16,392
Discovery research expenses	21,629	73,239
Clinical development expenses	102,563	153,648
Depreciation and amortization expenses	3,648	5,505
Others	2,698	3,001
Total	173,256	313,356

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Finance Costs

Our finance costs consist of interest on bank loans and interest on lease liabilities. The following table sets forth the components of our finance costs for the periods indicated.

	For the Year Ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Interest on bank loans	29	173
Interest on lease liabilities	893	1,216
	893	1,216
Total	922	1,389

Fair Value Changes on Financial Instruments Issued to Investors

Our fair value changes on financial instruments issued to investors resulted from changes in fair value of preferred shares and a warrant issued to investors.

The following table sets forth the components of our fair value changes on financial instruments issued to investors for the periods indicated.

	For the Year Ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Fair value changes on Preferred Shares	474,394	378,308
Fair value changes on Warrant	48,038	8,748
	48,038	8,748
Total	522,432	387,056

Since 2018, we have issued a series of Series Seeds Preferred Shares, Series A Preferred Shares, Series B Preferred Shares, Series C Preferred Shares, and Series D Preferred Shares to our Series Seeds investors, Series A investors, Series B investors, Series C investors, and Series D investors, respectively. For more details regarding preferred shares, please see “History, Development and Corporate Structure – [REDACTED] Investments” in this document. We designated the entire instrument of the preferred shares as financial liabilities at fair value through profit or loss. Any directly attributable transaction costs are recognized 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 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.

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On January 31, 2019, we entered into a warrant agreement with an individual investor pursuant to which we issued a warrant to such investor for a cash consideration of RMB11.7 million. Pursuant to such warrant agreement, the warrant holder may exercise the warrant to purchase 1,166,525 ordinary shares and 338,273 Series Seeds Preferred Shares for nil consideration on or before the 90th day after our board approves to initiate an [REDACTED] of our shares. The warrant is initially recognized at fair value on the date of issuance and is subsequently re-measured to the fair value at the end of each reporting period. We have engaged an independent qualified professional valuer to determine the fair value of the warrant. For additional information, see Note 21(b) of the Accountants’ Report set out in Appendix I to this document. On March 31, 2022, such warrant was exercised. Please refer to the section headed “History, Development and Corporate Structure – Establishment, Major Shareholding Changes and Development of Our Group” in this document for more details.

Financial Assets and Liabilities Measured At Fair Value

Fair Value Hierarchy

The following table presents the fair value of our financial instruments measured at the end of each reporting period on a recurring basis, categorized into the three-level fair value hierarchy as defined in IFRS 13, *Fair value measurement*. The level into which a fair value measurement is classified is determined with reference to the observability and significance of the inputs used in the valuation technique as follows:

- Level 1 valuations: Fair value measured using only Level 1 inputs, i.e. unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date;
- Level 2 valuations: Fair value measured using Level 2 inputs, i.e. observable inputs which fail to meet Level 1, and not using significant unobservable inputs. Unobservable inputs are inputs for which market data are not available; or
- Level 3 valuations: Fair value measured using significant unobservable inputs.

We have engaged an external valuer to perform valuations for the financial instruments, including but not limited to the warrant and preferred shares. A valuation report with analysis of changes in fair value measurement is prepared by the external valuer at each reporting date, and is reviewed and approved by our management.

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	Fair Value as of December 31, 2021 <i>RMB'000</i>	Fair Value Measurements As of December 31, 2021 Categorized Into		
		Level 1 <i>RMB'000</i>	Level 2 <i>RMB'000</i>	Level 3 <i>RMB'000</i>
Recurring fair value measurement				
Financial instruments issued to investors				
– Preferred shares	1,402,111	–	–	1,402,111
– Warrant	98,429	–	–	98,429

	Fair Value as of December 31, 2022 <i>RMB'000</i>	Fair Value Measurements As of December 31, 2022 Categorized Into		
		Level 1 <i>RMB'000</i>	Level 2 <i>RMB'000</i>	Level 3 <i>RMB'000</i>
Recurring fair value measurement				
Financial instruments issued to investors				
– Preferred shares	2,277,281	–	–	2,277,281

During the Track Record Period, there were no transfers between Level 1 and Level 2, or transfers into or out of Level 3. Our policy is to recognize transfers between levels of fair value hierarchy as of the end of each reporting period in which they occur.

During the Track Record Period, we had certain financial liabilities categorized within Level 3 of fair value measurement (“**Level 3 Financial Liabilities**”). Our Level 3 Financial Liabilities include financial instruments issued to investors consisting of Preferred Shares and a warrant to purchase Shares and Preferred Shares. The Preferred Shares and the warrant were valued by our Directors with reference to valuation reports carried out by an independent qualified professional valuer. We used the back-solve method and income approach to determine the underlying share value of our Company and performed an equity allocation based on a hybrid method of Binomial Option Pricing model (OPM model) and Probability Weighted Expected Return method (PWERM method) to arrive the fair value of the Preferred Shares and the warrant as of the dates of issuance and at the end of each reporting period. Key valuation assumptions used to determine the fair value of these financial instruments issued to investors are as follows:

	As of December 31,	
	2021	2022
Risk-free interest rate	1.06%	4.32%
Volatility	40.50%	45.54%

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As of December 31, 2021, increasing/decreasing expected volatility by 5% would decrease/increase the fair value of financial instruments by RMB986,000 and RMB331,000 respectively, and increasing/decreasing risk free rate by 1% would decrease/increase the fair value by RMB2,697,000 and RMB2,781,000 respectively.

As of December 31, 2022, increasing/decreasing expected volatility by 5% would decrease/increase the fair value of financial instruments by RMB149,000 and RMB594,000 respectively, and increasing/decreasing risk free rate by 1% would decrease/increase the fair value by RMB2,717,000 and RMB2,788,000 respectively.

Details of the fair value measurement of our level 3 financial instruments, particularly the fair value hierarchy, the valuation techniques and key inputs, are disclosed in Note 24(e) of the Accountants’ Report set out in Appendix I to this document. The Reporting Accountants performed its work in accordance with Hong Kong Standard on Investment Circular Reporting Engagement 200 “Accountants’ Report 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 information for the Track Record Period as a whole, and its opinion on the Group for the Track Record Period as a whole is set out in the Accountants’ Report in Appendix I to this document.

In relation to the valuation of the Level 3 Financial Liabilities, with reference to the “Guidance note on directors’ duties in the context of valuations in corporate transactions” issued by the SFC, our Directors have adopted the following procedures: (i) reviewing the terms of the relevant agreements and documents regarding the financial liabilities; (ii) engaging an independent valuer to perform valuation procedures with necessary financial and non-financial information and discussing with the valuer on the relevant assumptions; (iii) obtaining sufficient understanding of the valuation model, methodologies and techniques on which the valuation is based; and (iv) reviewing the valuation works and results and the financial statements prepared in accordance with IFRS. Based on the above procedures, our Directors are of the view that the valuation analysis performed during the Track Record Period is fair and reasonable, and our financial statements are properly prepared. In addition, our Directors are satisfied with the valuation work for the Level 3 Financial Liabilities performed during the Track Record Period.

In relation to the fair value assessment of the financial liabilities requiring Level 3 measurements under the fair value classification, the Sole Sponsor has conducted relevant due diligence work, including but not limited to, (i) obtaining and reviewing the terms of the relevant [REDACTED] Investments and warrant agreement; (ii) discussing with the management of our Company to understand the methodology, assumptions and information relied upon in respect of our valuation of the Level 3 Financial Liabilities of our Group and our views on the fairness and reasonableness of the assumptions, basis and approaches of the valuation; (iii) discussing with the management of our Company to understand the work performed in relation to such valuation; (iv) discussing with the Reporting Accountants to understand the work they have performed in this regard; and (v) reviewing the relevant notes in the Accountants’ Report as contained in Appendix I to this document and the Reporting

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Accountants' opinion on the historical financial information as a whole for the Track Record Period. Based upon the due diligence work conducted by the Sole Sponsor as stated above, and having considered the views of the Directors, nothing material has come to the Sole Sponsor's attention that would cause the Sole Sponsor to question the valuation in respect of the financial assets requiring Level 3 measurements under the fair value classification.

Income Tax

During the Track Record Period, we recorded nil income tax expense. Our Directors confirm that, during the Track Record Period, we had made all the required tax filings with the relevant tax authorities in the relevant jurisdictions and had paid all outstanding tax liabilities and we were not aware of any outstanding or potential disputes with such tax authorities.

We are 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, we are not subject to tax on income or capital gains.

Hong Kong

Our subsidiary incorporated in Hong Kong was subject to income tax at the rate of 16.5% on the estimated assessable profits arising in Hong Kong during the Track Record Period.

Mainland China

Pursuant to the Enterprise Income Tax Law of the PRC and the respective regulations, the subsidiaries which operate in PRC are subject to income tax at the rate of 25% on the taxable income.

United States

Our subsidiary incorporated in the United States is subject to Federal Tax at a rate of 21% and State Profits Tax at a rate of 0.75% to 9.99%, during the Track Record Period on the estimated assessable profits arising in the United States.

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PERIOD-TO-PERIOD COMPARISON OF RESULTS OF OPERATIONS

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

Other Income

Our other income increased significantly from RMB0.5 million in 2021 to RMB4.8 million in 2022, primarily due to an increase of RMB3.7 million in net gain on termination of leases and an increase of RMB0.4 million in interest income from bank deposits.

Other Losses

Our other losses increased significantly from RMB1.0 million in 2021 to RMB4.4 million in 2022, as a result of (i) the unrealized net foreign exchange losses due to fluctuations in foreign currency exchange rates and (ii) impairment loss on construction in progress in relation to our previously planned manufacturing facility.

Administrative Expenses

Our administrative expenses increased by 54.5% from RMB51.9 million in 2021 to RMB80.2 million in 2022, primarily due to (i) an increase of RMB10.9 million in staff costs due to an increase in our total headcount to support growth of our business, and (ii) an increase of RMB[REDACTED] in [REDACTED] expenses.

Research and Development Expenses

Our research and development expenses increased by 80.8% from RMB173.3 million in 2021 to RMB313.4 million in 2022, primarily due to (i) increases of RMB102.7 million in clinical development expenses and discovery research expenses incurred mainly from clinical trials for our Core Products, especially Phase II clinical trials for LAE002, and pre-clinical trials for our drug candidates such as LAE102, (ii) an increase of RMB24.9 million in staff costs mainly as a result of the expansion of our average R&D staff size by 55% from 2021 to 2022, and (iii) an increase of RMB10.4 million in equity settled share-based payments due to increases in the number and value of Share Options granted in 2022.

Finance Costs

Our finance costs increased by 55.6% from RMB0.9 million in 2021 to RMB1.4 million in 2022. This increase was primarily due to (i) an increase of RMB323 thousand in interest on lease liabilities, which primarily arose from the lease agreement we renewed in 2021 in relation to our office in Shanghai, and (ii) an increase of RMB144 thousand in interest on bank loans.

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Fair Value Changes on Financial Instruments Issued to Investors

Our fair value changes on financial instruments issued to investors decreased by 25.9% from RMB522.4 million in 2021 to RMB387.1 million in 2022. This decrease was primarily because of the slowdown in valuation growth of our financial instruments issued to investors.

Loss for the Year

For the reasons described above, our loss for the year increased by 4.4% from RMB749.0 million in 2021 to RMB781.6 million in 2022.

DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

During the Track Record Period, we maintained a net liabilities position, primarily due to the recognition of financial instruments issued to investors as our non-current liabilities. The following table sets forth our consolidated statements of financial position as of the dates indicated.

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Non-current assets		
Property, plant and equipment	5,768	5,273
Intangible assets	110,315	123,631
Right-of-use assets	23,911	8,246
Other non-current assets	9,954	8,083
	149,948	145,233
Total non-current assets		
Current assets		
Prepayments and other receivables	12,485	11,561
Cash and cash equivalents	296,412	323,070
	308,897	334,631
Total current assets		
Current liabilities		
Bank loans	2,000	19,782
Other payables	38,131	75,868
Lease liabilities	1,859	1,859
	41,990	97,509
Total current liabilities		
NET CURRENT ASSETS	266,907	237,122

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	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Total assets less current liabilities	416,855	382,355
Non-current liabilities		
Lease liabilities	23,984	6,660
Deferred income	3,500	3,500
Financial instruments issued to investors	1,500,540	2,277,281
Total non-current liabilities	1,528,024	2,287,441
NET LIABILITIES	(1,111,169)	(1,905,086)
Capital and Reserves		
Share capital	4	5
Reserves	(1,111,173)	(1,905,091)
TOTAL DEFICIT	(1,111,169)	(1,905,086)

The following table sets forth breakdowns of our current assets and current liabilities as of the dates indicated:

	As of December 31,		As of
	2021	2022	January 31,
	<i>RMB'000</i>	<i>RMB'000</i>	2023
			<i>RMB'000</i>
			<i>(unaudited)</i>
Current assets			
Prepayments and other receivables	12,485	11,561	5,768
Cash and cash equivalents	296,412	323,070	293,408
Total current assets	308,897	334,631	299,176
Current liabilities			
Bank loans	2,000	19,782	29,959
Other payables	38,131	75,868	57,642
Lease liabilities	1,859	1,859	1,850
Total current liabilities	41,990	97,509	89,451
NET CURRENT ASSETS	266,907	237,122	209,725

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We maintained a net current assets position during the Track Record Period. The decrease in net current assets during the Track Record Period were primarily due to the increase in other payables. For more details on the change in our other payables, please see “– Other Payables.” As of January 31, 2023, our current assets and current liabilities were RMB299.2 million and RMB89.5 million, respectively.

Property, Plant and Equipment

Property, plant and equipment primarily consist of laboratory equipment, electronics and office equipment. Our property, plant and equipment decreased from RMB5.8 million as of December 31, 2021 to RMB5.3 million as of December 31, 2022 primarily in relation to the impairment loss on construction in progress concerning our previously planned manufacturing facility.

Intangible Assets

Intangible assets consist of (i) our in-licensed rights in relation to LAE001, LAE002, LAE003 and LAE005, and (ii) the clinical data analysis software we purchased in 2021 and the molecular operating environment software and a series of software for clinical development we purchased in 2022. The following table sets forth our intangible assets as of the dates indicated.

	As of December 31,	
	2021	2022
	RMB'000	RMB'000
In-licensed rights	108,661	118,698
Software	<u>1,654</u>	<u>4,933</u>
Total	<u>110,315</u>	<u>123,631</u>

Our intangible assets increased from RMB110.3 million as of December 31, 2021 to RMB123.6 million as of December 31, 2022 primarily due to the molecular operating environment software and a series of software for clinical development we purchased in 2022.

We tested intangible assets not yet ready for commercial use annually, based on the recoverable amount of the cash-generating unit (“CGU”) to which the intangible asset is related. The appropriate CGU is at the product level. The annual impairment test was performed for each drug by engaging an independent appraiser to estimate fair value less costs of disposal as the recoverable amount of each drug. The fair value is based on the multi-period excessive earning method, and we estimated the forecast period till year 2035 for each drug based on the progress of clinical development and regulatory approval, commercial ramp up to reach expected peak revenue potential, and the length of exclusivity for each product. The estimated revenue of each drug is based on management’s expectations of timing of

FINANCIAL INFORMATION

commercialization. The costs and operating expenses are estimated as a percentage over the revenue forecast period based on the current margin levels of comparable companies with adjustments made to reflect the expected future price changes.

In order to perform the impairment assessment, we prepared cash flow projections of each of the pipeline products as of December 31, 2021 and 2022, respectively, in which we applied success rates for each of the pipeline products based on the specific clinical trial stage as of December 31, 2021 and 2022. As a result, specific risk associated with a particular pipeline product has been considered in the risk adjusted cash flow projections. In this regard, the discount rates used only reflect the general business and market risk of us. The discount rates are derived from capital asset pricing model by taking applicable market data into account, such as risk free rate, market premium, beta, company specific risk and size premium, etc. After considering all the inputs, the discount rates derived at each reporting date were 18% as the inputs to the model in determining the discount rate remained similar throughout the Track Record Period.

The key assumptions used for recoverable amount calculations as of December 31, 2021 and 2022 are as follows:

	As of December 31,	
	2021	2022
	<i>RMB'000'000, except for percentages</i>	
<i>LAE001</i>		
Discount rate	18%	18%
Revenue growth rate	-14% to 373%	-14% to 379%
Recoverable amount of CGU	501.5	573.6
<i>LAE002 & LAE003</i>		
Discount rate	18%	18%
Revenue growth rate	-7% to 486%	-7% to 456%
Recoverable amount of CGU	1,035.9	1,252.1
<i>LAE005</i>		
Discount rate	18%	18%
Revenue growth rate	-18% to 24%	-18% to 24%
Recoverable amount of CGU	221.1	252.4

Based on the result of the above assessment, there were no impairment for the intangible assets as of December 31, 2021 and 2022.

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We have performed sensitivity tests by increasing 1% of the discount rate or decreasing 1% of the revenue growth rate, which are the key assumptions for determining the recoverable amount of the intangible asset, with all other variables held constant. The impacts on the amount by which the intangible asset’s recoverable amount is more than its carrying amount (headroom) are as below:

	As of December 31,	
	2021	2022
	<i>RMB'000'000</i>	<i>RMB'000'000</i>
<i>LAE001</i>		
Carrying amount	11.5	12.1
Headroom	490.0	561.5
Impact by increasing discount rate	(41.7)	(57.3)
Impact by decreasing revenue growth rate	(25.6)	(38.1)
 <i>LAE002 & LAE003</i>		
Carrying amount	33.4	36.9
Headroom	1,002.5	1,215.2
Impact by increasing discount rate	(86.6)	(118.6)
Impact by decreasing revenue growth rate	(60.4)	(89.8)
 <i>LAE005</i>		
Carrying amount	63.8	69.7
Headroom	157.3	182.7
Impact by increasing discount rate	(18.0)	(21.1)
Impact by decreasing revenue growth rate	(8.7)	(13.8)

Considering there was still sufficient headroom based on the assessment, we believe that a reasonably possible change in any of the key assumptions that we made for the determination of each intangible asset’s recoverable amount would not cause such asset’s carrying amount to exceed its recoverable amount.

For additional information, see Note 11(a)(iv) of the Accountants’ Report set out in Appendix I to this document.

Right-of-use Assets

Right-of-use assets primarily consist of our rights to use underlying leased premises. Our right-of-use assets decreased from RMB23.9 million as of December 31, 2021 to RMB8.2 million as of December 31, 2022 primarily because we delivered a termination notice of the lease agreement for our previously planned manufacturing facility.

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Prepayments and Other Receivables

Prepayments and other receivables primarily consist of (i) prepayments to suppliers engaged for our pre-clinical and clinical research and development, (ii) deferred [REDACTED] expenses and (iii) other debtors and deposits. Other debtors and deposits primarily represent our rental deposits. The following table sets forth our prepayments and other receivables as of the dates indicated.

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Prepayments to suppliers	11,336	4,267
Deferred [REDACTED] expenses	[REDACTED]	[REDACTED]
Other debtors and deposits	1,149	1,514
	<u>12,485</u>	<u>11,561</u>
Total	12,485	11,561

Our prepayments and other receivables decreased from RMB12.5 million as of December 31, 2021 to RMB11.6 million as of December 31, 2022 primarily due to the decrease in prepayments to suppliers resulting from the fulfillment of contractual obligations under the service contract with a CDMO in relation to the pre-clinical development of LAE102, and partially offset by an increase in deferred [REDACTED] expenses.

Cash and Cash Equivalents

The following table sets forth a breakdown of our cash and cash equivalents by currency as of the dates indicated.

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Denominated in:		
RMB	34,557	25,383
USD	261,855	297,687
	<u>296,412</u>	<u>323,070</u>
Cash and cash equivalents	296,412	323,070

Our cash and cash equivalents increased by 9.0% from RMB296.4 million as of December 31, 2021 to RMB323.1 million as of December 31, 2022, primarily due to the cash inflow from our Series D financing.

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Bank Loans

The following table sets forth the breakdown of our interest-bearing bank borrowing as of the date indicated:

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Unsecured bank loan due within 1 year	2,000	19,782

We entered into a loan agreement with China Merchants Bank in 2021 with the principal amount of RMB2.0 million and bearing an interest rate of 4.5% per annum. Such bank loan was paid back on January 5, 2022.

On August 25, 2022, China Merchants Bank granted us a banking facility of RMB30.0 million, and we have utilized an aggregate principal amount of RMB19.8 million as of December 31, 2022, with the interest rates ranging from 2.75% to 4.35% per annum and the terms ranging from 6-month to one-year.

Other Payables

Our other payables primarily consist of (i) payroll payables, (ii) accrued research and development expenses and (iii) other payables and accrued charges. The following table sets forth a breakdown of our other payables as of the dates indicated.

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Payroll payables	5,883	14,700
Accrued research and development expenses	29,979	51,595
Other payables and accrued charges	2,269	9,573
Total	38,131	75,868

Our other payables increased by 99.2% from RMB38.1 million as of December 31, 2021 to RMB75.9 million as of December 31, 2022, primarily due to (i) an increase of RMB8.8 million in payroll payables from RMB5.9 million as of December 31, 2021 to RMB14.7 million as of December 31, 2022, which was primarily driven by increase in the headcount, and (ii) an increase of RMB21.6 million in accrued research and development expenses from RMB30.0 million as of December 31, 2021 to RMB51.6 million as of December 31, 2022, which was primarily driven by the progresses in our research and development activities.

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Lease Liabilities

The following table sets forth our lease liabilities as of the dates indicated.

	As of December 31,	
	2021	2022
	RMB'000	RMB'000
Current	1,859	1,859
Non-current	23,984	6,660
Total	25,843	8,519

Our lease liabilities decreased from RMB25.8 million as of December 31, 2021 to RMB8.5 million as of December 31, 2022 primarily because we delivered a termination notice of the lease agreement for our previously planned manufacturing facility.

Financial Instruments Issued to Investors

Our financial instruments issued to investors represent the carrying amount of preferred shares and a warrant issued pursuant to the [REDACTED] Investments. Our financial instruments issued to investors increased from RMB1,500.5 million as of December 31, 2021 to RMB2,277.3 million as of December 31, 2022 primarily due to (i) changes in the fair value of the Preferred Shares and the warrant issued to investors, and (ii) the issuance of Series D Preferred Shares in 2022.

LIQUIDITY AND CAPITAL RESOURCES

Overview

We monitor and maintain a level of cash and cash equivalents deemed adequate to finance our operations and mitigate the effects of fluctuations in cash flows. In addition, we monitor the utilization of borrowings and, from time to time, evaluate the options to renew the borrowings upon expiry based on our actual business requirement. We relied on equity financing as the major sources of liquidity during the Track Record Period.

During the Track Record Period, we incurred negative cash flows from our operations and substantially all of our operating cash outflows resulted from our research and development expenses and administrative expenses. Our operating activities used RMB198.0 million and RMB306.3 million of cash in 2021 and 2022, respectively. We expect to generate operating income and improve our net operating cash outflow position through launching and commercializing our products and enhancing our cost containment capacity and operating efficiency. In order to bring our research and development objectives to fruition, we will very likely need additional funding and there can be no assurances that such funding will be made available to us.

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Cash Flows

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

	For the Year Ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Operating activities		
Operating loss before changes in working capital	(208,166)	(364,675)
Changes in working capital	10,159	58,392
Income tax paid	—	—
	<hr/>	<hr/>
Net cash used in operating activities	(198,007)	(306,283)
Investing activities		
Payment for purchase of property, plant and equipment	(7,317)	(2,983)
Payment for purchase of intangible assets	(1,804)	(2,102)
Interest received from bank deposits	409	823
Payment for purchase of wealth management products	—	(22,847)
Proceeds from disposal of wealth management products upon maturity	—	22,889
	<hr/>	<hr/>
Net cash used in investing activities	(8,712)	(4,220)
Financing activities		
Proceeds from a bank loan	2,000	19,650
Repayment of a bank loan	—	(2,000)
Interest paid for a bank loan	(29)	(173)
Proceeds from issuance of preferred shares	412,538	301,028
Proceeds from shares issued under share option scheme	—	54
Payment for capital element of lease liabilities	(1,202)	(511)
Payment for interest element of lease liabilities	(893)	(439)
Payment for [REDACTED] expenses	<u>[REDACTED]</u>	<u>[REDACTED]</u>
Net cash generated from financing activities	412,414	312,580
Net increase in cash and cash equivalents	205,695	2,077
Cash and cash equivalents at January 1	94,760	296,412
Effect of foreign exchange rate changes	<hr/> (4,043)	<hr/> 24,581
Cash and cash equivalents at December 31	<u>296,412</u>	<u>323,070</u>

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Operating Activities

In 2022, our net cash used in operating activities was RMB306.3 million, which was primarily attributable to our loss before taxation of RMB781.6 million, positively adjusted by (i) fair value changes on financial instruments issued to investors of RMB387.1 million, (ii) equity settled share-based payments of RMB26.5 million and (iii) depreciation of right-of-use assets of RMB3.3 million.

In 2021, our net cash used in operating activities was RMB198.0 million, which was primarily attributable to our loss before taxation of RMB749.0 million, positively adjusted by (i) fair value changes on financial instruments issued to investors of RMB522.4 million, (ii) equity settled share-based payments of RMB12.0 million, (iii) depreciation of right-of-use assets of RMB3.1 million and (iv) depreciation of property, plant and equipment of RMB2.6 million.

We plan to improve our net operating cash flow position in view of potential net operating cash inflow which we expect to generate through launching and commercializing our products and enhancing our cost control and operating efficiency. In particular, we plan to:

- Rapidly advance the clinical development and commercialization of our Core Products and other pipeline products after obtaining the relevant regulatory approvals. In particular, we are conducting the global Phase II registrational MRCT for our Core Product, LAE002, and aim to make NDA submission to the FDA and the NMPA in the fourth quarter of 2023. Leveraging our strong clinical and development capabilities, we expect to rapidly advance our Core Products and other pipeline products to achieve commercialization globally. After the commercialization of our products, we expect to generate more cash from our operating activities. We also plan to start educating target hospitals and physicians to prepare for the formal commercial launch in the following years. As we optimize our product portfolio and cost structure, increase the sales of our products, and continue to grow our business, we expect to generate a steady inflow of cash from operations in the foreseeable future; and
- Adopt comprehensive measures to effectively control our cost and operating expenses. For example, we plan to continue to regularly evaluate our existing and future arrangements and actively seek strategic cooperation with our major suppliers to improve procurement efficiency and lower our cost of procurement. In addition, we will build up our manufacturing capacity to reduce our reliance on CDMO to manufacture our products once approved and thus reduce expenditures.

Investing Activities

In 2022, our net cash used in investing activities was RMB4.2 million, which was primarily attributable to (i) payment for purchase of wealth management products, (ii) payment for purchase of property, plant and equipment, and (iii) payment for purchase of intangible assets, representing the purchase of R&D-related softwares, partially offset by proceeds from disposal of wealth management products upon maturity and interest received from bank deposits.

FINANCIAL INFORMATION

In 2021, our net cash used in investing activities was RMB8.7 million, which was primarily attributable to payment for purchase of property, plant and equipment and payment for purchase of intangible assets, representing the purchase of clinical data analysis software, partially offset by the interest received from banks.

Financing Activities

During the Track Record Period, we derived our cash inflows from financing activities primarily from the issuance of preferred shares.

In 2022, we had RMB312.6 million of net cash generated from financing activities, primarily attributable to proceeds from the issuance of preferred shares of RMB301.0 million and proceeds from bank loans of RMB19.7 million.

In 2021, we had RMB412.4 million of net cash generated from financing activities, primarily attributable to proceeds from the issuance of preferred shares of RMB412.5 million and proceeds from bank loans of RMB2.0 million.

CASH OPERATING COSTS

The following table sets forth information on our cash operating costs for the periods indicated:

	For the Year Ended	
	December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Research and Development Costs for		
<i>Core Products</i>		
Staff costs	24,215	39,225
Discovery research	–	–
Clinical development	81,620	125,604
Others	1,379	1,855
<i>Other Product Candidates</i>		
Staff costs	10,217	16,390
Discovery research	23,367	57,485
Clinical development	9,402	13,406
Others	689	1,398
Total Research and Development Costs	150,899	255,363
Workforce employment cost	17,970	27,191
Non-income taxes and royalties	27	110
Total	168,886	282,664

FINANCIAL INFORMATION

WORKING CAPITAL CONFIRMATION

Our Directors are of the opinion that, taking into account the financial resources available to us, including cash and cash equivalents and the estimated net [REDACTED] from the [REDACTED], and considering our cash burn rate, we have sufficient working capital to cover at least 125% of our costs, including research and development expenses and administrative expenses for at least the next 12 months from the expected date of this document.

Our cash burn rate refers to our average monthly (i) net cash used in operating activities; (ii) capital expenditures; and (iii) lease payments. Assuming that the average cash burn rate going forward of 1.3 times the level in 2022 (which is primarily based on the difference between the average monthly burn rate in 2022 and the prospective burn rate based on the average monthly net cash used in operating activities, capital expenditures and lease payments in 2023 and 2024), we estimate that our cash and cash equivalents as of December 31, 2022 for the purpose of the indebtedness statement, will be able to maintain our financial viability for approximately 9.9 months or, if taking into account the estimated net [REDACTED] (based on the lower end of the indicative [REDACTED] and assuming [REDACTED] is not exercised) from the [REDACTED], for at least 30.7 months. We will continue to closely monitor our working capital, cash flows, and our business development status.

INDEBTEDNESS

The following table sets forth the breakdown of our indebtedness as of the dates indicated:

	As of December 31,		As of
	2021	2022	January 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(unaudited)</i>
Current			
Bank loans	2,000	19,782	29,959
Lease liabilities	1,859	1,859	1,850
Non-current			
Lease liabilities	23,984	6,660	6,234
Financial instruments issued to investors	1,500,540	2,277,281	2,210,512
Total	1,528,383	2,305,582	2,248,555

FINANCIAL INFORMATION

During the Track Record Period and up to the Latest Practicable Date, we did not have other types of indebtedness other than bank loans, lease liabilities and financial instruments issued to investors as set forth in the table above, and had not been in violation of any of the covenants under any loan agreements. On August 25, 2022, China Merchants Bank granted us a banking facility of RMB30.0 million. We entered into loan agreements with Bank of Communications in January 2023 with an aggregate principal amount of RMB10.0 million and bearing an interest rate of 3.4% per annum. As of the Latest Practicable Date, we had RMB10.0 million remained unutilized under all of our banking facilities. Except as discussed above, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of the Latest Practicable Date.

CAPITAL EXPENDITURES

The following table sets forth our capital expenditures for the periods indicated:

	For the Year Ended	
	December 31,	
	2021	2022
	RMB'000	RMB'000
Payment for purchase of property, plant and equipment	(7,317)	(2,983)
Payment for purchase of intangible assets	<u>(1,804)</u>	<u>(2,102)</u>
Total	<u>(9,121)</u>	<u>(5,085)</u>

Our historical capital expenditures during the Track Record Period primarily included purchases of equipment and intangible assets. We funded our capital expenditure requirements during the Track Record Period mainly by equity financing. We expect that our capital expenditures in 2023 will be approximately RMB20.3 million, which will primarily include purchases of lab equipment and intangible assets. We plan to fund our planned capital expenditures using our cash at bank and the net [REDACTED] from the [REDACTED]. Please refer to the section headed “Future Plans and Use of [REDACTED]” in this document for more details. We may reallocate the fund to be utilized on capital expenditure based on our ongoing business needs.

FINANCIAL INFORMATION

COMMITMENTS

We had the following capital commitment as of the dates indicated.

	As of December 31,	
	2021	2022
	RMB'000	RMB'000
Contracted for	11,173	10,723
Authorized but not contracted for	47,527	43,551
	<hr/>	<hr/>
Total	58,700	54,274
	<hr/> <hr/>	<hr/> <hr/>

CONTINGENT LIABILITIES

As of December 31, 2021 and 2022, we did not have any contingent liabilities. 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.

RELATED PARTY TRANSACTIONS

During the Track Record Period, our only related party transaction is the key management personnel remuneration. Details of our transactions with and the outstanding balances with related parties during the Track Record Period are set out in Note 26 to the Accountants' Report included in Appendix I to this document.

KEY FINANCIAL RATIOS

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

	As of December 31,	
	2021	2022
Current Ratio ⁽¹⁾	7.36	3.43

Note:

(1) Current ratio equals current assets divided by current liabilities as of the end of the year.

The decrease in current ratio was primarily due to the increase in other payables. For more details on the change in our other payables, please see “– Discussion of Certain Selected Items From the Consolidated Statements of Financial Position – Other Payables.”

FINANCIAL INFORMATION

MARKET RISK DISCLOSURE

Exposure to credit, liquidity, interest rate and currency risks arises in the normal course of our business. Our exposures to these risks and the financial risk management policies and practices used by us to manage these risks are described below.

Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in a financial loss. Our credit risk is primarily attributable to other receivables. Our exposure to credit risk arising from cash and cash equivalents is limited because the counterparties are state-owned banks or reputable banks, which we considered to have low credit risks. We have a credit policy in place and the exposure to credit risk is monitored on an ongoing basis.

We have assessed that during the Track Record Period, other receivables have not had a significant increase in credit risk since initial recognition. Thus, a 12-month expected credit loss approach that results from possible default event within 12 months of each reporting date is adopted by management. We expect the occurrence of losses from non-performance by counterparties of other receivables to be remote and a loss allowance provision for other receivables to be immaterial.

Liquidity Risk

Our policy is to regularly monitor our liquidity requirements and our compliance with lending covenants, to ensure that we maintains sufficient reserves of cash and adequate committed lines of funding from major financial institutions to meet our liquidity requirements in the short and longer term. For further details, see Note 24(b) to the Accountants' Report set out in Appendix I to this document.

Currency Risk

Foreign currency risk means the risk relating to the fluctuation of fair value or future cash flows of financial instruments which arises from changes in exchange rates.

We are exposed to currency risk primarily through different functional currencies in different subsidiaries which give rise to cash and bank balances and other payables that are denominated in a currency other than the functional currency of the operations to which the transactions relate. The currency giving rise to this risk is primarily USD. For further details, including relevant sensitivity analysis, please see Note 24(d) to the Accountants' Report set out in Appendix I to this document.

FINANCIAL INFORMATION

DIVIDEND

We have never declared or paid regular cash dividends on our Shares. Any declaration and payment as well as the amount of dividends will be subject to our Memorandum and Articles and the Cayman Companies Act. The declaration and payment of any dividends in the future will be determined by our Board of Directors, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. In addition, 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 counsel, 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 the 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.

If we pay dividends in the future, in order for us to distribute dividends to our Shareholders, we will rely to some extent on any dividends distributed by our PRC subsidiaries. Any dividend distributions from our PRC subsidiaries to us will be subject to PRC withholding tax. In addition, regulations in the PRC currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits as determined in accordance with its articles of association and the accounting standards and regulations in China. See “Risk Factors – Risks Relating to Doing Business in China” in this document.

DISTRIBUTABLE RESERVES

As of December 31, 2022, our Company did not have any distributable reserves.

[REDACTED] EXPENSE INCURRED AND TO BE INCURRED

Our [REDACTED] expenses represent professional fees, [REDACTED] commissions and other fees incurred in connection with the [REDACTED]. Assuming an [REDACTED] of HK\$[REDACTED] per Share at the mid-point of the indicative [REDACTED] range stated in this document and no [REDACTED] is exercised, we estimated that total [REDACTED] expenses for the [REDACTED] are approximately RMB[REDACTED], accounting for [REDACTED]% of the gross [REDACTED] from the [REDACTED], including RMB[REDACTED] that we have recognized as expenses for the year ended December 31, 2022, about RMB[REDACTED] that we expect to recognize as expenses after December 31, 2022 and about RMB[REDACTED] that we expect to deduct from equity upon [REDACTED]. The above expenses are comprised of (i) [REDACTED] expenses, including [REDACTED] commission and other expenses, of RMB[REDACTED]; and (ii) [REDACTED] expenses of RMB[REDACTED], including (a) fee paid and payable to legal advisors and reporting accountants of RMB[REDACTED], and (b) other fees and expenses, including sponsor fees, of RMB[REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

FINANCIAL INFORMATION

[REDACTED]

FINANCIAL INFORMATION

[REDACTED]

SUBSEQUENT EVENTS

Our Directors confirm that, since December 31, 2022 (being the date on which the latest consolidated financial information of our Group was prepared) and up to the date of this document, there has been no material subsequent event undertaken by our Company.

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 or trading position since December 31, 2022 (being the date on which the latest consolidated financial information of our Group was prepared) and there has been no event since December 31, 2022 which would materially and adversely affect the information shown in our historical financial information included in the Accountants’ Report in Appendix I to this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, as of the Latest Practicable Date, there was no circumstance 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 – 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], 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.

Assuming an [REDACTED] at the mid-point of the indicative [REDACTED] range, we intend to use the net [REDACTED] we will receive from this [REDACTED] for the following purposes:

- (i) Approximately [REDACTED]% of the net [REDACTED], or approximately HK\$[REDACTED], is expected to be used for rapidly advancing the clinical development and approval of one of our Core Products, LAE001:
 - approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for advancing our Phase II clinical trial in China to assess the safety and efficacy of LAE001 as a monotherapy at recommended Phase II dose (RP2D) in mCRPC patients. We expect to complete the Phase II study with preliminary results in the third quarter of 2023. We are planning to initiate a Phase III global MRCT registrational trial for metastatic hormone-sensitive prostate cancer (mHSPC) in the fourth quarter of 2023;
 - approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for advancing Phase II clinical trial in the U.S. to treat second-generation A/AR drug-resistant mCRPC patients as a combination therapy with LAE002. We plan to reach the preliminary clinical results of such trial by the second quarter of 2023. We also received IND approval in March 2022 to initiate the Phase II study in South Korea. Further, we expect to initiate a Phase III registrational trial in the second half of 2023;
 - approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for the potential R&D of LAE001 in Japan and EU, as well as recruiting additional research and development and clinical personnel for LAE001; and
 - approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for the pharmacological development and drug production for the clinical studies and NDA submissions, as well as preparation for registration filing of LAE001 in China, Japan and EU.

FUTURE PLANS AND USE OF [REDACTED]

(ii) Approximately [REDACTED]% of the net [REDACTED], or approximately HK\$[REDACTED], is expected to be used for advancing the clinical development and approval of the other Core Product of the Company, LAE002:

- approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for advancing the MRCT Phase II registrational trial in both the U.S. and China to treat PROC as a combination therapy with chemotherapy paclitaxel. We aim to have NDA submissions in the fourth quarter of 2023;
- approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for advancing Phase II clinical trial in the U.S. and South Korea to treat second-generation A/AR drug-resistant mCRPC patients as a combination therapy with LAE001, and we split and assign the estimated costs of such trials equally under LAE001 and LAE002 for use of [REDACTED] purposes. We plan to reach the preliminary clinical results of such trial in the U.S. by the second quarter of 2023. We also received IND approval in March 2022 to initiate the Phase II study in South Korea;
- approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for advancing the Phase Ib/III trial in China for the treatment of locally advanced or metastatic HR+/HER2- breast cancer with LAE002, in a combination therapy with fulvestrant. We plan to initiate the MRCT Phase III study in the second half of 2023;
- approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for the pharmacological development and drug production for the clinical studies and NDA submissions, as well as preparation for registration filing of LAE002 in the U.S. and China;
- approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for advancing the Phase I/II trial in China for the treatment of TNBC with LAE002, in a combination therapy with LAE005. We aim to obtain the preliminary clinical results in the first quarter of 2023. We plan to initiate the Phase II study in the first quarter of 2024; and
- approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for the potential R&D, registration and commercialization of LAE002 in Japan and EU, as well as establishing our commercialization capabilities, including building our commercialization team.

We plan to use a larger amount of existing working capital to support the clinical studies of LAE002 in addition to the [REDACTED] from the [REDACTED], resulting in a significantly less proposed [REDACTED] allocation to LAE002, which have more planned clinical trials, compared with that of LAE001.

FUTURE PLANS AND USE OF [REDACTED]

- (iii) Approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for accelerating the research and development of other existing pipeline products and continuously advancing and improving innovative pipeline products:
- approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for further exploration and research of pre-clinical stage assets. We plan to seek more innovative solutions in the field of cancer and liver fibrosis, by focusing on immune cells that are key to immune surveillance in both cases. These innovative assets such as LAE102 and LAE104 are in various drug discovery stages, and we plan to advance at least one drug candidate into IND submission each year starting from 2023; and
 - approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for ongoing development, planned clinical trials, preparation for registration filings related to existing clinical stage assets, including potential R&D, registration and commercialization of LAE005 in Japan and EU. We also have independent R&D programs for LAE005. In particular, subject to our future R&D strategy, we plan to further evaluate LAE005’s *in vitro* and *in vivo* activity, favorable safety profile, and ability to promote adaptive immune responses for anti-tumor effects in pre-clinical studies. We also plan to evaluate LAE005’s potential in combination with other self-developed or licensed drug candidates, such as a Phase I study of LAE005 in combination with LAE102 for solid tumors and a Phase I study of LAE005 in combination with LAE001 for solid tumors, over a three-year period. We may also collaborate with other potential partners to conduct studies of LAE005 in combination with other oncology drugs.
- (iv) Approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for improving our production capabilities and developing our manufacturing capacities. We plan to construct a cGMP compliant manufacturing facility in eastern China for the manufacturing of our products;
- (v) Approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for business development activities and enhancing our global reach. We plan to capture the underlying value of our assets through global collaboration including but not limited to merger and acquisition, as well as licensing opportunities, especially of assets with proven efficacy and safety profiles, validated mechanism of action, large addressable unmet medical needs and co-development partnerships, which strategy shall complement and diversify our pipeline to increase our competitiveness globally; and
- (vi) Approximately [REDACTED]%, or HK\$[REDACTED], is expected to be used for our working capital and other general corporate purposes.

FUTURE PLANS AND USE OF [REDACTED]

If the [REDACTED] is set at HK\$[REDACTED] per Share, being the high end of the indicative [REDACTED] range, the net [REDACTED] from the [REDACTED] will increase by approximately HK\$[REDACTED]. If the [REDACTED] is set at HK\$[REDACTED] per Share, being the low end of the indicative [REDACTED] range, the net [REDACTED] from the [REDACTED] will decrease by approximately HK\$[REDACTED]. 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] range stated in this document.

If the [REDACTED] is exercised in full, the net [REDACTED] that we will receive will be approximately HK\$[REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per Share (being the mid-point of the indicative [REDACTED] range). 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 authorized financial institutions (as defined under the SFO for Hong Kong based deposits or the applicable laws in the relevant jurisdiction for non-Hong Kong based deposits) 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]

[REDACTED]

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STRUCTURE OF THE [REDACTED]

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HOW TO APPLY FOR [REDACTED]

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[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

The following is the text of a report set out on pages I-[1] to I-[48], received from the Company’s reporting accountants, KPMG, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this document.



ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF LAEKNA, INC. AND CHINA INTERNATIONAL CAPITAL CORPORATION HONG KONG SECURITIES LIMITED

Introduction

We report on the historical financial information of Laekna, Inc. (the “Company”) and its subsidiaries (together, the “Group”) set out on pages I-[4] to I-[48], which comprises the consolidated statements of financial position of the Group and the statements of financial position of the Company as at 31 December 2021 and 2022 and the consolidated statements of profit or loss and other comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows, for each of the years ended 31 December 2021 and 2022 (the “Relevant Periods”), 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-[48] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [●] (the “Document”) in connection with the initial [REDACTED] of shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited.

Directors’ responsibility for Historical Financial Information

The directors of the Company are responsible for the preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of preparation and presentation set out in Note 1 to the Historical Financial Information, and for such internal control as the directors of the Company determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants’ responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 “Accountants’ Reports on Historical Financial Information in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants (“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.

APPENDIX I

ACCOUNTANTS’ REPORT

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgment, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of preparation and presentation set out in Note 1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purpose of the accountants’ report, a true and fair view of the Company’s and the Group’s financial position as at 31 December 2021 and 2022, and of the Group’s financial performance and cash flows for the Relevant Periods in accordance with the basis of preparation and presentation set out in Note 1 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited 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 23(b) to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

APPENDIX I

ACCOUNTANTS' REPORT

No statutory financial statements for the Company

No statutory statements have been prepared for the Company since its incorporation.

KPMG

Certified Public Accountants

8th Floor, Prince's Building

10 Chater Road

Central, Hong Kong

[●]

HISTORICAL FINANCIAL INFORMATION

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The consolidated financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by KPMG Huazhen LLP Shanghai Branch (畢馬威華振會計師事務所(特殊普通合伙)上海分所) in accordance with Hong Kong Standards on Auditing issued by the HKICPA (the “Underlying Financial Statements”).

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

		<u>Years ended 31 December</u>	
	<i>Note</i>	2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
Other income	4	520	4,798
Other losses		(990)	(4,353)
Administrative expenses		(51,884)	(80,238)
Research and development expenses		<u>(173,256)</u>	<u>(313,356)</u>
Loss from operations		(225,610)	(393,149)
Finance costs	5(a)	(922)	(1,389)
Fair value changes on financial instruments issued to investors	21	<u>(522,432)</u>	<u>(387,056)</u>
Loss before taxation	5	(748,964)	(781,594)
Income tax	6	<u>–</u>	<u>–</u>
Loss for the year		<u>(748,964)</u>	<u>(781,594)</u>
Other comprehensive income for the year			
(after tax and reclassification adjustments)			
<i>Items that will not be reclassified to profit or loss:</i>			
Exchange differences on translation of financial statements of the Company		10,781	(71,656)
<i>Item that may be reclassified subsequently to profit or loss:</i>			
Exchange differences on translation of financial statements of foreign subsidiaries		<u>8,156</u>	<u>(48,947)</u>
Total comprehensive income for the year/period		<u>(730,027)</u>	<u>(902,197)</u>
Loss per share			
Basic and diluted (RMB)	9	<u>(105.35)</u>	<u>(101.88)</u>

The accompanying notes form part of the Historical Financial Information.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	<i>Note</i>	As at 31 December	
		2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Non-current assets			
Property, plant and equipment	10	5,768	5,273
Intangible assets	11	110,315	123,631
Right-of-use assets	12	23,911	8,246
Other non-current assets	14	9,954	8,083
		149,948	145,233
Current assets			
Prepayments and other receivables	15	12,485	11,561
Cash and cash equivalents	16	296,412	323,070
		308,897	334,631
Current liabilities			
Bank loans	17	2,000	19,782
Other payables	18	38,131	75,868
Lease liabilities	19	1,859	1,859
		41,990	97,509
Net current assets		266,907	237,122
Total assets less current liabilities		416,855	382,355
Non-current liabilities			
Lease liabilities	19	23,984	6,660
Deferred income	20	3,500	3,500
Financial instruments issued to investors	21	1,500,540	2,277,281
		1,528,024	2,287,441
NET LIABILITIES		(1,111,169)	(1,905,086)
CAPITAL AND RESERVES			
Share capital	23	4	5
Reserves		(1,111,173)	(1,905,091)
TOTAL DEFICIT		(1,111,169)	(1,905,086)

The accompanying notes form part of the Historical Financial Information.

APPENDIX I

ACCOUNTANTS’ REPORT

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

		As at 31 December	
	<i>Note</i>	2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
Non-current assets			
Intangible assets	<i>11</i>	108,661	118,698
Investment in subsidiaries	<i>13</i>	24,754	780,529
Prepayments and other receivables	<i>15</i>	424,502	41,969
		<u>557,917</u>	<u>941,196</u>
Current assets			
Prepayments and other receivables	<i>15</i>	35	5,352
Cash and cash equivalents	<i>16</i>	234,425	248,985
		<u>234,460</u>	<u>254,337</u>
Current liabilities			
Other payables	<i>18</i>	392	3,821
Net current assets		<u>234,068</u>	<u>250,516</u>
Total assets less current liabilities		<u>791,985</u>	<u>1,191,712</u>
Non-current liabilities			
Financial instruments issued to investors	<i>21</i>	1,500,540	2,277,281
NET LIABILITIES		<u>(708,555)</u>	<u>(1,085,569)</u>
CAPITAL AND RESERVES			
Share capital	<i>23</i>	4	5
Reserves		(708,559)	(1,085,574)
TOTAL DEFICIT		<u>(708,555)</u>	<u>(1,085,569)</u>

The accompanying notes form part of the Historical Financial Information.

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CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	<i>Note</i>	Share capital RMB'000	Share premium RMB'000	Capital reserve RMB'000	Exchange reserve RMB'000	Accumulated losses RMB'000	Total deficit RMB'000
Balance at 1 January 2021		4	–	20,908	23,088	(437,169)	(393,169)
Changes in equity for 2021							
Total comprehensive income for the year		–	–	–	18,937	(748,964)	(730,027)
Equity settled share-based payment	22	–	–	12,027	–	–	12,027
Balance at 31 December 2021 and 1 January 2022		4	–	32,935	42,025	(1,186,133)	(1,111,169)
Changes in equity for 2022							
Total comprehensive income for the year		–	–	–	(120,603)	(781,594)	(902,197)
Equity settled share-based payment	22	–	–	26,461	–	–	26,461
Shares issued upon exercise of the warrant	23(c)	1	81,764	–	–	–	81,765
Shares issued under share option scheme	23(c)	–*	11,443	(11,389)	–	–	54
Balance at 31 December 2022		<u>5</u>	<u>93,207</u>	<u>48,007</u>	<u>(78,578)</u>	<u>(1,967,727)</u>	<u>(1,905,086)</u>

* The balance represents an amount less than RMB1,000.

The accompanying notes form part of the Historical Financial Information.

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CONSOLIDATED STATEMENTS OF CASH FLOWS

		Years ended 31 December	
	<i>Note</i>	2021	2022
		<i>RMB’000</i>	<i>RMB’000</i>
Operating activities			
Cash used in operations	<i>16(b)</i>	(198,007)	(306,283)
Net cash used in operating activities		(198,007)	(306,283)
Investing activities			
Payment for purchase of property, plant and equipment		(7,317)	(2,983)
Payment for purchase of intangible assets		(1,804)	(2,102)
Interest received from bank deposits	<i>4</i>	409	823
Payment for purchase of wealth management products		–	(22,847)
Proceeds from disposal of wealth management products upon maturity		–	22,889
Net cash used in investing activities		(8,712)	(4,220)
Financing activities			
Proceeds from bank loans	<i>16(c)</i>	2,000	19,650
Repayment of a bank loan	<i>16(c)</i>	–	(2,000)
Interest paid for bank loans	<i>16(c)</i>	(29)	(173)
Proceeds from issuance of preferred shares	<i>16(c)</i>	412,538	301,028
Proceeds from shares issued under share option scheme	<i>23(c)</i>	–	54
Payment for capital element of lease liabilities	<i>16(c)</i>	(1,202)	(511)
Payment for interest element of lease liabilities	<i>16(c)</i>	(893)	(439)
Payment for [REDACTED] expenses		[REDACTED]	[REDACTED]
Net cash generated from financing activities		412,414	312,580
Net increase in cash and cash equivalents		205,695	2,077
Cash and cash equivalents at 1 January	<i>16(a)</i>	94,760	296,412
Effect of foreign exchange rate changes		(4,043)	24,581
Cash and cash equivalents at 31 December	<i>16(a)</i>	296,412	323,070

The accompanying notes form part of the Historical Financial Information.

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ACCOUNTANTS’ REPORT

NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1 BASIS OF PREPARATION AND PRESENTATION OF HISTORICAL FINANCIAL INFORMATION

Laekna, Inc. (the “Company”) was incorporated in the Cayman Islands on 29 July 2016 as an exempted company with limited liability under the law of the Cayman Islands.

The Company is an investing holding company. During the Relevant Periods, the Company and its subsidiaries (together, “the Group”) are principally engaged in discovering, development and commercialising innovative therapies for cancer and liver diseases in the People’s Republic of China (the “PRC”), the United States of America (the “USA”), Europe and South Korea.

As at the date of this report, no audited financial statement has been prepared for the Company. The financial statements of the subsidiaries of the Group for which there are statutory requirements were prepared in accordance with the relevant accounting rules and regulations applicable to entities in the countries in which they were incorporated and/or established.

As at the date of this report, the Company has direct or indirect interests in the following subsidiaries, all of which are private companies:

Name of company	Place and date of incorporation/ establishment	Particulars of issued and paid up capital	Proportion of ownership interest		Principal activities
			Directly held by the Company	Indirectly held by the Company	
Laekna Limited (“Laekna HK”) (ii)(v)	26 August 2016 Hong Kong	USD104,255,223	100%	–	Research and development of drug candidates
Laekna LLC (“Laekna LLC”) (vi)	3 January 2020 The USA	–	100%	–	Research and development of drug candidates
Laekna Therapeutics Shanghai Co., Ltd. (“Laekna Therapeutics”) (來凱醫藥科技(上海)有限公司) (i)(iii)(v)	28 December 2016 The PRC	RMB102,177,006	–	100%	Research and development of drug candidates
Laekna Pharmaceutical Shanghai Co., Ltd. (“Laekna Pharmaceutical”) (來凱製藥(上海)有限公司) (i)(iv)(v)	8 December 2020 The PRC	RMB22,000,000	–	100%	Pharmaceutical

Notes:

- (i) The English translation of these entities is for reference only. The official names of the entities established in the PRC are in Chinese.
- (ii) The statutory financial statements of this entity for the year ended 31 December 2021 were audited by KPMG (畢馬威會計師事務所).
- (iii) The statutory financial statements of this entity for the year ended 31 December 2021 were audited by KPMG Huazhen LLP Shanghai Branch (畢馬威華振會計師事務所(特殊普通合夥)上海分所).
- (iv) The statutory financial statements of this entity for the period from 8 December 2020 (date of incorporation) to 31 December 2021 were audited by KPMG Huazhen LLP Shanghai Branch (畢馬威華振會計師事務所(特殊普通合夥)上海分所).
- (v) No audited financial statements for the year ended 31 December 2022 are available for these entities as at the date of this report.
- (vi) No audited financial statements are available as at the date of this report.

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All companies comprising the Group have adopted 31 December as their financial year end date.

The Historical Financial Information has been prepared in accordance with all applicable International Financial Reporting Standards (“IFRSs”) which collectively includes all applicable individual International Financial Reporting Standards, International Accounting Standards and Interpretations issued by the International Accounting Standards Board (“IASB”). Further details of the significant accounting policies adopted are set out in Note 2.

Notwithstanding that the Group recorded net liabilities of RMB1,111,169,000 and RMB1,905,086,000 as at 31 December 2021 and 2022, and incurred recurring losses from operations since incorporation, the Historical Financial Information has been prepared on a going concern basis as the directors of the Company believe that the preferred shares (see Note 21(a)) will not be redeemed within the next twelve months from 31 December 2022. The directors of the Company are satisfied that the Group will have sufficient financial resources to meet its financial obligations as they fall due and to sustain its operations for the foreseeable future after reviewing the Group’s cash flow projection, taking into account the expected working capital requirements covering the next twelve months from 31 December 2022.

The IASB has issued a number of new and revised IFRSs. For the purpose of preparing this Historical Financial Information, the Group has adopted all applicable new and revised IFRSs to the Relevant Periods. The accounting policies set out in Note 2 have been applied consistently throughout the Relevant Periods and the Group has not adopted any new standards or interpretations that are effective for the accounting year beginning on or after 1 January 2023. The revised and new accounting standards and interpretations issued but not yet effective for the accounting years beginning on or after 1 January 2023 are set out in Note 28.

The Historical Financial Information also complies with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

2 SIGNIFICANT ACCOUNTING POLICIES

(a) Basis of measurement

As the Group’s operations are primarily located in the PRC and most of the Group’s transactions are conducted and denominated in Renminbi (“RMB”), the Historical Financial Information is presented in RMB, rounded to the nearest thousand, unless otherwise stated. The functional currency of the Company is United States dollars (“USD”).

The measurement basis used in the preparation of the Historical Financial Information is the historical cost basis except that the financial assets and liabilities are stated at their fair value as explained in the accounting policies as set out in Notes 2(d)&(l).

(b) Use of estimates and judgements

The preparation of financial statements in conformity with IFRSs requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets, liabilities, income and expenses. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis of making the judgements about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

Judgements made by management in the application of IFRSs that have significant effect on the financial statements and major sources of estimation uncertainty are discussed in Note 3.

(c) Subsidiaries

Subsidiaries are entities controlled by the Group. The Group controls an entity when it is exposed, or has rights, to variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. When assessing whether the Group has power, only substantive rights (held by the Group and other parties) are considered.

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ACCOUNTANTS’ REPORT

An investment in a subsidiary is consolidated into the Historical Financial Information from the date that control commences until the date that control ceases. Intra-group balances, transactions and cash flows and any unrealised profits arising from intra-group transactions are eliminated in full in preparing the Historical Financial Information. Unrealised losses resulting from intra-group transactions are eliminated in the same way as unrealised gains but only to the extent that there is no evidence of impairment.

Changes in the Group’s interests in a subsidiary that do not result in a loss of control are accounted for as equity transactions, whereby adjustments are made to the amounts of controlling and non-controlling interests within consolidated equity to reflect the change in relative interests, but no gain or loss is recognised.

When the Group loses control of a subsidiary, it is accounted for as a disposal of the entire interest in that subsidiary, with a resulting gain or loss being recognised in profit or loss. Any interest retained in that former subsidiary at the date when control is lost is recognised at fair value and this amount is regarded as the fair value on initial recognition of a financial asset or, when appropriate, the cost on initial recognition of an investment in an associate or joint venture.

In the Company’s statement of financial position, an investment in a subsidiary is stated at cost less impairment losses (see Note 2(h)(ii)).

(d) Other investments in debt and equity securities

The Group’s policies for investments in debt and equity securities, other than investments in subsidiaries, associates and joint ventures, are set out below.

Investments in debt and equity securities are recognised/derecognised on the date the Group commits to purchase/sell the investment. The investments are initially stated at fair value plus directly attributable transaction costs, except for those investments measured at fair value through profit or loss (FVPL) for which transaction costs are recognised directly in profit or loss. For an explanation of how the Group determines fair value of financial instruments, see Note 24(e). These investments are subsequently accounted for as follows, depending on their classification.

(i) Investments other than equity investments

Non-equity investments held by the Group are classified into one of the following measurement categories:

- amortised cost, if the investment is held for the collection of contractual cash flows which represent solely payments of principal and interest. Interest income from the investment is calculated using the effective interest method.
- fair value through other comprehensive income (FVOCI) – recycling, if the contractual cash flows of the investment comprise solely payments of principal and interest and the investment is held within a business model whose objective is achieved by both the collection of contractual cash flows and sale. Changes in fair value are recognised in other comprehensive income, except for the recognition in profit or loss of expected credit losses, interest income (calculated using the effective interest method) and foreign exchange gains and losses. When the investment is derecognised, the amount accumulated in other comprehensive income is recycled from equity to profit or loss.
- fair value through profit or loss (FVPL) if the investment does not meet the criteria for being measured at amortised cost or FVOCI (recycling). Changes in the fair value of the investment (including interest) are recognised in profit or loss.

(ii) Equity investments

An investment in equity securities is classified as FVPL unless the equity investment is not held for trading purposes and on initial recognition of the investment the Group makes an irrevocable election to designate the investment at FVOCI (non-recycling) such that subsequent changes in fair value are recognised in other comprehensive income. Such elections are made on an instrument-by-instrument basis, but may only be made if the investment meets the definition of equity from the issuer’s perspective. Where such an election is made, the amount accumulated in other comprehensive income remains in the fair value reserve (non-recycling) until the investment is disposed of. At the time of disposal, the amount accumulated in the fair value reserve (non-recycling) is transferred to retained earnings. It is not recycled through profit or loss. Dividends from an investment in equity securities, irrespective of whether classified as at FVPL or FVOCI, are recognised in profit or loss as other income.

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(e) Property, plant and equipment

The following items of property, plant and equipment are stated at cost less accumulated depreciation and impairment losses (see Note 2(h)(ii)):

- right-of-use assets arising from leases over leasehold properties where the Group is not the registered owner of the property interests; and
- items of plant and equipment, including right-of-use assets arising from leases of underlying plant and equipment (see Note 2(g)).

The cost of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to working condition and location for its intended use. Subsequent expenditure relating to an item of property, plant and equipment that has already been recognised is added to the carrying amount of the asset when it is probable that the future economic benefits, in excess of the original assessed standard of performance of the existing asset, will flow to the Group or the Company. All other subsequent expenditure is recognised as an expense in profit or loss in the period in which it is incurred.

Gains or losses arising from the retirement or disposal of an item of property, plant and equipment are determined as the difference between the net disposal proceeds and the carrying amount of the item and are recognised in profit or loss on the date of retirement or disposal.

Depreciation is calculated to write off the cost of items of property, plant and equipment, less their estimated residual value, if any, using the straight line method over their estimated useful lives as follows:

Laboratory equipment	1-5 years
Office and other equipment	3-5 years
Leasehold improvement	Shorter of useful lives or lease term
Right-of-use assets	Over the lease term

Where parts of an item of property, plant and equipment have different useful lives, the cost of the item is allocated on a reasonable basis between the parts and each part is depreciated separately. Both the useful life of an asset and its residual value, if any, are reviewed annually.

Construction in progress represents properties under construction and machinery and equipment pending installation and is stated at cost (which is, in the case of assets acquired in a business combination, the acquisition date fair value) less impairment losses (see Note 2(h)(ii)). Cost comprises the purchase costs of the asset and the related construction and installation costs.

Construction in progress is transferred to relevant property, plant and equipment when the asset is substantially ready for its intended use and depreciation will be provided at the appropriate rates in accordance with the depreciation policies specified above. No depreciation is provided in respect of construction in progress.

(f) Intangible assets

(i) Research and development expenditures

The Group incurs significant costs and efforts on research and development activities, which include expenditures on drug products. Research expenditures are charged to profit or loss as an expense in the period the expenditures are incurred. Development costs are recognised as assets if they can be directly attributable to a newly developed drug product and all the following can be demonstrated:

- (i) the technical feasibility of completing the development project so that it will be available for use or sale;
- (ii) the Group's intention to complete the development project to use or sell it;
- (iii) the Group's ability to use or sell the development project;
- (iv) how the development project will generate probable future economic benefits for the Group;
- (v) the Group's availability of adequate technical, financial and other resources to complete the development and to use or sell the development project; and
- (vi) the ability to measure reliably the expenditures attributable to the development project.

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The cost of an internally generated intangible asset is the sum of the expenditures incurred from the date the asset meets the recognition criteria above to the date when it is available for use. The costs capitalised in connection with the intangible asset include costs of materials and services used or consumed, employee costs incurred in the creation of the asset and an appropriate portion of relevant overheads. The Group generally considers capitalisation criteria for internally generated intangible assets is met when obtaining regulatory approval of a new drug license.

Capitalised development expenditures are amortised using the straight-line method over the life of the related drug products. Amortisation shall begin when the asset is available for commercial use. Subsequent to initial recognition, internally generated intangible assets are reported as cost less accumulated amortisation and accumulated impairment losses (see Note 2(h)(ii)) (if any).

Development expenditures not satisfying the above criteria are recognised in the profit or loss as incurred, and development expenditures previously recognised as an expense are not recognised as an asset in a subsequent period.

(ii) *In-licenses*

Intangible assets acquired separately are measured at cost on initial recognition.

Certain intangible assets are for licenses of intellectual properties in development, with non-refundable upfront payments, milestone payments and royalty payments. Upfront payments are capitalised when paid. Milestone payments are capitalised as intangible assets when incurred and enhanced the expected future economic benefits of the intangible assets, unless the payments are for outsourced research and development work which would follow the capitalisation policy in Note 2(f)(i). Royalty payments would be accrued for in line with the underlying sales and recognised as a cost of sales.

The intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised when ready for commercial use and over the economic useful life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at the end of each reporting period. Intangible assets with indefinite useful lives or not ready for commercial use will not be amortised but tested for impairment annually either individually or at the cash generating unit level. The impairment test would compare the recoverable amount of the in-licensed asset to its carrying value. The useful life of an intangible asset with an indefinite life is reviewed annually to determine whether the indefinite life assessment continues to be supportable. If not, the change in the useful life assessment from indefinite to finite is accounted for on a prospective basis.

(iii) *Software*

Computer software is recognised at historical cost and subsequently carried at cost less accumulated amortisation and accumulated impairment losses (see Note 2(h)(ii)). The Group amortised on a straight-line basis over their estimated useful lives of 5 years based on the current functionalities and the daily operation needs of the software.

Both the period and method of amortisation are reviewed annually.

(g) *Leased assets*

At inception of a contract, the Group assesses whether the 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. Control is conveyed where the customer has both the right to direct the use of the identified asset and to obtain substantially all of the economic benefits from that use.

Where the contract contains lease component(s) and non-lease component(s), the Group has elected not to separate non-lease components and accounts for each lease component and any associated non-lease component as a single lease component for all leases.

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At the lease commencement date, the Group recognises a right-of-use asset and a lease liability, except for short-term leases that have a lease term of 12 months or less and leases of low-value assets. When the Group enters into a lease in respect of a low-value asset, the Group decides whether to capitalise the lease on a lease-by-lease basis. The lease payments associated with those leases which are not capitalised are recognised as an expense on a systematic basis over the lease term.

Where the lease is capitalised, the lease liability is initially recognised at the present value of the lease payments payable over the lease term, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, using a relevant incremental borrowing rate. After initial recognition, the lease liability is measured at amortised cost and interest expense is calculated using the effective interest method. Variable lease payments that do not depend on an index or rate are not included in the measurement of the lease liability and hence are charged to profit or loss in the accounting period in which they are incurred.

The right-of-use asset recognised when a lease is capitalised is initially measured at cost, which comprises the initial amount of the lease liability plus any lease payments made at or before the commencement date, and any initial direct costs incurred. Where applicable, the cost of the right-of-use assets also includes an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, discounted to their present value, less any lease incentives received. The right-of-use asset is subsequently stated at cost less accumulated depreciation and impairment losses (see Notes 2(h)(ii)).

The initial fair value of refundable rental deposits is accounted for separately from the right-of-use assets in accordance with the accounting policy applicable to investments in debt securities carried at amortised cost (see Notes 2(d)(i), 2(q)(i) and 2(h)(i)). Any difference between the initial fair value and the nominal value of the deposits is accounted for as additional lease payments made and is included in the cost of right-of-use assets.

The lease liability is remeasured when there is a change in future lease payments arising from a change in an index or rate, or there is a change in the Group’s estimate of the amount expected to be payable under a residual value guarantee, or there is a change arising from the reassessment of whether the Group will be reasonably certain to exercise a purchase, extension or termination option. When the lease liability is remeasured in this way, a corresponding adjustment is made to the carrying amount of the right-of-use asset, or is recorded in profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

The lease liability is also remeasured when there is a change in the scope of a lease or the consideration for a lease that is not originally provided for in the lease contract (“lease modification”) that is not accounted for as a separate lease. In this case the lease liability is remeasured based on the revised lease payments and lease term using a revised discount rate at the effective date of the modification. The only exceptions are rent concessions that occurred as a direct consequence of the COVID-19 pandemic and met the conditions set out in paragraph 46B of IFRS 16 Leases. In such cases, the Group has taken advantage of the practical expedient not to assess whether the rent concessions are lease modifications, and recognised the change in consideration as negative variable lease payments in profit or loss in the period in which the event or condition that triggers the rent concessions occurred.

In the consolidated statement of financial position, the current portion of long-term lease liabilities is determined as the present value of contractual payments that are due to be settled within twelve months after the reporting period.

(h) Credit losses and impairment of assets

(i) Credit losses from financial instruments

The Group recognises a loss allowance for expected credit losses (ECLs) on financial assets measured at amortised cost (including cash and cash equivalents and other receivables). Other financial assets measured at fair value are not subject to the ECL assessment.

Measurement of ECLs

ECLs are a probability-weighted estimate of credit losses. Credit losses are measured as the present value of all expected cash shortfalls (i.e. the difference between the cash flows due to the Group or the Company in accordance with the contract and the cash flows that the Group or the Company expects to receive).

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The expected cash shortfalls are discounted using the following discount rates where the effect of discounting is material:

- fix-rate financial assets and other receivables: effective interest rate determined at initial recognition or an approximation thereof; and
- variable-rate financial assets: current effective interest rate.

The maximum period considered when estimating ECLs is the maximum contractual period over which the Group is exposed to credit risk.

In measuring ECLs, the Group or the Company takes into account reasonable and supportable information that is available without undue cost or effort. This includes information about past events, current conditions and forecasts of future economic conditions.

ECLs are measured on either of the following bases:

- 12-month ECLs: these are losses that are expected to result from possible default events within the 12 months after the reporting date; and
- lifetime ECLs: these are losses that are expected to result from all possible default events over the expected lives of the items to which the ECL model applies.

Loss allowances for other receivables are always measured at an amount equal to lifetime ECLs. ECLs on these financial assets are estimated using a provision matrix based on the Group's historical credit loss experience, adjusted for factors that are specific to the debtors and an assessment of both the current and forecast general economic conditions at the reporting date.

For all other financial instruments, the Group recognises a loss allowance equal to 12-month ECLs unless there has been a significant increase in credit risk of the financial instrument since initial recognition, in which case the loss allowance is measured at an amount equal to lifetime ECLs.

Significant increases in credit risk

In assessing whether the credit risk of a financial instrument has increased significantly since initial recognition, the Group compares the risk of default occurring on the financial instrument assessed at the reporting date with that assessed at the date of initial recognition. In making this reassessment, the Group considers that a default event occurs when the borrower is unlikely to pay its credit obligations to the Group in full, without recourse by the Group to actions such as realising a security (if any is held). The Group considers both quantitative and qualitative information that is reasonable and supportable, including historical experience and forward-looking information that is available without undue cost or effort.

In particular, the following information is taken into account when assessing whether credit risk has increased significantly since initial recognition:

- failure to make payments of principal or interest on their contractually due dates;
- an actual or expected significant deterioration in a financial instrument's external or internal credit rating (if available);
- an actual or expected significant deterioration in the operating results of the debtor; and
- existing or forecast changes in the technological, market, economic or legal environment that have a significant adverse effect on the debtor's ability to meet its obligation to the Group.

Depending on the nature of the financial instruments, the assessment of a significant increase in credit risk is performed on either an individual basis or a collective basis. When the assessment is performed on a collective basis, the financial instruments are grouped based on shared credit risk characteristics, such as past due status and credit risk ratings.

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ECLs are remeasured at each reporting date to reflect changes in the financial instrument’s credit risk since initial recognition. Any change in the ECL amount is recognised as an impairment gain or loss in profit or loss. The Group recognises an impairment gain or loss for all financial instruments with a corresponding adjustment to their carrying amount through a loss allowance account.

Basis of calculation of interest income

Interest income recognised is calculated based on the gross carrying amount of the financial asset unless the financial asset is credit-impaired, in which case interest income is calculated based on the amortised cost (i.e. the gross carrying amount less loss allowance) of the financial asset.

At each reporting date, the Group assesses whether a financial asset is credit-impaired. A financial asset is credit-impaired when one or more events that have a detrimental impact on the estimated future cash flows of the financial asset have occurred.

Evidence that a financial asset is credit-impaired includes the following observable events:

- significant financial difficulties of the debtor;
- a breach of contract, such as a default or past due event;
- it becoming probable that the borrower will enter into bankruptcy or other financial reorganisation;
- significant changes in the technological, market, economic or legal environment that have an adverse effect on the debtor; or
- the disappearance of an active market for a security because of financial difficulties of the issuer.

Write-off policy

The gross carrying amount of a financial asset or contract asset is written off (either partially or in full) to the extent that there is no realistic prospect of recovery. This is generally the case when the Group determines that the debtor does not have assets or sources of income that could generate sufficient cash flows to repay the amounts subject to the write-off.

Subsequent recoveries of an asset that was previously written off are recognised as a reversal of impairment in profit or loss in the period in which the recovery occurs.

(ii) Impairment of other non-current assets

Internal and external sources of information are reviewed at the end of each reporting period to identify indications that the following assets may be impaired or, except in the case of goodwill, an impairment loss previously recognised no longer exists or may have decreased:

- property, plant and equipment, including right-of-use assets;
- intangible assets; and
- investments in subsidiaries in the Company’s statement of financial position.

If any such indication exists, the asset’s recoverable amount is estimated. In addition, for intangible assets that are not yet available for use, the recoverable amount is estimated annually whether or not there is any indication of impairment.

– Calculation of recoverable amount

The recoverable amount of an asset is the greater of its fair value less costs of disposal and value in use. 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. Where an asset does not generate cash inflows largely independent of those from other assets, the recoverable amount is determined for the smallest group of assets that

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generates cash inflows independently (i.e. a cash-generating unit). A portion of the carrying amount of a corporate asset (for example, head office building) is allocated to an individual cash-generating unit if the allocation can be done on a reasonable and consistent basis, or to the smallest group of cash-generating units if otherwise.

– *Recognition of impairment losses*

An impairment loss is recognised in profit or loss if the carrying amount of an asset, or the cash-generating unit to which it belongs, exceeds its recoverable amount. Impairment losses recognised in respect of cash-generating units are allocated first to reduce the carrying amount of any goodwill allocated to the cash-generating unit (or group of units) and then, to reduce the carrying amount of the other assets in the unit (or group of units) on a pro rata basis, except that the carrying value of an asset will not be reduced below its individual fair value less costs of disposal (if measurable) or value in use (if determinable).

– *Reversals of impairment losses*

In respect of assets other than goodwill, an impairment loss is reversed if there has been a favourable change in the estimates used to determine the recoverable amount. An impairment loss in respect of goodwill is not reversed.

A reversal of an impairment loss is limited to the asset’s carrying amount that would have been determined had no impairment loss been recognised in prior years. Reversals of impairment losses are credited to profit or loss in the year in which the reversals are recognised.

(i) Receivables

A receivable is recognised when the Group has an unconditional right to receive consideration. A right to receive consideration is unconditional if only the passage of time is required before payment of that consideration is due.

All receivables are subsequently stated at amortised cost, using the effective interest method and including an allowance for credit losses (see Note 2(h)(i)).

(j) Cash and cash equivalents

Cash and cash equivalents comprise cash at bank and on hand, demand deposits with banks and other financial institutions, and short-term, highly liquid investments that are readily convertible into known amounts of cash and which are subject to an insignificant risk of changes in value, having been within three months of maturity at acquisition. Cash and cash equivalents are assessed for expected credit losses (ECL) in accordance with the policy set out in Note 2(h)(i).

(k) Payables

Trade and other payables are initially recognised at fair value. Subsequent to initial recognition, trade and other payables are stated at amortised cost unless the effect of discounting would be immaterial, in which case they are stated at invoice amounts.

(l) Financial instruments issued to investors

Financial instruments issued to investors consist of preferred shares and a warrant for purchase of ordinary shares and preferred shares.

(i) Preferred shares

A preferred share is classified as a financial liability if the Company is required to be liquidated upon events beyond its control and the preferred share is not in the most subordinated class of instruments issued by the Company. The financial liability is mandatorily measured at fair value through profit or loss, if any embedded derivative required to be separated cannot be measured reliably; otherwise, the embedded derivatives are measured at fair value through profit or loss and the host debt is initially measured at fair value and subsequently at amortised cost.

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(ii) Warrant

During the Relevant Periods, the Company issued a warrant under which the holder has the right to subscribe for the Company’s ordinary shares and preferred shares at a predetermined price during a specific period.

A warrant is classified as a financial liability if it will not be settled only by the Company exchanging a fixed number of cash or another financial asset for a fixed number of its own equity instruments. A warrant liability is initially recognised at fair value on the date a warrant contract is entered into and is subsequently re-measured to its fair value at the end of each reporting period. Changes in fair value are recognised in profit or loss.

(m) Interest-bearing borrowings

Interest-bearing borrowings are measured initially at fair value less transaction costs. Subsequent to initial recognition, interest-bearing borrowings are stated at amortised cost using the effective interest method. Interest expense is recognised in accordance with the Group’s accounting policy for borrowing costs (see Note 2(s)).

(n) Employee benefits

(i) Short-term employee benefits and contributions to defined contribution retirement plans

Salaries, annual bonuses, paid annual leave, contributions to defined contribution retirement plans and the cost of non-monetary benefits are accrued in the year in which the associated services are rendered by employees. Where payment or settlement is deferred and the effect would be material, these amounts are stated at their present values.

(ii) Share-based payments

The fair value of share options granted to employee is recognised as an employee cost with a corresponding increase in a capital reserve within equity. The fair value is measured at grant date using the binomial lattice model, taking into account the terms and conditions upon which the options were granted. Where the employees have to meet vesting conditions before becoming unconditionally entitled to the options, the total estimated fair value of the options is spread over the vesting period, taking into account the probability that the options will vest.

During the vesting period, the number of share options that is expected to vest is reviewed. Any resulting adjustment to the cumulative fair value recognised in prior years is charged/credited to the profit or loss for the year of the review, unless the original employee expenses qualify for recognition as an asset, with a corresponding adjustment to the capital reserve. On vesting date, the amount recognised as an expense is adjusted to reflect the actual number of options that vest (with a corresponding adjustment to the capital reserve) except where forfeiture is only due to not achieving vesting conditions that related to the market price of the Company’s shares. The equity amount is recognised in the capital reserve until either the option is exercised (when it is included in the amount recognised in share capital for the shares issued) or the option expires (when it is released directly to retained profits).

The grant by the Company of options over its equity instruments to the employees of subsidiaries undertakings in the Group is treated as a capital contribution. The fair value of employee services received, measured by reference to the grant date fair value, is recognised over the vesting period as an increase to investment in subsidiary undertakings, with a corresponding credit to equity in separate financial statements of the Company.

(iii) Termination benefits

Termination benefits are recognised at the earlier of when the Group can no longer withdraw the offer of those benefits and when it recognises restructuring costs involving the payment of termination benefits.

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(o) Income tax

Income tax for the year comprises current tax and movements in deferred tax assets and liabilities. Current tax and movements in deferred tax assets and liabilities are recognised in profit or loss except to the extent that they relate to items directly in equity, in which case the relevant amounts of tax are recognised directly in equity, respectively.

Current tax is the expected tax payable on the taxable income for the year, using tax rates enacted or substantively enacted at the end of each reporting period, and any adjustment to tax payable in respect of previous years.

Deferred tax assets and liabilities arise from deductible and taxable temporary differences respectively, being the differences between the carrying amounts of assets and liabilities for financial reporting purposes and their tax bases. Deferred tax assets also arise from unused tax losses and unused tax credits.

Apart from certain limited exceptions, all deferred tax liabilities, and all deferred tax assets to the extent that it is probable that future taxable profits will be available against which the asset can be utilised, are recognised. Future taxable profits that may support the recognition of deferred tax assets arising from deductible temporary differences include those that will arise from the reversal of existing taxable temporary differences, provided those differences relate to the same taxation authority and the same taxable entity, and are expected to reverse either in the same period as the expected reversal of the deductible temporary difference or in periods into which a tax loss arising from the deferred tax asset can be carried back or forward. The same criteria are adopted when determining whether existing taxable temporary differences support the recognition of deferred tax assets arising from unused tax losses and credits, that is, those differences are taken into account if they relate to the same taxation authority and the same taxable entity, and are expected to reverse in a period, or periods, in which the tax loss or credit can be utilised.

The limited exceptions to recognition of deferred tax assets and liabilities are those temporary differences arising from the initial recognition of assets or liabilities that affect neither accounting nor taxable profit (provided they are not part of a business combination), and temporary differences relating to investments in subsidiaries to the extent that, in the case of taxable differences, the Group controls the timing of the reversal and it is probable that the differences will not reverse in the foreseeable future, or in the case of deductible differences, unless it is probable that they will reverse in the future.

The amount of deferred tax recognised is measured based on the expected manner of realisation or settlement of the carrying amount of the assets and liabilities, using tax rates enacted or substantively enacted at the end of each reporting period. Deferred tax assets and liabilities are not discounted.

The carrying amount of a deferred tax asset is reviewed at the end of each reporting period and is reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow the related tax benefit to be utilised. Any such reduction is reversed to the extent that it becomes probable that sufficient taxable profit will be available.

Additional income taxes that arise from the distribution of dividends are recognised when the liability to pay the related dividends is recognised.

Current tax balances and deferred tax balances, and movements therein, are presented separately from each other and are not offset. Current tax assets are offset against current tax liabilities, and deferred tax assets against deferred tax liabilities, if the Company or the Group has the legally enforceable right to set off current tax assets against current tax liabilities and the following additional conditions are met:

- in the case of current tax assets and liabilities, the Company or the Group intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously; or
- in the case of deferred tax assets and liabilities, if they relate to income taxes levied by the same taxation authority on either:
 - the same taxable entity; or
 - different taxable entities, which, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered, intend to realise the current tax assets and settle the current tax liabilities on a net basis or realise and settle simultaneously.

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(p) Provisions and contingent liabilities

Provisions are recognised when the Group has a legal or constructive obligation arising as a result of a past event, it is probable that an outflow of economic benefits will be required to settle the obligation and a reliable estimate can be made. Where the time value of money is material, provisions are stated at the present value of the expenditures expected to settle the obligation.

Where it is not probable that an outflow of economic benefits will be required, or the amount cannot be estimated reliably, the obligation is disclosed as a contingent liability, unless the probability of outflow of economic benefits is remote. Possible obligations, whose existence will only be confirmed by the occurrence or non-occurrence of one or more future events, are also disclosed as contingent liabilities unless the probability of outflow of economic benefits is remote.

Where some or all of the expenditure required to settle a provision is expected to be reimbursed by another party, a separate asset is recognised for any expected reimbursement that would be virtually certain. The amount recognised for the reimbursement is limited to the carrying amount of the provision.

(q) Other income

(i) Interest income

Interest income is recognised as it accrues using the effective interest method using the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the gross carrying amount of the financial asset. For financial assets measured at amortised cost or FVOCI (recycling) that are not credit-impaired, the effective interest rate is applied to the gross carrying amount of the asset. For credit-impaired financial assets, the effective interest rate is applied to the amortised cost (i.e. gross carrying amount net of loss allowance) of the asset (see Note 2(h)(i)).

(ii) Government grants

Government grants are recognised in the statement of financial position initially when there is reasonable assurance that they will be received and that the Group will comply with the conditions attaching to them. Grants that compensate the Group for expenses incurred are recognised as income in profit or loss on a systematic basis in the same periods in which the expenses are incurred. Grants that compensate the Group for the cost of an asset are presented in the consolidated statements of financial position by setting up the grant as deferred income and consequently are effectively recognised in profit or loss on a systematic basis over the useful life of the asset.

(r) Translation of foreign currencies

Foreign currency transactions during the Relevant Periods are translated at the foreign exchange rates ruling at the transaction dates. Monetary assets and liabilities denominated in foreign currencies are translated at the foreign exchange rates ruling at the end of the reporting period. Exchange gains and losses are recognised in profit or loss.

Non-monetary assets and liabilities that are measured in terms of historical cost in a foreign currency are translated using the foreign exchange rates ruling at the transaction dates. The transaction date is the date on which the Group initially recognises such non-monetary assets or liabilities. Non-monetary assets and liabilities denominated in foreign currencies that are stated at fair value are translated using the foreign exchange rates ruling at the dates the fair value was measured.

The results of foreign operations are translated into RMB at the exchange rates approximating the foreign exchange rates ruling at the dates of the transactions. Statement of financial position items are translated into RMB at the closing foreign exchange rates at the end of the reporting period. The resulting exchange differences are recognised in other comprehensive income and accumulated separately in equity in the exchange reserve.

(s) Borrowing costs

Borrowing costs that directly attributable to the acquisition, construction or production of an asset which necessarily takes a substantial period of time to get ready for its intended use or sale are capitalised as part of the cost of that asset. Other borrowing costs are expensed in the period in which they are incurred.

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The capitalisation of borrowing costs as part of the cost of a qualifying asset commences when expenditure for the asset is being incurred, borrowing costs are being incurred and activities that are necessary to prepare the asset for its intended use or sale are in progress. Capitalisation of borrowing costs is suspended or ceases when substantially all the activities necessary to prepare the qualifying asset for its intended use or sale are interrupted or complete.

(t) Related parties

- (a) A person, or a close member of that person's family, is related to the Group if 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 the Group's parent.
- (b) An entity is related to the Group if any of the following conditions applies:
 - (i) The entity and the Group are members of the same group (which means that each parent, subsidiary and fellow subsidiary is related to the others).
 - (ii) One entity is an associate or a joint venture of the other entity (or an associate or a joint venture of a member of a group of which the other entity is a member).
 - (iii) Both entities 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).
 - (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 Group's parent.

Close members of the family of a person are those family members who may be expected to influence, or be influenced by, that person in their dealings with the entity.

(u) Segment reporting

Operating segments, and the amounts of each segment item reported in the financial statements, are identified from the financial information provided regularly to the Group's most senior executive management for the purposes of allocating resources to, and assessing the performance of, the Group's various lines of business and geographical locations.

Individually material operating segments are not aggregated for financial reporting purposes unless the segments have similar economic characteristics and are similar in respect of the nature of products and services, the nature of production processes, the type or class of customers, the methods used to distribute the products or provide the services, and the nature of the regulatory environment. Operating segments which are not individually material may be aggregated if they share a majority of these criteria.

For the purpose of resource allocation and performance assessment, the Group's chief executive officer, being the chief operating decision maker, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole and hence. During the Relevant Periods, the Group has only one reportable segment which is engaged in the research and development of drugs.

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3 ACCOUNTING JUDGEMENTS AND ESTIMATES

(a) Critical accounting judgements in applying the Group’s accounting policies

In the process of applying the Group’s accounting policies, management has made the following accounting judgement:

(i) *Research and development expenses*

Development expenses incurred on the Group’s pipeline are 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, the Group’s intention to complete and the Group’s ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure reliably the expenditure during the development. Development expense which do not meet these criteria are expensed when incurred. Management will assess the progress of each of the research and development projects and determine the criteria met for capitalisation. All development expenses were expensed when incurred during the Relevant Periods.

(b) Key Sources of estimation uncertainty

Note 21 and Note 22 contain information about the assumptions and their risk factors relating to financial instruments issued to investors and fair value of equity settled share-based transactions. Other key sources of estimation uncertainty are as follows:

(i) *Recognition of deferred tax assets*

Deferred tax assets are recognised for deductible temporary differences and cumulative tax losses. As those deferred tax assets can only be recognised to the extent that it is probable that future taxable profit will be available against which they can be utilised, management’s judgement is required to assess the probability of future taxable profits. Management’s assessment is constantly reviewed and additional deferred tax assets are recognised if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered.

(ii) *Impairment of intangible assets not ready for commercial use*

Intangible assets not ready for commercial use are not subject to amortisation and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. The Group obtained in-licenses through acquisition for the purpose of continuing the research and development work and commercialisation of the products, which are classified as intangible assets not ready for commercial use.

An impairment loss is recognised for the amount by which the intangible asset’s carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an intangible asset’s fair value less costs of disposal and value in use. For the purposes of assessing impairment, each in-license is a cash-generating unit.

4 OTHER INCOME

	Years ended 31 December	
	2021 RMB’000	2022 RMB’000
Interest income from bank deposits	409	823
Realised gain on wealth management products	–	42
Net gain on termination of leases	–	3,653
Government grants	111	280
	<u>520</u>	<u>4,798</u>

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5 LOSS BEFORE TAXATION

Loss before taxation is arrived at after charging:

(a) Finance costs

	Years ended 31 December	
	2021 RMB’000	2022 RMB’000
Interest on bank loans	29	173
Interest on lease liabilities	893	1,216
	<u>922</u>	<u>1,389</u>

(b) Staff costs

	Years ended 31 December	
	2021 RMB’000	2022 RMB’000
Salaries, wages and other benefits	53,228	87,021
Contributions to defined contribution retirement plan (i)	2,644	4,602
Equity settled share-based payment expenses	12,027	26,461
	<u>67,899</u>	<u>118,084</u>

(c) Other items

	Years ended 31 December	
	2021 RMB’000	2022 RMB’000
Amortization of intangible assets (Note 11)	150	1,070
Depreciation charge		
– property, plant and equipment (Note 10)	2,551	2,219
– right-of-use assets (Note 12)	3,070	3,299
	<u>5,621</u>	<u>5,518</u>
Impairment loss on property, plant and equipment (Note 10)	–	807
[REDACTED] expenses	[REDACTED]	[REDACTED]
Auditors’ remuneration (ii)	402	3,126
Research and development costs (iii)	173,256	313,356
Net foreign exchange loss	989	3,544

(i) The full-time employees of the Group are entitled to various government-sponsored defined-contribution retirement plans. The Group contributes on a monthly basis to these funds based on certain percentages of the salaries of the employees, subject to certain ceiling. The Group’s liability in respect of these funds is limited to the contributions payable in each year.

(ii) During the year ended 31 December 2022, the Group recognised auditors’ remuneration in respect of [REDACTED] of RMB2,686,000, which is also included in the [REDACTED] expenses disclosed separately above.

(iii) During the years ended 31 December 2021 and 2022, research and development expenses include staff costs, depreciation and amortisation expenses of RMB46,366,000 and RMB83,468,000 respectively, in which the respective amounts are also disclosed separately above.

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6 INCOME TAX

(a) Taxation in the consolidated statements of profit or loss and other comprehensive income:

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.

(i) The Cayman Islands

Pursuant to the rules and regulations of the Cayman Islands, the Company is currently not subject to income tax.

(ii) Hong Kong

The Company’s subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at 16.5% of the estimated assessable profits. No provision for Hong Kong profit tax has been made for the Relevant Periods as there were no assessable profits during the Relevant Periods.

(iii) The USA

The Company’s subsidiary incorporated in the USA is subject to Federal Tax at a rate of 21% and State Profits Tax at a rate of 0.75% – 9.99%. Operations in the USA have incurred net accumulated operating losses for income tax purposes, and no income tax provisions has been made during the Relevant Periods.

(iv) Mainland China

Pursuant to the Corporate Income Tax Law of the PRC (the “CIT”), the Company’s PRC subsidiaries are subject to the CIT at a rate of 25%.

According to the new tax incentive policies promulgated by the State Tax Bureau of the PRC in September 2018 and March 2021, effective for the period from 1 January 2018 to 31 December 2023, an additional 75% of qualified research and development expenses incurred is allowed to be deducted from taxable income.

(b) Reconciliation between tax expense and accounting profit at applicable tax rates:

	Years ended 31 December	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Loss before taxation	(748,964)	(781,594)
Notional tax on loss before taxation, calculated at the rates applicable to losses in the jurisdictions concerned	(45,111)	(82,035)
Tax effect of non-deductible expenses	17,257	20,734
Tax effect of unused tax losses not recognised	29,534	64,372
Tax effect of deductible temporary differences not recognised	2,639	7,389
Tax effect of super deduction for research and development <i>(Note 6(a)(iv))</i>	(4,319)	(10,460)
Actual tax expense	–	–

(c) Deferred tax assets not recognised:

As at 31 December 2021 and 2022, the Group has not recognised deferred tax assets of certain entities in respect of their respective cumulative tax losses and temporary differences of RMB224,949,000 and RMB499,046,000 respectively, as it is not probable that future taxable profits against which the losses can be utilised will be available in the relevant tax jurisdiction and entity.

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7 DIRECTORS’ EMOLUMENTS

Directors’ emoluments disclosed pursuant to section 383(1) of the Hong Kong Companies Ordinance and Part 2 of the Companies (Disclosure of Information about Benefits of Directors) Regulation are as follows:

For the year ended 31 December 2021	Directors’ fees <i>RMB’000</i>	Salaries, allowances and benefits in kind <i>RMB’000</i>	Discretionary bonuses <i>RMB’000</i>	Retirement scheme contributions <i>RMB’000</i>	Sub total <i>RMB’000</i>	Share- based payments <i>RMB’000</i>	Total <i>RMB’000</i>
LU Chris Xiangyang	–	1,625	155	15	1,795	–	1,795
XIE Ling	–	1,279	163	58	1,500	1,520	3,020
LIN Dianhai	–	–	–	–	–	2,845	2,845
WANG Guowei	–	–	–	–	–	–	–
WEI Jun	–	–	–	–	–	–	–
ZHOU Yi (appointed on 30 March 2021)	–	–	–	–	–	–	–
Total	–	2,904	318	73	3,295	4,365	7,660

For the year ended 31 December 2022	Directors’ fees <i>RMB’000</i>	Salaries, allowances and benefits in kind <i>RMB’000</i>	Discretionary bonuses <i>RMB’000</i>	Retirement scheme contributions <i>RMB’000</i>	Sub total <i>RMB’000</i>	Share- based payments <i>RMB’000</i>	Total <i>RMB’000</i>
LU Chris Xiangyang	–	1,862	185	65	2,112	–	2,112
XIE Ling	–	1,609	129	65	1,803	4,014	5,817
GU Xiang Ju Justin (appointed on 9 May 2022)	–	1,814	235	65	2,114	2,291	4,405
LIN Dianhai (resigned on 9 May 2022)	–	–	–	–	–	–	–
WANG Guowei	–	–	–	–	–	–	–
WEI Jun (resigned on 28 April 2022)	–	–	–	–	–	–	–
ZHOU Yi (resigned on 28 April 2022)	–	–	–	–	–	–	–
JI Dongmei (appointed on 28 April 2022)	–	–	–	–	–	–	–
SUN Yuan (appointed on 28 April 2022)	–	–	–	–	–	–	–
Total	–	5,285	549	195	6,029	6,305	12,334

During the years ended 31 December 2021 and 2022, there were no amounts paid or payable by the Group to the directors or any of the highest paid individuals set out in Note 8 below as an inducement to join or upon joining the Group or as a compensation for loss of office.

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8 INDIVIDUALS WITH HIGHEST EMOLUMENTS

During the years ended 31 December 2021 and 2022, of the five individuals with the highest emoluments, two and two are directors whose emoluments are disclosed in Note 7. The aggregate of the emoluments in respect of the other three and three individuals are as follows:

	Years ended 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Salaries and other emoluments	5,883	7,846
Discretionary bonuses	700	1,165
Retirement scheme contributions	105	188
Share-based payments	3,562	5,089
	<u>10,250</u>	<u>14,288</u>

During the years ended 31 December 2021 and 2022, the emoluments of the three and three individuals with the highest emoluments are within the following bands:

	Years ended 31 December	
	2021 <i>Number of individuals</i>	2022 <i>Number of individuals</i>
Nil – HKD1,000,000	–	–
HKD1,000,001 – HKD1,500,000	–	–
HKD1,500,001 – HKD2,000,000	–	–
HKD2,000,001 – HKD2,500,000	–	–
HKD2,500,001 – HKD3,000,000	–	–
HKD3,000,001 – HKD3,500,000	1	–
HKD3,500,001 – HKD4,000,000	–	–
HKD4,000,001 – HKD4,500,000	1	–
HKD4,500,001 – HKD5,000,000	1	–
HKD5,000,001 – HKD5,500,000	–	1
HKD5,500,001 – HKD6,000,000	–	2
	<u>3</u>	<u>3</u>

9 LOSS PER SHARE

The calculation of the basic and diluted loss per share during the Relevant Periods is based on the loss attributable to equity shareholders of the Company divided by the weighted average number of shares, calculated as follows:

	Years ended 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Loss of the year attributable to equity shareholders of the Company	<u>(748,964)</u>	<u>(781,594)</u>

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	Years ended 31 December	
	2021 ’000	2022 ’000
Issued ordinary shares	5,942	5,942
Effect of an issued warrant (Note 21(b))	1,167	1,167
Effect of share options exercised (Note 23(c))	–	563
Weighted average number of shares for the purposes of basic loss per share	<u>7,109</u>	<u>7,672</u>

The calculation of diluted loss per share for the years ended 31 December 2021 and 2022 has not included the potential effects of the deemed conversion of the preferred shares and share options issued by the Company, as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the years ended 31 December 2021 and 2022 are the same as basic loss per share.

10 PROPERTY, PLANT AND EQUIPMENT

	Laboratory equipment RMB’000	Office and other equipment RMB’000	Leasehold improvement RMB’000	Construction in progress RMB’000	Total RMB’000
Cost:					
At 1 January 2021	2,645	422	5,203	–	8,270
Additions	<u>2,314</u>	<u>809</u>	<u>–</u>	<u>807</u>	<u>3,930</u>
At 31 December 2021 and 1 January 2022	4,959	1,231	5,203	807	12,200
Additions	2,318	215	–	–	2,533
Exchange adjustments	–	7	–	–	7
Disposal	<u>–</u>	<u>(7)</u>	<u>–</u>	<u>–</u>	<u>(7)</u>
At 31 December 2022	<u>7,277</u>	<u>1,446</u>	<u>5,203</u>	<u>807</u>	<u>14,733</u>
Accumulated depreciation:					
At 1 January 2021	(943)	(188)	(2,750)	–	(3,881)
Charge for the year	<u>(636)</u>	<u>(183)</u>	<u>(1,732)</u>	<u>–</u>	<u>(2,551)</u>
At 31 December 2021 and 1 January 2022	(1,579)	(371)	(4,482)	–	(6,432)
Charge for the year	(1,166)	(332)	(721)	–	(2,219)
Impairment loss	–	–	–	(807)	(807)
Exchange adjustments	<u>–</u>	<u>(2)</u>	<u>–</u>	<u>–</u>	<u>(2)</u>
At 31 December 2022	<u>(2,745)</u>	<u>(705)</u>	<u>(5,203)</u>	<u>(807)</u>	<u>(9,460)</u>
Net book value:					
At 31 December 2021	<u>3,380</u>	<u>860</u>	<u>721</u>	<u>807</u>	<u>5,768</u>
At 31 December 2022	<u>4,532</u>	<u>741</u>	<u>–</u>	<u>–</u>	<u>5,273</u>

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11 INTANGIBLE ASSETS

The Group	In-licensed rights RMB’000	Software RMB’000	Total RMB’000
Cost:			
At 1 January 2021	111,204	–	111,204
Additions	–	1,804	1,804
Exchange adjustments	(2,543)	–	(2,543)
	<u>108,661</u>	<u>1,804</u>	<u>110,465</u>
At 31 December 2021 and 1 January 2022	108,661	1,804	110,465
Additions	–	4,349	4,349
Exchange adjustments	10,037	–	10,037
	<u>118,698</u>	<u>6,153</u>	<u>124,851</u>
At 31 December 2022	----- 118,698	----- 6,153	----- 124,851
Accumulated amortisation:			
1 January 2021	–	–	–
Charge for the year	–	(150)	(150)
	<u>–</u>	<u>(150)</u>	<u>(150)</u>
At 31 December 2021 and 1 January 2022	–	(150)	(150)
Charge for the year	–	(1,070)	(1,070)
	<u>–</u>	<u>(1,070)</u>	<u>(1,070)</u>
At 31 December 2022	----- –	----- (1,220)	----- (1,220)
Net book value:			
At 31 December 2021	<u>108,661</u>	<u>1,654</u>	<u>110,315</u>
At 31 December 2022	<u>118,698</u>	<u>4,933</u>	<u>123,631</u>
The Company		In-licensed rights RMB’000	
Cost:			
At 1 January 2021		111,204	
Exchange adjustments		(2,543)	
		<u>108,661</u>	
At 31 December 2021 and 1 January 2022		108,661	
Exchange adjustments		10,037	
		<u>118,698</u>	
At 31 December 2022		----- 118,698	
Accumulated amortisation:			
At 31 December 2021 and 31 December 2022		----- –	
Net book value:			
At 31 December 2021		<u>108,661</u>	
At 31 December 2022		<u>118,698</u>	

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(a) In-licensed rights

The balance of in-licensed rights represents payments made to acquire development and commercialization rights of drug products from third parties and are not available for commercial use. Due to the inherent uncertainties in the research and development processes, these assets are particularly at risk of impairment if the project is not expected to result in a commercialised product. Key terms of these licenses are set out below:

(i) LAE001

On 30 June 2017, the Group entered into a license agreement with Novartis Pharma AG (“Novartis”), pursuant to which Novartis granted the Group an exclusive license to develop, manufacture and commercialise the licensed product LAE001 world widely.

Under the terms of the agreement, the Group made an one-time and non-refundable upfront payment of USD1 million (equivalent to RMB6.6 million) and granted 776,437 ordinary shares of the Company to Novartis. The Group capitalised a total amount of USD1.8 million (equivalent to RMB12.2 million) which was equal to the cash payment and the fair value of the shares as at the grant date. The fair value of shares as at the grant date was determined by an independent qualified professional valuer. The Group also agreed to make regulatory milestone payment, as well as royalty payment on net sales to Novartis.

(ii) LAE002 & LAE003

On 9 May 2018, the Group entered into a license agreement with Novartis, pursuant to which Novartis granted the Group an exclusive license to develop, manufacture and commercialise the licensed products LAE002 and LAE003 world widely.

Under the terms of the agreement, the Group made an one-time and non-refundable upfront payment of USD5 million (equivalent to RMB31.9 million) and granted 165,200 ordinary shares of the Company to Novartis. The Group capitalised a total amount of USD5.2 million (equivalent to RMB33.5 million) which was equal to the cash payment and the fair value of the shares as at the grant date. The fair value of shares as at the grant date was determined by an independent qualified professional valuer. The Group also agreed to make regulatory milestone payments, sales milestone payment, as well as royalty payment on net sales to Novartis.

(iii) LAE005

On 4 February 2020, the Group entered into a license agreement with Novartis, pursuant to which Novartis granted the Group an exclusive license to develop, manufacture and commercialise the products LAE005 world widely.

Under the terms of the agreement, the Group made an one-time and non-refundable upfront payment of USD10 million (equivalent to RMB69.4 million) to Novartis and capitalised such payment. The Group also agreed to make regulatory milestone payments, sales milestone payment, as well as royalty payment on net sales to Novartis.

(iv) Impairment test

Intangible assets not yet ready for commercial use are tested annually based on the recoverable amount of the cash-generating unit (“CGU”) to which the intangible asset is related. The appropriate CGU is at the product level. The annual impairment test was performed for each drug by engaging an independent appraiser to estimate fair value less costs of disposal as the recoverable amount of each drug. The fair value is based on the multi-period excessive earning method and the Group estimated the forecast period till year 2035 for each drug based on the timing of clinical development and regulatory approval, commercial ramp up to reach expected peak revenue potential, and the length of exclusivity for each product. The estimated revenue of each drug is based on management’s expectations of timing of commercialization. The costs and operating expenses are estimated as a percentage over the revenue forecast period based on the current margin levels of comparable companies with adjustments made to reflect the expected future price changes. The discount rates used are post-tax and reflect the general business and market risk of the Group. The discount rates are derived from capital asset pricing model by taking applicable market data into account, such as risk free rate, market premium, beta, company specific risk and size premium, etc. After considering all the inputs, the discount rates derived at each reporting date were 18% during the Relevant Periods.

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The key assumptions used for recoverable amount calculations as at 31 December 2021 and 2022 are as follows:

	<u>As at 31 December</u>	
	2021	2022
<i>LAE001</i>		
Discount rate	18%	18%
Revenue growth rate	-14% to 373%	-14% to 379%
Recoverable amount of CGU (in RMB million)	501.5	573.6
<i>LAE002 & LAE003</i>		
Discount rate	18%	18%
Revenue growth rate	-7% to 486%	-7% to 456%
Recoverable amount of CGU (in RMB million)	1,035.9	1,252.1
<i>LAE005</i>		
Discount rate	18%	18%
Revenue growth rate	-18% to 24%	-18% to 24%
Recoverable amount of CGU (in RMB million)	221.1	252.4

Based on the result of the above assessment, there were no impairment for the intangible assets as at 31 December 2021 and 2022.

Impairment test – sensitivity

The Group has performed sensitivity tests by increasing 1% of the discount rate or decreasing 1% of the revenue growth rate, which are the key assumptions for determining the recoverable amount of the intangible asset, with all other variables held constant. The impacts on the amount by which the intangible asset’s recoverable amount above its carrying amount (headroom) are as below:

	<u>As at 31 December</u>	
	2021	2022
<i>LAE001</i>		
Carrying amount	11.5	12.1
Headroom	490.0	561.5
Impact by increasing discount rate	(41.7)	(57.3)
Impact by decreasing revenue growth rate	(25.6)	(38.1)
<i>LAE002 & LAE003</i>		
Carrying amount	33.4	36.9
Headroom	1,002.5	1,215.2
Impact by increasing discount rate	(86.6)	(118.6)
Impact by decreasing revenue growth rate	(60.4)	(89.8)
<i>LAE005</i>		
Carrying amount	63.8	69.7
Headroom	157.3	182.7
Impact by increasing discount rate	(18.0)	(21.1)
Impact by decreasing revenue growth rate	(8.7)	(13.8)

Considering there was still sufficient headroom based on the assessment, management believes that a reasonably possible change in any of the key assumptions on which management has based its determination of each intangible asset’s recoverable amount would not cause its carrying amount to exceed its recoverable amount.

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12 RIGHT-OF-USE ASSETS

The Group has obtained the right to use certain office buildings through tenancy agreements during the Relevant Periods. The leases typically run for an initial period from 3-10 years. Some leases include an option to renew the lease when all terms are renegotiated. None of the leases includes variable lease payments. The analysis of the net book value of right-of-use assets by class of underlying asset is as follows:

	Office Building <i>RMB’000</i>
At 1 January 2021	16,564
Additions	10,417
Charge for the year	(3,070)
	<hr/>
At 31 December 2021 and 1 January 2022	23,911
Additions	
Charge for the year	(3,299)
Termination of leases	(12,366)
	<hr/>
At 31 December 2022	<u>8,246</u>

The analysis of expense items in relation to leases recognised in profit or loss is as follows:

	Years ended 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Depreciation charge of right-of-use assets by class of underlying asset – properties leased for own use	3,070	3,299
Interest on lease liabilities (<i>Note 5(a)</i>)	893	1,216
Expense relating to short-term leases	1,292	2,466
COVID-19-related rent concessions	–	(950)

The total cash outflow for leases and the maturity analysis of lease liabilities are set out in Note 16(d) and Note 19, respectively.

13 INVESTMENTS IN SUBSIDIARIES

The carrying amount of interest in subsidiaries is listed below:

	As at 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Unlisted, at cost		
Laekna LLC	3,236	7,059
Laekna HK	21,518	773,470
	<hr/>	<hr/>
	<u>24,754</u>	<u>780,529</u>

Details of the subsidiaries are set forth in Note 1.

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14 OTHER NON-CURRENT ASSETS

	As at 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Value-add tax recoverable	4,961	3,251
Prepayments for equipment	3,660	4,110
Long-term rental deposits	1,236	615
Others	97	107
	<u>9,954</u>	<u>8,083</u>

As at 31 December 2021 and 2022, value-added tax recoverable amounting to RMB4,961,000 and RMB3,251,000 respectively were recognised as other non-current assets as they are expected to be deducted from future value-added tax payables arising on the Group’s revenue which are not expected to be generated within the next 12 months from the end of each of the reporting period.

15 PREPAYMENTS AND OTHER RECEIVABLES

The Group

	As at 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Current:		
Prepayments to suppliers	11,336	4,267
Deferred [REDACTED] expenses	[REDACTED]	[REDACTED]
Other debtors and deposits	1,149	1,514
	<u>12,485</u>	<u>11,561</u>

The Company

	As at 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Current:		
Prepayments to suppliers	35	202
Deferred [REDACTED] expenses	[REDACTED]	[REDACTED]
	<u>35</u>	<u>5,352</u>
Non-current:		
Amounts due from subsidiaries	424,502	41,969

All of the current prepayments and other receivables are expected to be recovered or recognised as expense within one year.

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16 CASH AND CASH EQUIVALENTS AND OTHER CASH FLOW INFORMATION

(a) Cash and cash equivalents comprise:

<i>The Group</i>	As at 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Cash at banks	296,412	267,333
Deposits with banks	–	55,737
	<u>296,412</u>	<u>323,070</u>

<i>The Company</i>	As at 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Cash at banks	<u>234,425</u>	<u>248,985</u>

As at 31 December 2021 and 2022, cash and cash equivalents of the Group held in banks and financial institutions in the PRC amounted to RMB60,271,000 and RMB63,180,000, respectively. The remittance of funds out of the PRC is subject to the relevant rules and regulations of foreign exchange control promulgated by the PRC government.

(b) Reconciliation of loss before taxation to cash used in operations:

	<i>Note</i>	Years ended 31 December	
		2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Loss before taxation		(748,964)	(781,594)
Adjustments for:			
Depreciation of property, plant and equipment	10	2,551	2,219
Impairment loss on property, plant and equipment	10	–	807
Amortisation of intangible assets	11	150	1,070
Amortisation of other non-current assets		55	79
Depreciation of right-of-use assets	12	3,070	3,299
Equity settled share-based payments	22	12,027	26,461
Realised gain on wealth management products	4	–	(42)
Interest income from bank deposits	4	(409)	(823)
Finance costs	5(a)	922	1,389
Net loss on disposal of property, plant and equipment		–	7
Net gain on termination of leases	4	–	(3,653)
COVID-19-related rent concessions	12	–	(950)
Fair value changes on financial instruments issued to investors	21	<u>522,432</u>	<u>387,056</u>
Operating loss before changes in working capital		(208,166)	(364,675)
Changes in working capital:			
(Increase)/decrease in operating receivables		(11,762)	2,544
Increase in operating payables		<u>21,921</u>	<u>55,848</u>
Cash used in operations		<u>(198,007)</u>	<u>(306,283)</u>

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(c) Reconciliation of liabilities arising from financing activities

The table below details changes in the Group’s liabilities from financing activities, including both cash and non-cash changes. Liabilities arising from financing activities are liabilities for which cash flows were, or future cash flows will be, classified in the Group’s consolidated cash flow statements as cash flows from financing activities.

	Bank loans	Lease	Financial	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>instruments</i>	<i>RMB’000</i>
	<i>(Note 17)</i>	<i>(Note 19)</i>	<i>issued to</i>	
			<i>investors</i>	
			<i>RMB’000</i>	
			<i>(Note 21)</i>	
At 1 January 2021	–	16,628	595,708	612,336
Changes from financing cash flows:				
Proceeds from a bank loan	2,000	–	–	2,000
Payment for capital element of lease liabilities	–	(1,202)	–	(1,202)
Payment for interest element of lease liabilities	–	(893)	–	(893)
Proceeds from issuance of preferred shares	–	–	412,538	412,538
Interest paid	(29)	–	–	(29)
Total changes from financing cash flows	1,971	(2,095)	412,538	412,414
Exchange adjustments	–	–	(30,138)	(30,138)
Other changes:				
Interest expenses <i>(Note 5(a))</i>	29	893	–	922
Increase in lease liabilities from entering into new leases during the year	–	10,417	–	10,417
Fair value changes on financial instruments issued to investors	–	–	522,432	522,432
At 31 December 2021 and 1 January 2022	2,000	25,843	1,500,540	1,528,383
Changes from financing cash flows:				
Proceeds from bank loans	19,650	–	–	19,650
Repayment of a bank loan	(2,000)	–	–	(2,000)
Payment for capital element of lease liabilities	–	(511)	–	(511)
Payment for interest element of lease liabilities	–	(439)	–	(439)
Proceeds from the issuance of preferred shares	–	–	301,028	301,028
Interest paid	(173)	–	–	(173)
Total changes from financing cash flows	17,477	(950)	301,028	317,555
Exchange adjustments	–	–	170,422	170,422

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	Bank loans <i>RMB’000</i> <i>(Note 17)</i>	Lease liabilities <i>RMB’000</i> <i>(Note 19)</i>	Financial instruments issued to investors <i>RMB’000</i> <i>(Note 21)</i>	Total <i>RMB’000</i>
Other changes:				
Bank loans arising from supplier finance arrangements <i>(Note 17)</i>	132	–	–	132
COVID-19-related rent concessions <i>(Note 12)</i>	–	(950)	–	(950)
Interest expenses <i>(Note 5(a))</i>	173	1,216	–	1,389
Fair value changes on financial instruments issued to investors	–	–	387,056	387,056
Termination of leases	–	(16,640)	–	(16,640)
Shares issued upon exercise of the warrant	–	–	(81,765)	(81,765)
	<u>19,782</u>	<u>8,519</u>	<u>2,277,281</u>	<u>2,305,582</u>
At 31 December 2022	19,782	8,519	2,277,281	2,305,582

(d) Total cash outflow for leases

	Years ended 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Within operating cash flows	1,421	2,841
Within financing cash flows	2,095	950
	<u>3,516</u>	<u>3,791</u>

17 BANK LOANS

	As at 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Unsecured bank loans due within 1 year	2,000	19,782

During the year ended 31 December 2021, the Group entered into a loan agreement with China Merchants Bank, with the principal amount of RMB2,000,000 and bearing an interest rate of 4.46% per annum. On 5 January 2022, the bank loan was fully repaid.

During the year ended 31 December 2022, the Group further entered into loan agreements with China Merchants Bank, with the principal amount of RMB19,650,000 and bearing an interest rate of 4.35% per annum. The Group also entered into supplier finance arrangement with China Merchants Bank, under which the Group obtained credit in respect of the amounts due to certain suppliers. Under this arrangement, the bank pays suppliers the amounts owned by the Group on the original due dates, and then the Group settles the bank 6 months later than the original due dates with the suppliers, with an interest rate of 2.75% per annum. In the consolidated statements of financial position, the Group has presented payables to the bank under this arrangement as “Bank loans”, having compared the nature and function of such liabilities with trade payables to suppliers. In the consolidated statements of cash flows, payments to the banks are included within financing cash flows based on the nature of this arrangement, and payments to the suppliers by the bank amounting to RMB132,000 (2021: Nil) are non-cash transactions.

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18 Other payables

<i>The Group</i>	As at 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Payroll payables	5,883	14,700
Accrued research and development expenses	29,979	51,595
Other payables and accrued charges	2,269	9,573
	<u>38,131</u>	<u>75,868</u>
<i>The Company</i>	As at 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Accrued research and development expenses	291	234
Other payables and accrued charges	101	3,587
	<u>392</u>	<u>3,821</u>

All of the other payables are expected to be settled within one year or repayable on demand.

19 LEASE LIABILITIES

The following table shows the remaining contractual maturities of the Group’s lease liabilities at the end of each of the Relevant Periods.

	As at 31 December 2021		As at 31 December 2022	
	Present value of the minimum lease payments <i>RMB’000</i>	Total minimum lease payments <i>RMB’000</i>	Present value of the minimum lease payments <i>RMB’000</i>	Total minimum lease payments <i>RMB’000</i>
Within 1 year	1,859	1,900	1,859	1,900
After 1 year but within 2 years	3,847	4,134	1,828	1,961
After 2 year but within 5 years	11,329	13,406	4,832	5,659
After 5 years	8,808	12,153	–	–
	<u>23,984</u>	<u>29,693</u>	<u>6,660</u>	<u>7,620</u>
	<u>25,843</u>	<u>31,593</u>	<u>8,519</u>	<u>9,520</u>
Less: total future interest expenses		<u>(5,750)</u>		<u>(1,001)</u>
Present value of lease liabilities		<u>25,843</u>		<u>8,519</u>

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20 DEFERRED INCOME

	As at 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
At the beginning of the year	–	3,500
Government grants received	3,500	–
At the end of the year	<u>3,500</u>	<u>3,500</u>

21 FINANCIAL INSTRUMENTS ISSUED TO INVESTORS

The Group and the Company

	As at 31 December	
	2021 <i>RMB’000</i>	2022 <i>RMB’000</i>
Preferred shares	1,402,111	2,277,281
Warrant	98,429	–
	<u>1,500,540</u>	<u>2,277,281</u>

(a) Preferred shares

On 11 May 2018, the Company issued 3,986,840 series A preferred shares with a par value of US\$0.0001 each (“Series A Preferred Shares”) to a Series A investor for a cash consideration of USD12,500,000.

On 8 November 2019, the Company issued 1,691,367 series Seed preferred shares with a par value of US\$0.0001 each (“Series Seed Preferred Shares”) to a Series Seed investor for a cash consideration of USD4,787,000.

On 16 August 2019 and 21 February 2020, the Company issued 4,542,984 series B preferred shares with a par value of US\$0.0001 each (“Series B Preferred Shares”) to Series B investors for a total cash consideration of USD27,500,000.

On 28 October 2020 and 30 March 2021, the Company issued 6,858,071 series C preferred shares with a par value of US\$0.0001 each (“Series C Preferred Shares”) to Series C investors for a total cash consideration of USD61,000,000.

On 4 October 2021, 19 November 2021 and 28 April 2022, the Company issued 3,866,186 series D preferred shares with a par value of US\$0.0001 each (“Series D Preferred Shares”) to Series D investors for a total cash consideration of USD61,000,000.

The key terms of Series Seed Preferred Shares, Series A Preferred Shares, Series B Preferred Shares, Series C Preferred Shares and Series D Preferred Shares (collectively, the “Preferred Shares”) are summarised as follows:

Dividends

The Preferred Shares, except for the Series Seed Preferred Shares, shall be entitled to receive non-cumulative dividends at the rate of 8% of the original issue price per annum if declared by the Board.

Redemption rights

The Preferred Shares, except for the Series Seed Preferred Shares and the Series A Preferred Shares, shall be redeemable by the Company if a qualified [REDACTED] (“[REDACTED]”) has not occurred on or prior to 30 June 2025, at a price equal to the applicable issue price per share plus a simple interest of 8% per annum and minus all paid dividends thereon.

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For the Series A Preferred Shares, two third or any lesser portion of the shares shall be redeemable by the Company after 11 May 2024; any remaining shares shall be redeemable after 11 May 2025. The redemption price will be original issue price plus a simple interest of 8% per annum and all declared but unpaid dividends thereon.

Conversion rights

The Preferred Shares are convertible into such number of fully paid ordinary shares at any time after the date of issuance of such shares, or are automatically converted upon the closing of a qualified [REDACTED]. The initial conversion ratio is 1:1, and the conversion ratio is subject to adjustments (including but not limited to dividends, share splits and combinations, capital reorganization or reclassification).

Liquidation preference

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, all assets and funds of the Company legally available for distribution shall be distributed to the shareholders of the Company in the sequence as follows: Series D Preferred Shares, Series C Preferred Shares, Series B Preferred Shares, Series A Preferred Shares, Series Seeds Preferred Shares and ordinary shares.

In the event of Trade Sale (as defined below) of the Company, the Trade Sale shall be deemed to be a liquidation, dissolution or winding up of the Company, and any proceeds resulting from the Trade Sale shall be distributed in accordance with the terms stated above.

“Trade Sale” refer an event involving (i) any merger, consolidation, amalgamation, scheme of arrangement or share sale involving the Company with or into any other person or other reorganisation in which the shareholders of the Company immediately prior to such merge, consolidation, amalgamation, scheme of arrangement or reorganisation own less than 50% of the Company’s voting power in the aggregate immediately after such event; (ii) a sale, transfer, lease or other disposition of all or substantially all of the assets of the Group or any series of related transactions resulting in such sale, transfer, lease or other disposition of all or substantially all of the assets of the Group; or (iii) the exclusive licensing of all or substantially all of the Group’s intellectual properties to a third party.

Presentation and classification

In accordance with the Group’s accounting policy set out in Note 2(1)(i), the Preferred Shares are initially recognised at fair value on the date of issuance and are subsequently re-measured to their fair value at the end of each reporting period. The Company has engaged an independent qualified professional valuer to determine the fair value of the Preferred Shares, and the movements during the Relevant Periods are set out below:

The Group and the Company	Preferred Shares <i>RMB’000</i>
As at 1 January 2021	543,547
Issuance of Preferred Shares	412,538
Fair value changes	474,394
Exchange adjustments	(28,368)
	<hr/>
As at 31 December 2021 and 1 January 2022	1,402,111
Issuance of Preferred Shares	326,006
Fair value changes	378,308
Exchange adjustments	170,856
	<hr/>
As at 31 December 2022	<u><u>2,277,281</u></u>

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ACCOUNTANTS’ REPORT

(b) Warrant

On 31 January 2019, the Company entered into a warrant agreement (the “Warrant Agreement”) with an individual investor pursuant to which the Company issued a warrant to the investor for a cash consideration of RMB11,728,000. Pursuant to the Warrant Agreement, the holder may exercise the warrant to purchase 1,166,525 ordinary shares and 338,273 Series Seed Preferred Shares for nil consideration on or before the 90th day after the board of the Company approves to initiate an [REDACTED] of the Company’s shares.

On 31 March 2022, the warrant was exercised. Accordingly, the Company issued 1,166,525 ordinary shares and 338,273 Series Seed Preferred Shares to the investor.

In accordance with the Group’s accounting policy set out in Note 2(1)(ii), the warrant is initially recognised at fair value on the date of issuance and is subsequently re-measured to the fair value at the end of each reporting period. The Company has engaged an independent qualified professional valuer to determine the fair value of the warrant, and the movements during the Relevant Periods are set out below:

The Group and the Company	Warrant RMB’000
As at 1 January 2021	52,161
Fair value changes	48,038
Exchange adjustments	(1,770)
	<hr/>
As at 31 December 2021 and 1 January 2022	98,429
Fair value changes	8,748
Exchange adjustments	(434)
Exercise of the Warrant	(106,743)
	<hr/>
As at 31 December 2022	<hr/> <hr/> –

22 EQUITY SETTLED SHARE-BASED PAYMENT

The Company adopted an employee share option scheme (“[REDACTED] Share Option Scheme”) on 11 April 2018 (which was subsequently amended on 30 October 2019, 20 April 2021 and 31 March 2022), pursuant to which, 4,245,352 ordinary shares of the Company are authorised for issuance of share options to employees, directors, and advisors of the Group. Each option gives the holder the right to subscribe for one ordinary share of the Company.

(a) The terms and conditions of the grants are as follows:

	Number of instruments	Contractual life of options
Options granted to directors	853,275	10 years
Options granted to employees	2,075,800	10 years
Options granted to advisors	25,250	10 years
	<hr/>	
Total share options granted	<hr/> <hr/> 2,954,325	

Unless otherwise approved by the Board of Directors, the Company adopted three vesting conditions for the above share options granted:

- (i) 20% of the share options are expected to vest after twelve months of the grant date, and the remaining are expected to vest ratably over the following sixteen quarters;
- (ii) 40% of the share options are expected to vest after twenty-four months of the grant date, and the remaining are expected to vest ratably over the following twelve quarters; or
- (iii) 100% of the share options are expected to vest upon the grant date.

APPENDIX I

ACCOUNTANTS’ REPORT

(b) The movement of the number of share options are as follows:

	Years ended 31 December	
	2021 '000	2022 '000
Outstanding at the beginning of the year	2,270	3,376
Granted during the year	1,410	433
Exercised during the year	–	(833)
Forfeited during the year	(304)	(22)
	<u>3,376</u>	<u>2,954</u>
Outstanding at the end of the year		
	<u>–</u>	<u>–</u>
Exercisable at the end of the year		

All the share options granted are exercisable upon vesting and after the occurrence of an [REDACTED] of the Company’s shares, unless otherwise approved by the Board of Directors, and will expire on or before the latter of (1) the third anniversary after the aforementioned occurrence of [REDACTED], and (2) the tenth anniversary after the granting date. As at 31 December 2021 and 2022, the weighted average remaining contractual life for the share options granted was 8.0 and 7.5 years respectively.

(c) Key assumptions of share options

	Years ended 31 December	
	2021	2022
Expected volatility	41.03%~42.03%	43.00% ~ 43.47%
Expected dividends yield	0%	0%
Risk-free interest rate	0.94%~1.66%	3.03% ~ 3.98%

The fair value of services received in return for share options granted is measured by reference to the fair value of share options granted. The estimate of the fair value of the share options granted is measured based on a binomial lattice model. The contractual life of the share option is used as an input into this model. Expectations of early exercise are incorporated into the binomial lattice model.

The expected volatility is based on the historic volatility (calculated based on the weighted average remaining life of the share options), adjusted for any expected changes to future volatility based on publicly available information. Expected dividends are based on historical dividends. Changes in the subjective input assumptions could materially affect the fair value estimate.

23 CAPITAL, RESERVES AND DIVIDENDS

(a) Movements in components of equity

The reconciliation between the opening and closing balances of each component of the Group’s consolidated equity is set out in the consolidated statements of changes in equity. Details of the changes in the Company’s individual components of equity between the beginning and the end of each year are set out below:

Note	Share capital RMB'000	Share premium RMB'000	Capital reserve RMB'000	Exchange reserve RMB'000	Accumulated losses RMB'000	Total deficit RMB'000
	4	–	20,908	11,547	(229,049)	(196,590)
Balance at 1 January 2021						
Changes in equity for 2021:						
Total comprehensive income for the year	–	–	–	10,781	(534,773)	(523,992)
Equity settled share-based payments	22	–	12,027	–	–	12,027

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ACCOUNTANTS’ REPORT

	<i>Note</i>	Share capital <i>RMB’000</i>	Share premium <i>RMB’000</i>	Capital reserve <i>RMB’000</i>	Exchange reserve <i>RMB’000</i>	Accumulated losses <i>RMB’000</i>	Total deficit <i>RMB’000</i>
Balance at 31 December 2021 and 1 January 2022		4	–	32,935	22,328	(763,822)	(708,555)
Changes in equity for 2022:							
Total comprehensive income for the year		–	–	–	(71,656)	(413,638)	(485,294)
Equity settled share-based payments	22	–	–	26,461	–	–	26,461
Shares issued upon exercise of the warrant		1	81,764	–	–	–	81,765
Shares issued under share option scheme		–*	11,443	(11,389)	–	–	54
Balance at 31 December 2022		<u>5</u>	<u>93,207</u>	<u>48,007</u>	<u>(49,328)</u>	<u>(1,177,460)</u>	<u>(1,085,569)</u>

* The balance represents an amount less than RMB1,000.

(b) Dividends

No dividends were paid or declared by the Company or any of its subsidiaries during the Relevant Periods.

(c) Share capital

The Company was incorporated in the Cayman Islands with authorised share capital of USD50,000 divided into 500,000,000 shares with par value of USD0.0001 each.

As at 31 December 2022 the authorised share capital of the Company was USD50,000 divided into (i) 472,582,465 ordinary shares with par value of USD0.0001 each and (ii) 27,417,535 preferred shares with par value of USD0.0001 each.

	No. of shares <i>’000</i>	Nominal value of shares <i>RMB’000</i>
Ordinary shares, issued and fully paid:		
At 1 January 2021 and 31 December 2021	5,942	4
Shares issued under share option scheme (i)	833	–*
Shares issued upon exercise of the warrant (ii)	1,167	1
At 31 December 2022	<u>7,942</u>	<u>5</u>

* The balance represents an amount less than RMB1,000.

(i) Approved by the Board of Directors on 20 January 2022, 833,475 vested share options are early exercised before the occurrence of the [REDACTED]. Accordingly, on 28 April 2022, the Company issued 833,475 ordinary shares with a par value of US\$0.0001 to the relevant employees.

(ii) On 31 March 2022, the warrant was exercised. Accordingly, the Company issued 1,166,525 ordinary shares with a par value of US\$0.0001 to the holder of the warrant.

(d) Nature and purpose of reserves

(i) Share premium

The application of the share premium account is governed by the Companies Act of the Cayman Islands.

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ACCOUNTANTS’ REPORT

(ii) Capital reserve

The capital reserve primarily comprises the fair value of the actual or estimated number of unexercised share options granted to directors, employees and advisors of the Group in accordance with the accounting policy adopted for share-based payments in Note 2(n)(ii).

(iii) Exchange reserve

The exchange reserve comprises all foreign exchange differences arising from the translation of the financial statements of the Company and certain subsidiaries within the Group. The reserve is dealt with in accordance with the accounting policies set out in Note 2(r).

(e) Capital management

The Group’s primary objectives when managing capital are to safeguard the Group’s ability to continue as a going concern, so that it can continue to provide returns for shareholders and benefits for other stakeholders.

The Group actively and regularly reviews and manages its capital structure to maintaining a balance between the higher shareholders returns that might be possible with higher levels of borrowings and the advantages and security afforded by a sound capital position, and makes adjustments to the capital structure in light of changes in economic conditions.

The Group monitors its capital structure on the basis of an adjusted net debt-to-capital ratio. For this purpose, adjusted net debt is defined as total debt (which includes bank loans and lease liabilities but excludes financial instruments issued to investors) less cash and cash equivalents. Adjusted capital comprises all components of equity and financial instruments issued to investors.

The Group’s adjusted net debt-to-capital ratio as at 31 December 2021 and 2022 are as follows:

	Note	As at 31 December	
		2021 RMB’000	2022 RMB’000
Current liabilities:			
– Bank loans	17	2,000	19,782
– Lease liabilities	19	1,859	1,859
		3,859	21,641
Non-current liabilities:			
– Lease liabilities	19	23,984	6,660
Total debt		27,843	28,301
Less: Cash and cash equivalents	16	(296,412)	(323,070)
Adjusted net debt		(268,569)	(294,769)
Total deficit		(1,111,169)	(1,905,086)
Add: Financial instruments issued to investors	21	1,500,540	2,277,281
Adjusted capital		389,371	372,195
Adjusted net debt-to-capital ratio		N/A	N/A

Neither the Company nor any of its subsidiaries are subject to externally imposed capital requirements.

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ACCOUNTANTS’ REPORT

24 FINANCIAL RISK MANAGEMENT AND FAIR VALUES OF FINANCIAL INSTRUMENTS

Exposure to credit, liquidity, interest rate and currency risks arises in the normal course of the Group’s business. The Group’s exposures to these risks and the financial risk management policies and practices used by the Group to manage these risks are described below.

(a) Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in a financial loss to the Group. The Group’s credit risk is primarily attributable to other receivables. The Group’s exposure to credit risk arising from cash and cash equivalents is limited because the counterparties are state-owned banks or reputable banks, which the Group considered to have low credit risks. Management has a credit policy in place and the exposure to credit risk is monitored on an ongoing basis.

Management has assessed that during the Relevant Periods, other receivables have not had a significant increase in credit risk since initial recognition. Thus, a 12-month expected credit loss approach that results from possible default event within 12 months of each reporting date is adopted by management. The management of the Company expect the occurrence of losses from non-performance by counterparties of other receivables to be remote and a loss allowance provision for other receivables to be immaterial.

(b) Liquidity risk

The Group’s policy is to regularly monitor its liquidity requirements and its compliance with lending covenants, to ensure that it maintains sufficient reserves of cash and adequate committed lines of funding from major financial institutions to meet its liquidity requirements in the short and longer term.

The following tables show the remaining contractual maturities at the end of each reporting period of the Group’s non-derivative financial liabilities, which are based on contractual undiscounted cash flows (including interest payments computed using contractual rates or, if floating, based on rates current at the end of each reporting period) and the earliest date the Group can be required to pay:

As at 31 December 2021

	Contractual undiscounted cash outflow					Carrying amount
	Within 1 year or on demand	More than 1 year but less than 2 years	More than 2 years but less than 5 years	More than 5 years	Total	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Bank loans	2,032	–	–	–	2,032	2,000
Other payables	38,131	–	–	–	38,131	38,131
Lease liabilities	1,900	4,134	13,406	12,153	31,593	25,843
Preferred shares	–	37,197	1,007,292	–	1,044,489	1,402,111
	<u>42,063</u>	<u>41,331</u>	<u>1,020,698</u>	<u>12,153</u>	<u>1,116,245</u>	<u>1,468,085</u>

As at 31 December 2022

	Contractual undiscounted cash outflow					Carrying amount
	Within 1 year or on demand	More than 1 year but less than 2 years	More than 2 years but less than 5 years	More than 5 years	Total	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Bank loans	19,975	–	–	–	19,975	19,782
Other payables	75,868	–	–	–	75,868	75,868
Lease liabilities	1,900	1,961	5,659	–	9,520	8,519
Preferred shares	–	85,922	1,495,124	–	1,581,046	2,277,281
	<u>97,743</u>	<u>87,883</u>	<u>1,500,783</u>	<u>–</u>	<u>1,686,409</u>	<u>2,381,450</u>

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ACCOUNTANTS’ REPORT

(c) Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates.

The Group is primarily exposed to fair value interest rate risk in relation to lease liabilities, bank loans and cash flow risk in relation to variable-rate bank balances. The Group currently does not have an interest rate hedging policy to mitigate interest rate risk; nevertheless, the management monitors interest rate exposure and will consider hedging significant interest rate risk should the need arise.

The Company considers that the exposure of cash flow interest rate risk arising from variable-rate bank balances is insignificant because the current market interest rates are relatively low and stable.

(d) Currency risk

The Group is exposed to currency risk primarily through different functional currencies in different subsidiaries which give rise to cash and bank balances and other payables that are denominated in a currency other than the functional currency of the operations to which the transactions relate. The currency giving rise to this risk is primarily USD.

(i) Exposure to currency risk

The following table details the Group’s exposure as at 31 December 2021 and 2022 to currency risk arising from the recognised assets or liabilities denominated in a currency other than the functional currency of the entity to which they relate. For presentation purpose, the amounts of the exposure are shown in RMB translated using the spot rate of the end of each reporting period. Differences resulting from the translation of the financial statements of the Group’s subsidiaries with functional currency other than RMB into the Group’s presentation currency are excluded.

	As at 31 December	
	2021	2022
	<i>USD</i> <i>RMB’000</i>	<i>USD</i> <i>RMB’000</i>
Cash and cash equivalents	18,183	527
Other payables	(23)	(7)
Overall net exposure	<u>18,160</u>	<u>520</u>

(ii) Sensitivity analysis

The following table indicates the instantaneous change in the Group’s loss after tax (and accumulated losses) that would arise if foreign exchange rates to which the Group has significant exposure at the end of each reporting period had changed at that date, assuming all other risk variables remained constant.

	As at 31 December 2021		As at 31 December 2022	
	Increase/ (decrease) in foreign exchange rates	Effect on loss after tax and accumulated losses	Increase/ (decrease) in foreign exchange rates	Effect on loss after tax and accumulated losses
	<i>%</i>	<i>RMB’000</i>	<i>%</i>	<i>RMB’000</i>
USD	10%	(1,816)	10%	(52)
	-10%	1,816	-10%	52

Results of the analysis as presented in the above table represent an aggregation of the instantaneous effects on each of the Group entities’ losses after tax and equity measured in the respective functional currencies, translated into RMB at the exchange rate ruling at the end of each reporting period for presentation purpose.

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ACCOUNTANTS’ REPORT

The sensitivity analysis assumes that the change in foreign exchange rates had been applied to re-measure those financial instruments held by the Group which expose the Group to foreign currency risk as at the end of each reporting period. The analysis is performed on the same basis during the Relevant Periods.

(e) Fair value measurement

(i) Financial assets and liabilities measured at fair value

Fair value hierarchy

The following table presents the fair value of the Group’s financial instruments measured at the end of each reporting period on a recurring basis, categorised into the three-level fair value hierarchy as defined in IFRS 13, *Fair value measurement*. The level into which a fair value measurement is classified is determined with reference to the observability and significance of the inputs used in the valuation technique as follows:

- Level 1 valuations: Fair value measured using only Level 1 inputs i.e. unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date;
- Level 2 valuations: Fair value measured using Level 2 inputs i.e. observable inputs which fail to meet Level 1, and not using significant unobservable inputs. Unobservable inputs are inputs for which market data are not available;
- Level 3 valuations: Fair value measured using significant unobservable inputs.

The Group has engaged an external valuer to perform valuations for the financial instruments, including but limited to warrant and preferred shares. A valuation report with analysis of changes in fair value measurement is prepared by the external valuer at each reporting date, and is reviewed and approved by the Group’s management.

	Fair value at 31-Dec 2021 RMB’000	Fair value measurements as at 31 December 2021 categorised into		
		Level 1 RMB’000	Level 2 RMB’000	Level 3 RMB’000
Recurring fair value measurement				
Financial instruments issued to investors				
– Preferred shares	1,402,111	–	–	1,402,111
– Warrant	98,429	–	–	98,429

	Fair value at 31-Dec 2022 RMB’000	Fair value measurements as at 31 December 2022 categorised into		
		Level 1 RMB’000	Level 2 RMB’000	Level 3 RMB’000
Recurring fair value measurement				
Financial instruments issued to investors				
– Preferred shares	2,277,281	–	–	2,277,281

During the Relevant Periods, there were no transfers between Level 1 and Level 2, or transfers into or out of Level 3. The Group’s policy is to recognise transfers between levels of fair value hierarchy as at the end of each reporting period in which they occur.

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ACCOUNTANTS’ REPORT

The preferred shares and warrant were valued by the directors of the Company with reference to valuation reports carried out by an independent qualified professional valuer which has appropriate qualifications and experience in valuation of similar instruments. The Company used the back-solve method and income approach to determine the underlying share value of the Company and performed an equity allocation based on a hybrid method of Binomial Option Pricing model (“OPM model”) and Probability Weighted Expected Return method (“PWERM method”) to arrive the fair value of the preferred shares and warrant as at the dates of issuance and at the end of each reporting period. Key valuation assumption used to determine the fair value of these financial instruments issued to investors as follows:

	As at 31 December	
	2021	2022
Risk-free interest rate	1.06%	4.32%
Volatility	40.50%	45.54%

As at 31 December 2021, increasing/decreasing expected volatility by 5% would decrease/increase the fair value of financial instruments by RMB986,000 and RMB331,000 respectively, and increasing/decreasing risk free rate by 1% would decrease/increase the fair value by RMB2,697,000 and RMB2,781,000 respectively.

As at 31 December 2022, increasing/decreasing expected volatility by 5% would decrease/increase the fair value of financial instruments by RMB149,000 and RMB594,000 respectively, and increasing/decreasing risk free rate by 1% would decrease/increase the fair value by RMB2,717,000 and RMB2,788,000 respectively.

(ii) *Fair values of financial assets and liabilities carried at other than fair value*

All financial instruments carried at amortised cost were not materially different from their fair values as at 31 December 2021 and 2022.

25 COMMITMENT

Commitments outstanding at the end of each of the reporting period not provided for in the Historical Financial Information were as follows:

	As at 31 December	
	2021	2022
Contracted for	11,173	10,723
Authorised but not contracted for	47,527	43,551
	<u>58,700</u>	<u>54,274</u>

26 MATERIAL RELATED PARTY TRANSACTIONS

(a) **Key management personnel remuneration**

Remuneration for key management personnel of the Group, including amounts paid to the Company’s directors as disclosed in Note 7 and certain of the highest paid employees as disclosed in Note 8, is as follows:

	Years ended 31 December	
	2021 RMB’000	2022 RMB’000
Salaries and other benefits	8,508	10,179
Discretionary bonuses	773	802
Equity-settled share-based payment expenses	7,883	10,159
	<u>17,164</u>	<u>21,140</u>

APPENDIX I

ACCOUNTANTS’ REPORT

(b) Other transactions with related parties

Except for the disclosure in Note 26(a), the Group did not enter into other material related party transactions during the Relevant Periods.

27 IMMEDIATE AND ULTIMATE CONTROLLING PARTY

At 31 December 2021 and 2022, the directors consider that the Group has no immediate and ultimate controlling party.

28 POSSIBLE IMPACT OF AMENDMENTS, NEW STANDARDS AND INTERPRETATIONS ISSUED BUT NOT YET EFFECTIVE FOR THE RELEVANT PERIODS

As at the date of this report, the IASB has issued a number of new or amended standards which are not yet effective for the Relevant Periods and which have not been adopted in the Historical Financial Information. These developments include the following which may be relevant to the Group.

	Effective for accounting periods beginning on or after
Amendments to IAS 1, <i>Presentation of financial statements: Classification of liabilities as current or non-current</i>	1 January 2023
Amendments to IAS 1, <i>Presentation of financial statements</i> and IFRS Practice Statement 2, <i>Making materiality judgements: Disclosure of accounting policies</i>	1 January 2023
Amendments to IAS 8, <i>Accounting policies, changes in accounting estimates and errors: Definition of accounting estimates</i>	1 January 2023
Amendments to IAS 12, <i>Income taxes: Deferred tax related to assets and liabilities arising from a single transaction</i>	1 January 2023
IFRS 17, <i>Insurance Contracts</i>	1 January 2023
Amendments to IFRS 10 and IAS 28, <i>Sale or Contribution of Assets between an Investor and its Associate or Joint venture</i>	No mandatory effective date yet determined

The Group is in the process of making an assessment of what the impact of these developments is expected to be in the period of initial application. So far it has concluded that the adoption of them is unlikely to have a significant impact on the Group’s results of operations and financial position.

29 SUBSEQUENT EVENTS

[•]

Subsequent financial statements

No audited financial statements have been prepared by the Company and any of its subsidiaries in respect of any period subsequent to 31 December 2022.

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX II

[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 constitution of the Company and certain aspects of the company laws of the Cayman Islands.

The Company was incorporated in the Cayman Islands as an exempted company with limited liability on July 29, 2016 under the Companies Act. The Company's constitutional documents consist of the Memorandum of Association and the Articles of Association.

1. MEMORANDUM OF ASSOCIATION

The Memorandum provides, *inter alia*, that the liability of the members of the Company is limited, that the objects for which the Company is established are unrestricted (and therefore include acting as an investment holding company) and that the Company shall have full power and authority to carry out any object not prohibited by the Companies Act or any other law of the Cayman Islands.

2. ARTICLES OF ASSOCIATION

The Articles were conditionally adopted on [●] and will become effective on the [REDACTED]. A summary of certain provisions of the Articles is set out below.

2.1 Shares

(a) Classes of Shares

The share capital of the Company consists of a single class of ordinary shares.

(b) Variation of Rights of Existing Shares or Classes of Shares

If at any time the share capital of the Company is divided into different classes of Shares, all or any of the rights attached to any class of Shares for the time being issued (unless otherwise provided by the terms of issue of the Shares of that class) may, whether or not the Company is being wound up, be varied with the consent in writing of the holders of at least three-fourths of the issued Shares of that class, or with the approval of a resolution passed by at least three-fourths of the votes cast by the holders of the Shares of that class present and voting in person or by proxy at a separate meeting of such holders. The provisions of the Articles relating to general meetings shall apply *mutatis mutandis* to every such separate meeting, except that the necessary quorum shall be two persons together holding (or, in the case of a member being a corporation, by its duly authorized representative), or representing by proxy, at least one-third of the issued Shares of that class. Every holder of Shares of the class shall be entitled on a poll to one vote for every such Share held by him, and any holder of Shares of the class present in person or by proxy may demand a poll.

APPENDIX III **SUMMARY OF THE CONSTITUTION OF**
OUR COMPANY AND CAYMAN COMPANIES ACT

For the purposes of a separate class meeting, the Board may treat two or more classes of Shares as forming one class of Shares if the Board considers that such classes of Shares would be affected in the same way by the proposals under consideration, but in any other case shall treat them as separate classes of Shares.

Any rights conferred upon the holders of Shares of any class shall not, unless otherwise expressly provided in the rights attaching to the terms of issue of the Shares of that class, be deemed to be varied by the creation or issue of further Shares ranking *pari passu* therewith.

(c) *Alteration of Capital*

The Company may by ordinary resolution:

- (i) increase its share capital by the creation of new Shares of such amount and with such rights, priorities and privileges attached to such Shares as it may determine;
- (ii) consolidate and divide all or any of its share capital into Shares of a larger amount than its existing Shares. On any consolidation of fully paid Shares and division into Shares of a larger amount, the Board may settle any difficulty which may arise as it thinks expedient and, in particular (but without prejudice to the generality of the foregoing), may as between the holders of Shares to be consolidated determine which particular Shares are to be consolidated into a consolidated Share, and if it shall happen that any person shall become entitled to fractions of a consolidated Share or Shares, such fractions may be sold by some person appointed by the Board for that purpose and the person so appointed may transfer the Shares so sold to the purchaser(s) thereof and the validity of such transfer shall not be questioned, and the net proceeds of such sale (after deduction of the expenses of such sale) may either be distributed among the persons who would otherwise be entitled to a fraction or fractions of a consolidated Share or Shares ratably in accordance with their rights and interests or may be paid to the Company for the Company's benefit;
- (iii) sub-divide its Shares or any of them into Shares of an amount smaller than that fixed by the Memorandum; and
- (iv) cancel any Shares which, as at the date of passing of the resolution, have not been taken or agreed to be taken by any person and diminish the amount of its share capital by the amount of the Shares so canceled.

The Company may by special resolution reduce its share capital or any undistributable reserve, subject to the provisions of the Companies Act.

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(d) Transfer of Shares

Subject to the terms of the Articles, any member of the Company may transfer all or any of his Shares by an instrument of transfer. If the Shares in question were issued in conjunction with rights, options, warrants or units issued pursuant to the Articles on terms that one cannot be transferred without the other, the Board shall refuse to register the transfer of any such Share without evidence satisfactory to it of the like transfer of such right, option, warrant or unit.

Subject to the Articles and the requirements of the Stock Exchange, all transfers of Shares shall be effected by an instrument of transfer in the usual or common form or in such other form as the Board may approve and may be under hand or, if the transferor or transferee is a recognized clearing house or its nominee(s), under hand or by machine imprinted signature, or by such other manner of execution as the Board may approve from time to time.

Execution of the instrument of transfer shall be by or on behalf of the transferor and the transferee, provided that the Board may dispense with the execution of the instrument of transfer by the transferor or transferee or accept mechanically executed transfers. The transferor shall be deemed to remain the holder of a Share until the name of the transferee is entered in the register of members of the Company in respect of that Share.

Subject to the provisions of the Companies Act, if the Board considers it necessary or appropriate, the Company may establish and maintain a branch register or registers of members at such location or locations within or outside the Cayman Islands as the Board thinks fit. The Board may, in its absolute discretion, at any time transfer any Share on the principal register to any branch register or any Share on any branch register to the principal register or any other branch register.

The Board may, in its absolute discretion, decline to register a transfer of any Share (not being a fully paid Share) to a person of whom it does not approve or on which the Company has a lien, or a transfer of any Share issued under any share option scheme upon which a restriction on transfer subsists or a transfer of any Share to more than four joint holders. It may also decline to recognize any instrument of transfer if the proposed transfer does not comply with the Articles or any requirements of the Listing Rules.

The Board may decline to recognize 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).

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The register of members may, subject to the Listing Rules and the relevant section of the Companies Ordinance, be closed at such time or for such period not exceeding in the whole 30 days in each year as the Board may determine (or such longer period as the members of the Company may by ordinary resolution determine, provided that such period shall not be extended beyond 60 days in any year).

Fully paid Shares shall be free from any restriction on transfer (except when permitted by the Stock Exchange) and shall also be free from all liens.

(e) Redemption of Shares

Subject to the provisions of the Companies Act, the Listing Rules and any rights conferred on the holders of any Shares or attaching to any class of Shares, the Company may issue Shares that are to be redeemed or are liable to be redeemed at the option of the members or the Company. The redemption of such Shares shall be effected in such manner and upon such other terms as the Company may by special resolution determine before the issue of such Shares.

(f) Power of the Company to Purchase its own Shares

Subject to the Companies Act, or any other law or so far as not prohibited by any law and subject to any rights conferred on the holders of any class of Shares, the Company shall have the power to purchase or otherwise acquire all or any of its own Shares (which includes redeemable Shares), provided that the manner and terms of purchase have first been authorized by ordinary resolution and that any such purchase shall only be made in accordance with the relevant code, rules or regulations issued from time to time by the Stock Exchange and/or the Securities and Futures Commission of Hong Kong from time to time in force.

(g) Power of any Subsidiary of the Company to own Shares in the Company

There are no provisions in the Articles relating to the ownership of Shares in the Company by a subsidiary.

(h) Calls on Shares and Forfeiture of Shares

Subject to the terms of allotment and issue of any Shares (if any), the Board may, from time to time, make such calls as it thinks fit upon the members in respect of any monies unpaid on the Shares held by them (whether in respect of par value or share premium). A member who is the subject of the call shall (subject to receiving at least 14 clear days' notice specifying the time or times for payment) pay to the Company at the time or times so specified the amount called on his Shares. A call may be made payable either in one sum or by installments, and shall be deemed to have been made at the time when the resolution of the Board authorizing such call was passed. The joint holders of a Share shall be severally as well as jointly liable for the payment of all calls and installments due in respect of such Share.

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If a call remains unpaid after it has become due and payable, the member from whom the sum is due shall pay interest on the unpaid amount at such rate as the Board shall determine (together with any expenses incurred by the Company as a result of such non-payment) from the day it became due and payable until it is paid, but the Board may waive payment of such interest or expenses in whole or in part.

If a member fails to pay any call or installment of a call after it has become due and payable, the Board may, for so long as any part of the call or installment remains unpaid, give to such member not less than 14 clear days' notice requiring payment of the unpaid amount together with any interest which may have accrued and which may still accrue up to the date of payment (together with any expenses incurred by the Company as a result of such non-payment). The notice shall specify a further day on or before which the payment required by the notice is to be made. The notice shall also state that, in the event of non-payment at or before the appointed time, the Shares in respect of which the call was made will be liable to be forfeited.

If such notice is not complied with, any Share in respect of which the notice was given may, before the payment required by the notice has been made, be forfeited by a resolution of the Board. Such forfeiture shall include all dividends, other distributions and other monies payable in respect of the forfeited Share and not paid before the forfeiture.

A person whose Shares have been forfeited shall cease to be a member in respect of the forfeited Shares, shall surrender to the Company for cancellation the certificate(s) for the Shares forfeited and shall remain liable to pay to the Company all monies which, as at the date of forfeiture, were payable by him to the Company in respect of the Shares together with (if the Board shall in its discretion so require) interest thereon from the date of forfeiture until the date of payment as the Board may determine and any expenses incurred by the Company as a result of such non-payment.

2.2 Directors

(a) Appointment, Retirement and Removal

The Company may by ordinary resolution of the members elect any person to be a Director. The Board may also appoint any person to be a Director at any time, either to fill a casual vacancy or as an additional Director subject to any maximum number fixed by the members in general meeting or the Articles. Any Director so appointed shall hold office only until the first annual general meeting of the Company after his appointment and shall then be eligible for re-election at such meeting. Any Director so appointed by the Board shall not be taken into account in determining the Directors or the number of Directors who are to retire by rotation at an annual general meeting.

There is no shareholding qualification for Directors nor is there any specified age limit for Directors.

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The members may by ordinary resolution remove any Director (including a managing or executive Director) before the expiration of his term of office, notwithstanding anything in the Articles or any agreement between the Company and such Director, and may by ordinary resolution elect another person in his stead. Nothing shall be taken as depriving a Director so removed of any compensation or damages payable to such Director in respect of the termination of his appointment as Director or of any other appointment or office as a result of the termination of his appointment as Director.

The office of a Director shall be vacated if:

- (i) the Director gives notice in writing to the Company that he resigns from his office as Director;
- (ii) the Director is absent, without being represented by proxy or an alternate Director appointed by him, for a continuous period of 12 months without special leave of absence from the Board, and the Board passes a resolution that he has by reason of such absence vacated his office;
- (iii) the Director becomes bankrupt or has a receiving order made against him or suspends payment or compounds with his creditors generally;
- (iv) the Director dies or an order is made by any competent court or official on the grounds that he is or may be suffering from mental disorder or is otherwise incapable of managing his affairs and the Board resolves that his office be vacated;
- (v) the Director is prohibited from being or ceases to be a Director by operation of law;
- (vi) the Director has been required by the Stock Exchange to cease to be a Director or no longer qualifies to be a Director pursuant to the Listing Rules; or
- (vii) the Director is removed from office by notice in writing served upon him signed by not less than three-fourths in number (or, if that is not a round number, the nearest lower round number) of the Directors (including himself) then in office.

At each annual general meeting, one-third of the Directors for the time being shall retire from office by rotation. If the number of Directors is not a multiple of three, then the number nearest to but not less than one-third shall be the number of retiring Directors, provided that every Director shall be subject to retirement by rotation at least once every three years. The Directors to retire at each annual general meeting shall be those who have been in office longest since their last re-election or appointment and, as between persons who became or were last re-elected Directors on the same day, those to retire shall (unless they otherwise agree among themselves) be determined by lot.

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(b) Power to Allot and Issue Shares and other Securities

Subject to the provisions of the Companies Act, the Memorandum and Articles and, where applicable, the Listing Rules, and without prejudice to any rights or restrictions for the time being attached to any Shares, the Board may allot, issue, grant options over or otherwise dispose of Shares with or without preferred, deferred or other rights or restrictions, whether with regard to dividend, voting, return of capital or otherwise, to such persons, at such times, for such consideration and on such terms and conditions as it in its absolute discretion thinks fit, provided that no Shares shall be issued at a discount to their par value.

The Company may issue rights, options, warrants or convertible securities or securities of a similar nature conferring the right upon the holders thereof to subscribe for, purchase or receive any class of Shares or other securities in the Company on such terms as the Board may from time to time determine.

Neither the Company nor the Board shall be obliged, when making or granting any allotment of, offer of, option over or disposal of Shares, to make, or make available, any such allotment, offer, option or Shares to members or others whose registered addresses are in any particular territory or territories where, in the absence of a registration statement or other special formalities, this is or may, in the opinion of the Board, be unlawful or impracticable. However, no member affected as a result of the foregoing shall be, or be deemed to be, a separate class of members for any purpose whatsoever.

(c) Power to Dispose of the Assets of the Company or any of its Subsidiaries

Subject to the provisions of the Companies Act, the Memorandum and Articles and any directions given by special resolution of the Company, the Board may exercise all powers and do all acts and things which may be exercised or done by the Company to dispose of the assets of the Company or any of its subsidiaries. No alteration to the Memorandum or Articles and no direction given by special resolution of the Company shall invalidate any prior act of the Board which would have been valid if such alteration or direction had not been made or given.

(d) Borrowing Powers

The Board may exercise all the powers of the Company to raise or borrow money, secure the payment of any sum or sums of money for the purposes of the Company, mortgage or charge all or any part of its undertaking, property and uncalled capital of the Company, and, subject to the Companies Act, issue debentures, debenture stock, bonds and other securities, whether outright or as collateral security for any debt, liability or obligation of the Company or of any third party.

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(e) Remuneration

A Director shall be entitled to receive such sums as shall from time to time be determined by the Board or the Company in general meetings. The Directors shall also be entitled to be repaid all expenses reasonably incurred by them in connection with attendance at meetings of the Board or committees of the Board, or general meetings of the Company or separate meetings of the holders of any class of Shares or debentures of the Company, or otherwise in connection with the business of the Company and the discharge of their duties as Directors, and/or to receive fixed allowances in respect thereof as may be determined by the Board.

The Board or the Company in general meetings may also approve additional remuneration to any Director for any services which in the opinion of the Board or the Company in general meetings go beyond such Director's ordinary routine work as a Director.

(f) Compensation or Payments for Loss of Office

There are no provisions in the Articles relating to compensation or payment for loss of office.

(g) Loans to Directors

There are no provisions in the Articles relating to making of loans to Directors.

(h) Disclosure of Interest in Contracts with the Company or any of its Subsidiaries

With the exception of the office of auditor of the Company, a Director may hold any other office or place of profit with the Company in conjunction with his office of Director for such period and upon such terms as the Board may determine, and may be paid such extra remuneration for that other office or place of profit, in whatever form, in addition to any remuneration provided for by or pursuant to the Articles. A Director may be or become a director, officer or member of any other company in which the Company may be interested, and shall not be liable to account to the Company or the members for any remuneration or other benefits received by him as a director, officer or member of such other company.

No person shall be disqualified from the office of Director or alternate Director or prevented by such office from contracting with the Company, nor shall any such contract or any other contract or transaction entered into by or on behalf of the Company in which any Director or alternate Director is in any way interested be or be liable to be avoided, nor shall any Director or alternate Director so contracting or being so interested be liable to account to the Company for any profit realized by or arising in connection with any such contract or transaction by reason of such Director or alternate Director holding such office or of the fiduciary relationship established by it, provided that the nature of interest of any Director or alternate Director in any such contract or transaction shall be disclosed by such Director or alternate Director at or prior to the consideration and vote thereon.

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A Director shall not vote on (or be counted in the quorum in relation to) any resolution of the Board in respect of any contract or arrangement or other proposal in which he or any of his close associate(s) has a material interest, and if he shall do so his vote shall not be counted and he shall not be counted in the quorum for such resolution. This prohibition shall not apply to any of the following matters:

- (i) the giving of any security or indemnity to the Director or his close associate(s) in respect of money lent or obligations incurred or undertaken by him or any of them at the request of or for the benefit of the Company or any of its subsidiaries;
- (ii) the giving of any security or indemnity to a third party in respect of a debt or obligation of the Company or any of its subsidiaries for which the Director or his close associate(s) has/have himself/themselves assumed responsibility in whole or in part whether alone or jointly under a guarantee or indemnity or by the giving of security;
- (iii) any proposal concerning an offer of Shares, debentures or other securities of or by the Company or any other company which the Company may promote or be interested in for subscription or purchase, where the Director or his close associate(s) is/are or is/are to be interested as a participant in the [REDACTED] or [REDACTED] of the offer;
- (iv) any proposal or arrangement concerning the benefit of employees of the Company or any of its subsidiaries, including the adoption, modification or operation of (A) any employees' share scheme or any share incentive or share option scheme under which the Director or his close associate(s) may benefit or (B) any pension fund or retirement, death or disability benefits scheme which relates to the Director, his close associates and employees of the Company or any of its subsidiaries and does not provide in respect of any Director or his close associate(s) any privilege or advantage not generally accorded to the class of persons to which such scheme or fund relates; and
- (v) any contract or arrangement in which the Director or his close associate(s) is/are interested in the same manner as other holders of Shares, debentures or other securities of the Company by virtue only of his/their interest in those Shares, debentures or other securities.

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2.3 Proceedings of the Board

The Board may meet anywhere in the world for the despatch of business and may adjourn and otherwise regulate its meetings as it thinks fit. Unless otherwise determined, two Directors shall be a quorum. Questions arising at any meeting shall be determined by a majority of votes. In the case of an equality of votes, the chairman of the meeting shall have a second or casting vote.

2.4 Alterations to the Constitutional Documents and the Company's Name

The Memorandum and Articles may only be altered or amended, and the name of the Company may only be changed, by special resolution of the Company.

2.5 Meetings of Members

(a) *Special and Ordinary resolutions*

A special resolution must be passed by a majority of not less than three-fourths of the voting rights held by such members as, being entitled so to do, vote in person or by proxy or, in the case of any members which is a corporation, by its duly authorized representative(s) or by proxy, at a general meeting of which notice specifying the intention to propose the resolution as a special resolution has been duly given. A special resolution may also be approved in writing by all the members entitled to vote at a general meeting in one or more instruments each signed by one or more of such members.

An ordinary resolution, in contrast, is a resolution passed by a simple majority of the voting rights held by such members as, being entitled to do so, vote in person or by proxy or, in the case of any member which is a corporation, by its duly authorized representative(s) or by proxy, at a general meeting. An ordinary resolution may also be approved in writing by all the members entitled to vote at a general meeting in one or more instruments each signed by one or more of such members.

Subject to paragraph 2.1(b) of this Appendix III, the provisions of special resolutions and ordinary resolutions shall apply *mutatis mutandis* to any resolutions passed by the holders of any class of shares.

(b) *Voting Rights and Right to Demand a Poll*

Subject to any rights, restrictions or privileges as to voting for the time being attached to any class or classes of Shares, at any general meeting: (a) on a poll every member present in person (or, in the case of a member being a corporation, by its duly authorized representative) or by proxy shall have one vote for every Share and (b) on a show of hands every member who is present in person (or, in the case of a member being a corporation, by its duly authorized representative) or by proxy shall have one vote.

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In the case of joint holders, the vote of the senior holder who tenders a vote, whether in person or by proxy shall be accepted to the exclusion of the votes of the other joint holders, and seniority shall be determined by the order in which the names of the holders stand in the register of members of the Company.

No person shall be counted in a quorum or be entitled to vote at any general meeting unless he is registered as a member on the record date for such meeting, nor unless all calls or other monies then payable by him in respect of the relevant Shares have been paid.

At any general meeting a resolution put to the vote of the meeting shall be decided by way of poll save that the chairman of the meeting may, pursuant to the Listing Rules, allow a resolution which relates purely to a procedural or administrative matter to be voted on by a show of hands.

Any corporation or other non-natural person which is a member of the Company may in accordance with its constitutional documents, or in the absence of such provision by resolution of its directors or other governing body or by power of attorney, authorize such person as it thinks fit to act as its representative at any meeting of the Company or of any class of members, and the person so authorized shall be entitled to exercise the same powers as the corporation or other non-natural person could exercise as if it were a natural person member of the Company.

If a recognised clearing house or its nominee(s) is a member of the Company, it may appoint proxies or authorize such person or persons as it thinks fit to act as its representative(s), who enjoy rights equivalent to the rights of other members, at any meeting of the Company (including but not limited to general meetings and creditors meetings) or at any meeting of any class of members of the Company, provided that if more than one person is so authorized, the authorization shall specify the number and class of Shares in respect of which each such person is so authorized. A person so authorized shall be entitled to exercise the same rights and powers on behalf of the recognized clearing house or its nominee(s) as if such person were a natural person member of the Company, including the right to speak and vote individually on a show of hands or on a poll.

All members of the Company (including a member which is a recognized clearing house (or its nominee(s))) shall have the right to (i) speak at a general meeting and (ii) vote at a general meeting except where a member is required by the Listing Rules to abstain from voting to approve the matter under consideration. Where any member is, under the Listing Rules, required to abstain from voting on any particular resolution or restricted to voting only for or only against any particular resolution, any votes cast by or on behalf of such member in contravention of such requirement or restriction shall not be counted.

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(c) Annual General Meetings and Extraordinary General Meetings

The Company must hold a general meeting as its annual general meeting in each financial year. Such meeting shall be specified as such in the notices calling it, and must be held within six months after the end of the Company's financial year. A meeting of the members or any class thereof may be held by telephone, tele-conferencing or other electronic means, provided that all participants are able to communicate contemporaneously with one another, and participation in a meeting in such manner shall constitute presence at such meetings.

The Board may convene an extraordinary general meeting whenever it thinks fit. In addition, one or more members holding, as at the date of deposit of the requisition, in aggregate not less than one-tenth of the voting rights (on a one vote per Share basis) in the share capital of the Company may make a requisition to convene an extraordinary general meeting and/or add resolutions to the agenda of a meeting. Such requisition, which must state the objects and the resolutions to be added to the agenda of the meeting and must be signed by the requisitionists, shall be deposited at the principal place of business of the Company in Hong Kong or, in the event the Company ceases to have such a principal place of business, the registered office of the Company. If the Board does not within 21 days from the date of deposit of such requisition duly proceed to convene a general meeting to be held within the following 21 days, the requisitionists or any of them representing more than one-half of the total voting rights of all the requisitionists may themselves convene a general meeting, but any such meeting so convened shall be held no later than the day falling three months after the expiration of the said 21-day period. A general meeting convened by requisitionists shall be convened in the same manner as nearly as possible as that in which general meetings are to be convened by the Board, and all reasonable expenses incurred by the requisitionists shall be reimbursed to the requisitionists by the Company.

(d) Notices of Meetings and Business to be Conducted

An annual general meeting of the Company shall be called by at least 21 days' notice in writing, and any other general meeting of the Company shall be called by at least 14 days' notice in writing. The notice shall be exclusive of the day on which it is served or deemed to be served and of the day for which it is given, and must specify the date, time, place and agenda of the meeting, the particulars of the resolution(s) to be considered at the meeting and the general nature of the business to be considered at the meeting.

Except where otherwise expressly stated, any notice or document (including a share certificate) to be given or issued under the Articles shall be in writing, and may be served by the Company on any member personally, by post to such member's registered address, (to the extent permitted by the Listing Rules and all applicable laws and regulations) by electronic means or (in the case of a notice) by advertisement published in the manner prescribed under the Listing Rules.

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Notwithstanding that a meeting of the Company is called by shorter notice than as specified above, if permitted by the Listing Rules, such meeting may be deemed to have been duly called if it is so agreed:

- (i) in the case of an annual general meeting, by all members of the Company entitled to attend and vote thereat; and
- (ii) in the case of an extraordinary general meeting, by a majority in number of the members having a right to attend and vote at the meeting holding not less than 95% of the total voting rights held by such members.

If, after the notice of a general meeting has been sent but before the meeting is held, or after the adjournment of a general meeting but before the adjourned meeting is held (whether or not notice of the adjourned meeting is required), the Board in its absolute discretion consider that it is impractical or unreasonable for any reason to hold a general meeting on the date or at the time and place specified in the notice calling such meeting, it may change or postpone the meeting to another date, time and place.

The Board also has the power to provide in every notice calling a general meeting that in the event of a gale warning, a black rainstorm warning or extreme conditions is/are in force at any time on the day of the general meeting (unless such warning is canceled at least a minimum period of time prior to the general meeting as the Board may specify in the relevant notice), the meeting shall be postponed without further notice to be reconvened on a later date.

Where a general meeting is postponed:

- (A) the Company shall endeavor to cause a notice of such postponement, which shall set out the reason for the postponement in accordance with the Listing Rules, to be placed on the Company's website and published on the Stock Exchange's website as soon as practicable, provided that failure to place or publish such notice shall not affect the automatic postponement of a general meeting due to a gale warning, a black rainstorm warning or extreme conditions being in force on the day of the general meeting;
- (B) the Board shall fix the date, time and place for the reconvened meeting and at least seven clear days' notice shall be given for the reconvened meeting. Such notice shall specify the date, time and place at which the postponed meeting will be reconvened and the date and time by which proxies shall be submitted in order to be valid at such reconvened meeting (provided that any proxy submitted for the original meeting shall continue to be valid for the reconvened meeting unless revoked or replaced by a new proxy); and

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(C) only the business set out in the notice of the original meeting shall be considered at the reconvened meeting, and notice given for the reconvened meeting does not need to specify the business to be considered at the reconvened meeting, nor shall any accompanying documents be required to be recirculated. Where any new business is to be considered at such reconvened meeting, the Company shall give a fresh notice for such reconvened meeting in accordance with the Articles.

(e) Quorum for Meetings and Separate Class Meetings

No business shall be considered at any general meeting unless a quorum is present when the meeting proceeds to business, and continues to be present until the conclusion of the meeting.

The quorum for a general meeting shall be two members present in person (or in the case of a member being a corporation, by its duly authorized representative) or by proxy and entitled to vote. In respect of a separate class meeting (other than an adjourned meeting) convened to approve the variation of class rights, the necessary quorum shall be two persons holding or representing by proxy not less than one-third of the issued Shares of that class.

(f) Proxies

Any member of the Company (including a member which is a recognised clearing house (or its nominee(s)) entitled to attend and vote at a meeting of the Company is entitled to appoint another person (being a natural person) as his proxy to attend and vote in his place. A member who is the holder of two or more Shares may appoint more than one proxy to represent him and vote on his behalf at a general meeting of the Company or at a class meeting. A proxy need not be a member of the Company and shall be entitled to exercise the same powers on behalf of a member who is a natural person and for whom he acts as proxy as such member could exercise. In addition, a proxy shall be entitled to exercise the same powers on behalf of a member which is a corporation and for which he acts as proxy as such member could exercise as if it were a natural person member present in person at any general meeting. On a poll or on a show of hands, votes may be given either personally (or, in the case of a member being a corporation, by its duly authorized representative) or by proxy.

The instrument appointing a proxy shall be in writing and executed under the hand of the appointor or of his attorney duly authorized in writing, or if the appointor is a corporation or other non-natural person, either under its seal or under the hand of a duly authorized representative.

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The Board shall, in the notice convening any meeting or adjourned meeting, or in an instrument of proxy sent out by the Company, specify the manner by which the instrument appointing a proxy shall be deposited and the place and time (being no later than the time appointed for the commencement of the meeting or adjourned meeting to which the instrument of proxy relates) at which such instrument shall be deposited.

Every instrument of proxy, whether for a specified meeting or otherwise, shall be in such form that complies with the Listing Rules as the Board may from time to time approve. Any form issued to a member for appointing a proxy to attend and vote at a general meeting at which any business is to be considered shall be such as to enable the member, according to his intentions, to instruct the proxy to vote in favor of or against (or, in default of instructions, to exercise the discretion of the proxy in respect of) each resolution dealing with any such business.

2.6 Accounts and Audit

The Board shall cause to be kept such books of account as are necessary to give a true and fair view of the state of the Company's affairs and to explain its transactions in accordance with the Companies Act.

The books of accounts of the Company shall be kept at the principal place of business of the Company in Hong Kong or, subject to the provisions of the Companies Act, at such other place or places as the Board thinks fit and shall always be open to inspection by any Director. No member (not being a Director) or other person shall have any right to inspect any account, book or document of the Company except as conferred by the Companies Act or ordered by a court of competent jurisdiction or as authorized by the Board or the Company in general meeting.

The Board shall cause to be prepared and laid before the Company at every annual general meeting a profit and loss account for the period since the preceding account, together with a balance sheet as at the date to which the profit and loss account is made up, a Directors' report with respect to the profit or loss of the Company for the period covered by the profit and loss account and the state of the Company's affairs as at the end of such period, an auditors' report on such accounts and such other reports and accounts as may be required by law and the Listing Rules.

The members shall at each annual general meeting by ordinary resolution of the members appoint one or more firms of 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 members at the annual general meeting at which they are appointed by ordinary resolution of the members or in any other manner as specified in such ordinary resolution. The members may, at any general meeting convened and held in accordance with the Articles, remove the auditors by ordinary resolution at any time before the expiration of the term of office and shall, by ordinary resolution, at that meeting appoint new auditors in their place for the remainder of the term. Any auditor appointed pursuant to the Memorandum and Articles of Association shall hold office until the next annual general meeting and shall be eligible for re-election.

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The accounts of the Company shall be prepared and audited based on the generally accepted accounting principles of Hong Kong, the International Accounting Standards or such other standards as may be permitted by the Stock Exchange.

2.7 Dividends and other Methods of Distribution

Subject to the Companies Act and the Articles, the Company may by ordinary resolution resolve to declare dividends and other distributions on Shares in issue in any currency and authorize payment of the dividends or distributions out of the funds of the Company lawfully available therefor, provided that (i) no dividends shall exceed the amount recommended by the Board, and (ii) no dividends or distributions shall be paid except out of the realized or unrealized profits of the Company, out of the share premium account or as otherwise permitted by law.

The Board may from time to time pay to the members of the Company such interim dividends as appear to the Board to be justified by the financial conditions and the profits of the Company. In addition, the Board may from time to time declare and pay special dividends on Shares of such amounts and on such dates as it thinks fit.

Except as otherwise provided by the rights attached to any Shares, all dividends and other distributions shall be paid according to the amounts paid up on the Shares that a member holds during the period in respect of which the dividends and distributions are paid. No amount paid up on a Share in advance of calls shall for this purpose be treated as paid up on the Share.

The Board may deduct from any dividends or other distributions payable to any member of the Company all sums of money (if any) then payable by him to the Company on account of calls or otherwise. The Board may retain any dividends or distributions payable on or in respect of a Share upon which the Company has a lien, and may apply the same in or towards satisfaction of the debts, liabilities or engagements in respect of which the lien exists.

No dividends or other distributions payable by the Company on or in respect of any Share shall carry interest against the Company.

Where the Board or the Company in general meeting has resolved that a dividend should be paid or declared, the Board may further resolve:

- (a) that such dividend be satisfied in whole or in part in the form of an allotment of Shares credited as fully paid on the basis that the Shares so allotted shall be of the same class as the class already held by the allottee, provided that the members entitled thereto will be entitled to elect to receive such dividend (or part thereof) in cash in lieu of such allotment; or

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- (b) that the members entitled to such dividend will be entitled to elect to receive an allotment of Shares credited as fully paid in lieu of the whole or such part of the dividend as the Board may think fit on the basis that the Shares so allotted shall be of the same class as the class already held by the allottee.

Upon the recommendation of the Board, the Company may by ordinary resolution resolve in respect of any one particular dividend of the Company determine that notwithstanding the foregoing, a dividend may be satisfied wholly in the form of an allotment of Shares credited as fully paid without offering any right to members to elect to receive such dividend in cash in lieu of such allotment.

Any dividends, distributions or other monies payable in cash in respect of Shares may be paid by wire transfer to the holder of such Shares or by cheque or warrant sent by post to the registered address of such holder, or in the case of joint holders, to the registered address of the holder who is first named on the register of members of the Company, or to such person and to such address as the holder or joint holders may in writing direct. Any one of two or more joint holders may give effectual receipts for any dividends, distributions or other monies payable in respect of the Shares held by them as joint holders.

Whenever the Board or the Company in general meeting has resolved that a dividend be paid or declared, the Board may further resolve that such dividend be satisfied in whole or in part by the distribution of specific assets of any kind.

Any dividends or other distributions which remain unclaimed for six years from the date on which such dividends or distributions become payable shall be forfeited and shall revert to the Company.

2.8 Inspection of Corporate Records

For so long as any part of the share capital of the Company is [REDACTED] on the Stock Exchange, any member may inspect any register of members of the Company maintained in Hong Kong (except when the register of members is closed in accordance with the Companies Ordinance) without charge and require the provision to him of copies or extracts of such register in all respects as if the Company were incorporated under and were subject to the Companies Ordinance.

2.9 Rights of Minorities in relation to Fraud or Oppression

There are no provisions in the Articles concerning the rights of minority members in relation to fraud or oppression. However, certain remedies may be available to members of the Company under the Cayman Islands laws, as summarized in paragraph 3.6 below.

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2.10 Procedures on Liquidation

Subject to the Companies Act, the members of the Company may by special resolution resolve to wind up the Company voluntarily or by the court.

Subject to any rights, privileges or restrictions as to the distribution of available surplus assets on liquidation for the time being attached to any class or classes of Shares:

- (a) if the assets available for distribution among the members of the Company are more than sufficient to repay the whole of the Company's paid up capital at the commencement of the winding up, the surplus shall be distributed *pari passu* among such members in proportion to the amount paid up on the Shares held by them at the commencement of the winding up; and
- (b) if the assets available for distribution among the members of the Company are insufficient to repay the whole of the Company's paid up capital, such assets shall be distributed so that, as nearly as may be, the losses shall be borne by the members in proportion to the capital paid up, or ought to be paid up, on the Shares held by them at the commencement of the winding up.

If the Company is wound up (whether the liquidation is voluntary or compelled by the court), the liquidator may, with the approval of a special resolution and any other approval required by the Companies Act, divide among the members in kind the whole or any part of the assets of the Company, whether the assets consist of property of one kind or different kinds, and the liquidator may, for such purpose, set such value as he deems fair upon any one or more class or classes of property to be so divided and may determine how such division shall be carried out as between the members or different classes of members and the members within each class. The liquidator may, with the like approval, vest any part of the assets in trustees upon such trusts for the benefit of the members as the liquidator thinks fit, provided that no member shall be compelled to accept any shares or other property upon which there is a liability.

3. COMPANY LAWS OF THE CAYMAN ISLANDS

The Company was incorporated in the Cayman Islands as an exempted company on July 29, 2016 subject to the Companies Act. Certain provisions of the company laws of the Cayman Islands are set out below but this section does not purport to contain all applicable qualifications and exceptions or to be a complete review of all matters of the company laws of the Cayman Islands, which may differ from equivalent provisions in jurisdictions with which interested parties may be more familiar.

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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 authorized share capital.

3.2 Share Capital

Under the Companies Act, a Cayman Islands company may issue ordinary, preference or redeemable shares or any combination thereof. Where a company issues shares at a premium, whether for cash or otherwise, a sum equal to the aggregate amount or value of the premium on those shares shall be transferred to an account, to be called the share premium account. At the option of a company, these provisions may not apply to premium on shares of that company allotted pursuant to any arrangements in consideration of the acquisition or cancellation of shares in any other company and issued at a premium. The share premium account may be applied by the company subject to the provisions, if any, of its memorandum and articles of association, in such manner as the company may from time to time determine including, but without limitation, the following:

- (a) paying distributions or dividends to members;
- (b) paying up unissued shares of the company to be issued to members as fully paid bonus shares;
- (c) any manner provided in section 37 of the Companies Act;
- (d) writing-off the preliminary expenses of the company; and
- (e) writing-off the expenses of, or the commission paid or discount allowed on, any issue of shares or debentures of the company.

Notwithstanding the foregoing, no distribution or dividend may be paid to members out of the share premium account unless, immediately following the date on which the distribution or dividend is proposed to be paid, the company will be able to pay its debts as they fall due in the ordinary course of business.

Subject to confirmation by the court, a company limited by shares or a company limited by guarantee and having a share capital may, if authorized to do so by its articles of association, by special resolution reduce its share capital in any way.

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3.3 Financial Assistance to Purchase Shares of a Company or its Holding Company

There are no statutory prohibitions in the Cayman Islands on the granting of financial assistance by a company to another person for the purchase of, or subscription for, its own, its holding company's or a subsidiary's shares. Therefore, a company may provide financial assistance provided the directors of the company, when proposing to grant such financial assistance, discharge their duties of care and act in good faith, for a proper purpose and in the interests of the company. Such assistance should be on an arm's-length basis.

3.4 Purchase of Shares and Warrants by a Company and its Subsidiaries

A company limited by shares or a company limited by guarantee and having a share capital may, if so authorized by its articles of association, issue shares which are to be redeemed or are liable to be redeemed at the option of the company or a member and, for the avoidance of doubt, it shall be lawful for the rights attaching to any shares to be varied, subject to the provisions of the company's articles of association, so as to provide that such shares are to be or are liable to be so redeemed. In addition, such a company may, if authorized to do so by its articles of association, purchase its own shares, including any redeemable shares; an ordinary resolution of the company approving the manner and terms of the purchase will be required if the articles of association do not authorize the manner and terms of such purchase. A company may not redeem or purchase its shares unless they are fully paid. Furthermore, a company may not redeem or purchase any of its shares if, as a result of the redemption or purchase, there would no longer be any issued shares of the company other than shares held as treasury shares. In addition, a payment out of capital by a company for the redemption or purchase of its own shares is not lawful unless, immediately following the date on which the payment is proposed to be made, the company shall be able to pay its debts as they fall due in the ordinary course of business.

Shares that have been purchased or redeemed by a company or surrendered to the company shall not be treated as canceled but shall be classified as treasury shares if held in compliance with the requirements of section 37A(1) of the Companies Act. Any such shares shall continue to be classified as treasury shares until such shares are either canceled or transferred pursuant to the Companies Act.

A Cayman Islands company may be able to purchase its own warrants subject to and in accordance with the terms and conditions of the relevant warrant instrument or certificate. Thus there is no requirement under the Cayman Islands laws that a company's memorandum or articles of association contain a specific provision enabling such purchases. The directors of a company may under the general power contained in its memorandum of association be able to buy, sell and deal in personal property of all kinds.

A subsidiary may hold shares in its holding company and, in certain circumstances, may acquire such shares.

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3.5 Dividends and Distributions

Subject to a solvency test, as prescribed in the Companies Act, and the provisions, if any, of the company's memorandum and articles of association, a company may pay dividends and distributions out of its share premium account. In addition, based upon English case law which is likely to be persuasive in the Cayman Islands, dividends may be paid out of profits.

For so long as a company holds treasury shares, no dividend may be declared or paid, and no other distribution (whether in cash or otherwise) of the company's assets (including any distribution of assets to members on a winding up) may be made, in respect of a treasury share.

3.6 Protection of Minorities and Shareholders' Suits

It can be expected that the Cayman Islands courts will ordinarily follow English case law precedents (particularly the rule in the case of *Foss vs. Harbottle* and the exceptions to that rule) which permit a minority member to commence a representative action against or derivative actions in the name of the company to challenge acts which are ultra vires, illegal, fraudulent (and performed by those in control of the Company) against the minority, or represent an irregularity in the passing of a resolution which requires a qualified (or special) majority which has not been obtained.

Where a company (not being a bank) is one which has a share capital divided into shares, the court may, on the application of members holding not less than one-fifth of the shares of the company in issue, appoint an inspector to examine the affairs of the company and, at the direction of the court, to report on such affairs. In addition, any member of a company may petition the court, which may make a winding up order if the court is of the opinion that it is just and equitable that the company should be wound up.

In general, claims against a company by its members must be based on the general laws of contract or tort applicable in the Cayman Islands or be based on potential violation of their individual rights as members as established by a company's memorandum and articles of association.

3.7 Disposal of Assets

There are no specific restrictions on the power of directors to dispose of assets of a company, however, the directors are expected to exercise certain duties of care, diligence and skill to the standard that a reasonably prudent person would exercise in comparable circumstances, in addition to fiduciary duties to act in good faith, for proper purpose and in the best interests of the company under English common law (which the Cayman Islands courts will ordinarily follow).

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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 (2021 Revision) of the Cayman Islands, make available, in electronic form or any other medium, at its registered office copies of its books of account, or any part or parts thereof, as are specified in such order or notice.

3.9 Exchange Control

There are no exchange control regulations or currency restrictions in effect in the Cayman Islands.

3.10 Taxation

The Cayman Islands currently levy no taxes on individuals or corporations based upon profits, income, gains or appreciations and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to the Company levied by the Government of the Cayman Islands save for certain stamp duties which may be applicable, from time to time, on certain instruments.

3.11 Stamp Duty on Transfers

No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies save for those which hold interests in land in the Cayman Islands.

3.12 Loans to Directors

There is no express provision prohibiting the making of loans by a company to any of its directors. However, the company's articles of association may provide for the prohibition of such loans under specific circumstances.

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3.13 Inspection of Corporate Records

The members of a company have no general right to inspect or obtain copies of the register of members or corporate records of the company. They will, however, have such rights as may be set out in the company's articles of association.

3.14 Register of Members

A Cayman Islands exempted company may maintain its principal register of members and any branch registers in any country or territory, whether within or outside the Cayman Islands, as the company may determine from time to time. There is no requirement for an exempted company to make any returns of members to the Registrar of Companies in the Cayman Islands. The names and addresses of the members are, accordingly, not a matter of public record and are not available for public inspection. However, an exempted company shall make available at its registered office, in electronic form or any other medium, such register of members, including any branch register of member, as may be required of it upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act (2021 Revision) of the Cayman Islands.

3.15 Register of Directors and Officers

Pursuant to the Companies Act, the Company is required to maintain at its registered office a register of directors, alternate directors and officers. The Registrar of Companies shall make available the list of the names of the current directors of the Company (and, where applicable, the current alternate directors of the Company) for inspection by any person upon payment of a fee by such person. A copy of the register of directors and officers must be filed with the Registrar of Companies in the Cayman Islands, and any change must be notified to the Registrar of Companies within 30 days of any change in such directors or officers, including a change of the name of such directors or officers.

3.16 Winding up

A Cayman Islands company may be wound up by: (i) an order of the court; (ii) voluntarily by its members; or (iii) under the supervision of the court.

The court has authority to order winding up in a number of specified circumstances including where, in the opinion of the court, it is just and equitable that such company be so wound up.

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A voluntary winding up of a company (other than a limited duration company, for which specific rules apply) occurs where the company resolves by special resolution that it be wound up voluntarily or where the company in general meeting resolves that it be wound up voluntarily because it is unable to pay its debt as they fall due. In the case of a voluntary winding up, the company is obliged to cease to carry on its business from the commencement of its winding up except so far as it may be beneficial for its winding up. Upon appointment of a voluntary liquidator, all the powers of the directors cease, except so far as the company in general meeting or the liquidator sanctions their continuance.

In the case of a members' voluntary winding up of a company, one or more liquidators are appointed for the purpose of winding up the affairs of the company and distributing its assets.

As soon as the affairs of a company are fully wound up, the liquidator must make a report and an account of the winding up, showing how the winding up has been conducted and the property of the company disposed of, and call a general meeting of the company for the purposes of laying before it the account and giving an explanation of that account.

When a resolution has been passed by a company to wind up voluntarily, the liquidator or any contributory or creditor may apply to the court for an order for the continuation of the winding up under the supervision of the court, on the grounds that: (i) the company is or is likely to become insolvent; or (ii) the supervision of the court will facilitate a more effective, economic or expeditious liquidation of the company in the interests of the contributories and creditors. A supervision order takes effect for all purposes as if it was an order that the company be wound up by the court except that a commenced voluntary winding up and the prior actions of the voluntary liquidator shall be valid and binding upon the company and its official liquidator.

For the purpose of conducting the proceedings in winding up a company and assisting the court, one or more persons may be appointed to be called an official liquidator(s). The court may appoint to such office such person or persons, either provisionally or otherwise, as it thinks fit, and if more than one person is appointed to such office, the court shall declare whether any act required or authorized to be done by the official liquidator is to be done by all or any one or more of such persons. The court may also determine whether any and what security is to be given by an official liquidator on his appointment; if no official liquidator is appointed, or during any vacancy in such office, all the property of the company shall be in the custody of the court.

3.17 Mergers and consolidations

The Companies Act permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (a) "merger" means the merging of two or more constituent companies and the vesting of their undertaking, property and liabilities in one of such companies as the surviving company, and (b) "consolidation" means the combination of two or more constituent companies into a consolidated company and the vesting of the undertaking, property and liabilities of such companies to the consolidated company. In order to effect such a merger or

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consolidation, the directors of each constituent company must approve a written plan of merger or consolidation, which must then be authorized by (a) a special resolution of each constituent company and (b) such other authorization, if any, as may be specified in such constituent company's articles of association. The written plan of merger or consolidation must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. Dissenting members have the right to be paid the fair value of their shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) if they follow the required procedures, subject to certain exceptions. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

3.18 Mergers and Consolidations involving a Foreign Company

Where the merger or consolidation involves a foreign company, the procedure is similar, save that with respect to the foreign company, the directors of the Cayman Islands exempted company are required to make a declaration to the effect that, having made due enquiry, they are of the opinion that the requirements set out below have been met: (i) that the merger or consolidation is permitted or not prohibited by the constitutional documents of the foreign company and by the laws of the jurisdiction in which the foreign company is incorporated, and that those laws and any requirements of those constitutional documents have been or will be complied with; (ii) that no petition or other similar proceeding has been filed and remains outstanding or order made or resolution adopted to wind up or liquidate the foreign company in any jurisdictions; (iii) that no receiver, trustee, administrator or other similar person has been appointed in any jurisdiction and is acting in respect of the foreign company, its affairs or its property or any part thereof; (iv) that no scheme, order, compromise or other similar arrangement has been entered into or made in any jurisdiction whereby the rights of creditors of the foreign company are and continue to be suspended or restricted.

Where the surviving company is the Cayman Islands exempted company, the directors of the Cayman Islands exempted company are further required to make a declaration to the effect that, having made due enquiry, they are of the opinion that the requirements set out below have been met: (i) that the foreign company is able to pay its debts as they fall due and that the merger or consolidated is bona fide and not intended to defraud unsecured creditors of the foreign company; (ii) that in respect of the transfer of any security interest granted by the foreign company to the surviving or consolidated company (a) consent or approval to the transfer has been obtained, released or waived; (b) the transfer is permitted by and has been approved in accordance with the constitutional documents of the foreign company; and (c) the laws of the jurisdiction of the foreign company with respect to the transfer have been or will be complied with; (iii) that the foreign company will, upon the merger or consolidation becoming effective, cease to be incorporated, registered or exist under the laws of the relevant foreign jurisdiction; and (iv) that there is no other reason why it would be against the public interest to permit the merger or consolidation.

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3.19 Reconstructions and Amalgamations

Reconstructions and amalgamations may be approved by (i) 75% in value of the members or class of members or (ii) a majority in number representing 75% in value of the creditors or class of creditors, in each case, depending on the circumstances, as are present at a meeting called for such purpose and thereafter sanctioned by the Grand Court of the Cayman Islands. Whilst a dissenting member has the right to express to the court his view that the transaction for which approval is being sought would not provide the members with a fair value for their shares, it can be expected that the court would approve the transaction if it is satisfied that (i) the company is not proposing to act illegally or beyond the scope of our corporate authority and the statutory provisions as to majority vote have been complied with, (ii) the members have been fairly represented at the meeting in question, (iii) the transaction is such as a businessman would reasonable approve and (iv) the transaction is not one that would more properly be sanctioned under some other provisions of the Companies Act or that would amount to a "fraud on the minority".

If the transaction is approved, no dissenting member would have any rights comparable to the appraisal rights (namely the right to receive payment in cash for the judicially determined value of his shares), which may be available to dissenting members of corporations in other jurisdictions.

3.20 Takeovers

Where an offer is made by a company for the shares of another company and, within four months of the offer, the holders of not less than 90% of the shares which are the subject of the offer accept, the offeror may, at any time within two months after the expiration of that four-month period, by notice require the dissenting members to transfer their shares on the terms of the offer. A dissenting member may apply to the Cayman Islands courts within one month of the notice objecting to the transfer. The burden is on the dissenting member to show that the court should exercise its discretion, which it will be unlikely to do unless there is evidence of fraud or bad faith or collusion as between the offeror and the holders of the shares who have accepted the offer as a means of unfairly forcing out minority members.

3.21 Indemnification

The Cayman Islands laws do not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, save to the extent any such provision may be held by the court to be contrary to public policy, for example, where a provision purports to provide indemnification against the consequences of committing a crime.

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3.22 Economic Substance

The Cayman Islands enacted the International Tax Co-operation (Economic Substance) Act (2021 Revision) 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 July 1, 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 laws, has sent to the Company a letter of advice summarizing the aspects of the Companies Act set out in section 3 above. This letter, together with copies of the Companies Act, the Memorandum and the Articles, is on display on the websites of the Stock Exchange and the Company as referred to in the paragraph headed “Documents Delivered to the Registrar of Companies and Available on Display” in Appendix V. Any person wishing to have a detailed summary of the Companies Act or advice on the differences between it and the laws of any jurisdiction with which he is more familiar is recommended to seek independent legal advice.

APPENDIX IV

STATUTORY AND GENERAL INFORMATION

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 July 29, 2016. Our registered office address is at 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman, KY1-1002, 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 “Summary of the Constitution of our Company and Cayman Companies Act” in Appendix III.

Our Company was registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on June 7, 2022. Our principal place of business in Hong Kong is at 46F, Hopewell Centre, 183 Queen’s Road East, Wan Chai, Hong Kong. Ms. TANG Wing Shan Winza (鄧穎珊) 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.

Our Company’s head offices are located at 5th Floor, No. 987 Cailun Road, Zhangjiang Hi-Tech Park, Pudong New District, Shanghai, 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, one subscriber share was allotted and issued at par value to our initial subscriber, Offshore Incorporations (Cayman) Limited, which was subsequently transferred at par value to Dr. Lu. On the same day, 49,999 ordinary shares were allotted and issued at nominal value to Dr. Lu.

The following sets out the changes in the share capital of our Company during the two years immediately preceding the date of this document:

- (1) On October 4, 2021, our Company allotted and issued 633,801 Series D Preferred Shares to Worldstar Global Holdings Limited and 101,408 Series D Preferred Shares to Infinity-HB Ventures Fund LP.
- (2) On November 19, 2021, our Company allotted and issued 158,450 Series D Preferred Shares to Yanchuang Biotech Investment L.P..
- (3) On March 31, 2022, our Company allotted and issued 1,166,525 ordinary shares and 338,273 Series Seed Preferred Shares to Rococean Technology Holdings Limited.

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- (4) On April 28, 2022, our Company allotted and issued certain ordinary shares and Series D Preferred Shares in the following manner:
- (i) 750,000 ordinary shares to Linbell Technology Holdings Limited;
 - (ii) 83,475 ordinary shares to Rococean Technology Holdings Limited;
 - (iii) 1,901,403 Series D Preferred Shares to Future Industry Investment Fund II;
 - (iv) 348,591 Series D Preferred Shares to Ningbo Yanchuang Borong Venture Capital Partnership (Limited Partnership);
 - (v) 278,873 Series D Preferred Shares to Chengdu Infinity Kechuang Jingrong Venture Capital Partnership (Limited Partnership);
 - (vi) 253,520 Series D Preferred Shares to Shenzhen Leaguer Infinity Innovation Investment Fund (Limited Partnership); and
 - (vii) 190,140 Series D Preferred Shares to Ningbo Yanchuang Xiangshang Venture Capital Partnership (Limited Partnership).

For details of our Company’s authorized and issued share capital and consideration relating to the allotment of the Preferred Shares above, see “Share Capital – Authorized and Issued Share Capital” and “History, Development and Corporate Structure – [REDACTED] Investments”.

Save as disclosed above, there has been no alternation in our share capital within the two years immediately preceding the date of this document.

3. Changes in the Share Capital of Our Subsidiaries

A summary of the corporate information and the particulars of our subsidiaries are set out in Note 1 to the Accountants’ Report set out in Appendix I.

The following sets out the changes in the share capital of our subsidiaries within the two years immediately preceding the date of this document:

Laekna Pharmaceutical

On April 25, 2021, the registered capital of Laekna Pharmaceutical increased from RMB1,000,000 to RMB6,000,000. On July 22, 2021, the registered capital of Laekna Pharmaceutical increased from RMB6,000,000 to RMB22,000,000.

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Laekna HK

On June 29, 2022, Laekna HK allotted and issued 130,000,000 ordinary shares to our Company.

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 Accountants' Report set out in Appendix I, our Company has no other subsidiaries.

4. Corporate Reorganization

Our Company has not gone through any corporate reorganization. For details of the history and development of our Company, see "History, Development and Corporate Structure".

5. Resolutions of our Shareholders

Resolutions of our Shareholders were passed on [●], 2023 pursuant to which, among others:

- (a) conditional on (i) the Listing 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 dealing in the Shares on the Stock Exchange; (ii) the [REDACTED] having been determined; (iii) the obligations of the [REDACTED] under the [REDACTED] becoming unconditional and not being terminated in accordance with the terms of the [REDACTED] or otherwise, in each case on or before such dates as may be specified in the [REDACTED]; and (iv) the [REDACTED] having been duly executed by the [REDACTED] and our Company:
 - (1) the [REDACTED] and the [REDACTED] (including the [REDACTED]) were 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];
 - (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

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allotted, issued or dealt with, otherwise than pursuant to the [REDACTED] or pursuant to a right issue or pursuant to the exercise of any subscription rights attaching to any warrants or any option scheme or similar arrangement which may be allotted and issued by our Company from time to time on a specific authority granted by the Shareholders in general meeting or, pursuant to the allotment and issue of Shares in lieu of the whole or part of a dividend on Shares in accordance with the Articles, Shares not exceed 20% of the aggregate number of issued Shares immediately following completion of the [REDACTED], such mandate to remain in effect until the conclusion of the next annual general meeting of our Company, or the expiration of the period within which the next annual general meeting of our Company is required to be held by the Articles or any applicable laws, or until revoked or varied by an ordinary resolution of Shareholders in general meeting, whichever is the earliest;

- (3) a general unconditional mandate (the "**Repurchase Mandate**") was given to our Directors to exercise all powers of our Company to repurchase its own Shares on the Stock Exchange or on any other approved 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 will represent up to 10% of the number of the Shares in issue immediately following the completion of the [REDACTED], such mandate to remain in effect until the conclusion of the next annual general meeting of our Company, or the expiration of the period within which the next annual general meeting of our Company is required to be held by the Articles or any applicable laws, or until revoked or varied by an ordinary resolution of Shareholders in general meeting, whichever occurs first;
 - (4) the general mandate as mentioned in paragraph (2) above be extended by the addition to the number of Shares which may be allotted, issued or agreed conditionally or unconditionally to be allotted and issued by our Directors pursuant to such general mandate of an amount representing the number of Shares repurchased by the Company pursuant to the Repurchase Mandate referred to in paragraph (3) above;
 - (5) immediately prior to the completion of the [REDACTED], each share in the Company's issued and unissued share capital with a par value of US\$0.0001 each be subdivided into [10] shares of the corresponding class with a par value of US\$[0.00001] each, and each of the Preferred Shares be converted into ordinary Shares at the conversion of one-to-one by way of re-designation; and
- (b) our Company conditionally approved and adopted the Memorandum and the Articles with effect from the [REDACTED].

6. Repurchase of Our Own Securities

The following paragraphs include, among others, certain information required by the Stock Exchange to be included in this document concerning the repurchase of our own 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 [●], 2023, the Repurchase Mandate was given to our Directors authorizing them to exercise all powers of our Company to repurchase its own Shares on the Stock Exchange or on any other approved 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 will represent up to 10% of the number of the Shares in issue immediately following the completion of the [REDACTED], such mandate to remain in effect until the conclusion of the next annual general meeting of our Company, or the expiration of the period within which the next annual general meeting of our Company is required to be held by the Articles or any applicable laws, or until revoked or varied by an ordinary resolution of Shareholders in general meeting, whichever occurs first.

(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 [REDACTED] 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.

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(iii) Trading Restrictions

The total number of shares which a [REDACTED] 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 [REDACTED] 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 [REDACTED] 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 [REDACTED] of all purchased securities (whether on the Stock Exchange or otherwise) is automatically canceled and the relevant certificates must be canceled and destroyed. Under the laws of the Cayman Islands, unless 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 canceled and the amount of our Company's issued share capital shall be diminished by the nominal value of those Shares. However, the purchase of shares will not be taken as reducing the amount of the authorized share capital under Cayman Islands law.

(v) Suspension of Repurchase

A [REDACTED] 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 [REDACTED] 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 [REDACTED] 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 [REDACTED] 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 [REDACTED] company has breached the Listing Rules.

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(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 [REDACTED] 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.

(c) Funding of Repurchases

Repurchase of the Shares must be funded out of funds legally available for such purpose in accordance with the Memorandum and 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.

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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] is 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.

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.

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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 third amended and restated shareholders agreement dated October 4, 2021 entered into among our Company, Laekna Limited, Laekna Therapeutics Shanghai Co., Ltd., (來凱醫藥科技(上海)有限公司), Laekna Pharmaceutical Shanghai Co., Ltd. (來凱製藥(上海)有限公司), Laekna LLC, Ealex LLC, HongRun Limited, Dr. Lu, Novartis Pharma AG, OrbiMed Asia Partners III, L.P., GP Healthcare Capital, Inc., Shanghai GP Healthcare Phase III Equity Investment Fund Partnership (Limited Partnership) (上海金浦健康三期股權投資基金合夥企業(有限合夥)), Shanghai Haoyao Information Technology Partnership (Limited Partnership) (上海灝藥信息科技合夥企業(有限合夥)), Beijing Longmaide Venture Capital Fund (Limited Partnership) (北京龍脈得創業投資基金(有限合夥)), Shenzhen Capital Group Company, Ltd. (深圳市創新投資集團有限公司), HTYL Investment Holdings Limited, Jiangsu Yanyuan Oriental Venture Capital Investment Partnership (LP) (江蘇燕園東方創業投資合夥企業(有限合夥)), Ningbo Yanchuang Yaoshang Yangming Venture Capital Investment Partnership (LP) (寧波燕創姚商陽明創業投資合夥企業(有限合夥)), Ningbo Yanyuan Innovation Venture Capital Investment Partnership (LP) (寧波燕園創新創業投資合夥企業(有限合夥)), Ningbo Rongshun Yanyuan Venture Capital Investment Partnership (LP) (寧波榮舜燕園創業投資合夥企業(有限合夥)), CDIB Yida Healthcare Private Equity (Kunshan) Enterprise (Limited Partnership) (昆山華創毅達生醫股權投資企業(有限合夥)), CMBI Private Equity Series B SPC on behalf of and for the account of Health Innovation Fund I SP, Sushang United PE Investment Fund (Limited Partnership) (蘇州蘇商聯合產業投資合夥企業(有限合夥)), Future Industry Investment Fund II (先進製造產業投資基金二期(有限合夥)), Worldstar Global Holdings Limited, Ningbo Yanchuang Xiangshang Venture Capital Partnership (Limited Partnership) (寧波燕創象商創業投資合夥企業(有限合夥)), Ningbo Yanchuang Borong Venture Capital Partnership (Limited Partnership) (寧波燕創勃榮創業投資合夥企業(有限合夥)), Shenzhen Grandway Capital Management Co. Ltd. (深圳市嘉遠資本管理有限公司), Zhuhai Zhongyi Yingfei New Industry Investment Fund (Limited Partnership) (珠海中以英飛新興產業投資基金(有限合夥)), and Infinity-HB Ventures Fund LP, pursuant to which the parties agreed on the terms and conditions to regulate the affairs of the Company and the rights of the shareholders; and
- (b) [REDACTED].

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2. Intellectual Property Rights

(a) Trademarks

As of the Latest Practicable Date, our Group has registered the following material trademarks:

No.	Trademark	Registered Owner	Class	Registration Number	Place of registration
1.		Laekna Therapeutics	5 35	33125903 33125904	PRC
2.		Laekna Therapeutics	42	33006214	PRC
3.		Laekna Therapeutics	42	25916159	PRC
4.	(A)  (B) 	Laekna HK	5, 35, 42	305869711	Hong Kong
5.		Laekna Therapeutics	10 44	61681250 61669473	PRC
6.	Laekna	Laekna Therapeutics	5 10 35 42 44	61685395 61677452 61670774 61692019 61676500	PRC
7.	来凯	Laekna Therapeutics	5 42 44	61857933 61866373 61874686	PRC

(b) Domain Names

As of the Latest Practicable Date, our Group had registered the following domain names which we consider to be material to our Group’s business:

Domain name	Registered owner	Expiry date
laekna.com	Laekna Therapeutics	September 2, 2024
laeknatp.com	Laekna Therapeutics	July 18, 2023

(c) Patents

For a discussion of the details of the material granted patents and filed patent applications in connection with our clinical and pre-clinical drug candidates, see “Business – Intellectual Property”.

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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 Directors 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 until terminated in accordance with the terms and conditions of the service contract or by either party giving to the other not less than three months’ prior notice.

Pursuant to the service contracts entered into with us, none of the executive Directors 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 signed an appointment letter with our Company for a term of three years effective upon the date of this document (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 [●] commencing on the effective date of their appointment.

For details of our Company’s remuneration policy, see “Directors and Senior Management – Remuneration of Directors and Senior Management”.

2. Remuneration of Directors

For the two years ended December 31, 2021 and 2022:

- (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 and RMB6.0 million, respectively;
- (b) the total amount of share-based payment expenses incurred by us in respect of the Directors were approximately RMB4.4 million and RMB6.3 million, respectively.

The aggregate amount of emoluments which the Company incurred in respect of the five highest paid individuals of the Group (including both employees and Directors) for the two years ended December 31, 2021 and 2022 were approximately RMB16.1 million and RMB24.5 million, respectively.

It is estimated that emoluments of approximately RMB11.0 million in aggregate will be incurred in respect of our Directors and proposed Directors for the financial year ending December 31, 2023 under arrangements in force as of the Latest Practicable Date.

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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 and chief executive in the share capital of our Company and its associated corporations following completion of the [REDACTED]*

Immediately following completion of the [REDACTED] (assuming the [REDACTED] is 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 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 [REDACTED] 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	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. Lu	Beneficial interest	[REDACTED] ⁽³⁾	[REDACTED]%
	Founder of a discretionary trust	[REDACTED] ⁽³⁾	[REDACTED]%
Ms. Xie	Interest in controlled corporation	[REDACTED] ⁽⁴⁾	[REDACTED]%
	Interest in controlled corporations	[REDACTED] ⁽⁵⁾	[REDACTED]%
Dr. GU Xiang Ju Justin	Beneficial interest	[REDACTED] ⁽⁶⁾	[REDACTED]%

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Notes:

1. Assuming the [REDACTED] and the Conversion have been completed prior to the [REDACTED].
2. Assuming the [REDACTED] is not exercised.
3. Includes (i) Shares held by Dr. Lu beneficially under his own name; and (ii) Shares held by the Family Trust which Dr. Lu is the settlor. Accordingly, Dr. Lu is deemed to be interested in the Shares held by the Family Trust. Further, pursuant to the [REDACTED] Share Option Scheme, Dr. Lu was granted Share Options to subscribe for 2,635,520 Shares.
4. Includes Shares held by Ms. Xie through Linbell Technology Holdings Limited, a limited liability company incorporated in the BVI wholly-owned by her.
5. Includes Shares held under the ESOP Trusts. Pursuant to the trust deed dated [●], Futu Trustee Limited (as the trustee of the ESOP Trusts) will exercise their voting rights in accordance with the instructions of Ms. Xie. Further, pursuant to the [REDACTED] Share Option Scheme, Ms. Xie was granted Share Options to subscribe for 2,482,750 Shares.
6. Includes the underlying Shares under the Share Options granted to Dr. GU Xiang Ju Justin pursuant to the [REDACTED] Share Option Scheme.

(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], have 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, see “Substantial Shareholders”.

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 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;

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- (ii) none of the Directors or the experts named in the sub-section headed “F. Other Information – 4. Consents of Experts” in this Appendix has any direct or indirect interest in the promotion of, or in any assets which have been, within the two years immediately preceding the date of this document, acquired or disposed of by or leased to any member of 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 immediately preceding the date of this document; and
- (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.

D. [REDACTED] SHARE OPTION SCHEME

The [REDACTED] Share Option Scheme was adopted by the Board on April 11, 2018 and was amended on October 30, 2019, April 20, 2021 and March 31, 2022.

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 and 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 Share Options granted under the [REDACTED] Share Option Scheme. For further details, see “Waivers and Exemptions – Waiver and Exemption in relation to the [REDACTED] Share Option Scheme”.

The following is a summary of the principal terms of the [REDACTED] Share Option Scheme. The terms of the [REDACTED] Share Option Scheme are not subject to the provisions of Chapter 17 of the Listing Rules as it does not involve any grant of Share Options by our Company to subscribe for new Shares after [REDACTED].

1. Summary of terms

(a) *Who may join*

We may grant Share Options to employees, officers, directors, contractors, advisors or consultants of the Group (the “**Eligible Participant(s)**”).

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(b) Maximum number of Shares

Subject to capitalization adjustments, the maximum aggregate number of Shares in respect of the Share Options which may be issued pursuant to the [REDACTED] Share Option Scheme shall not exceed 5,699,943 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) (subject to adjustment to reflect any rights issue, consolidation, share splits, or similar transactions).

As of the Latest Practicable Date, the Company has granted Share Options pursuant to the [REDACTED] Share Option Scheme representing a total of 4,245,352 underlying shares (or [REDACTED] Shares as adjusted after the [REDACTED]) (including those that have been exercised but excluding those that were terminated or lapsed). Taking into account the adjustments required as a result of the [REDACTED], Share Options correspond to [14,545,910] Shares remain available for grant under the [REDACTED] Share Option Scheme. No further Share Option will be granted by the Company under the [REDACTED] Share Option Scheme after the [REDACTED], and that any unused scheme limit of the [REDACTED] Share Option Scheme will not be utilized after the [REDACTED].

(c) Administration

The [REDACTED] Share Option Scheme shall be administered by the Board or a duly authorized committee of the Board (if any) (the “**Administrator**”) and the decision of the Board shall be final and binding on all parties.

The Administrator shall have the right to, among others, (i) interpret and construe the provisions of the [REDACTED] Share Option Scheme, (ii) to determine the persons who will be awarded Share Options under the [REDACTED] Share Option Scheme and the relevant terms of the Share Options awarded (such as exercise price and any performance conditions upon which the exercise of an Share Option is conditioned), (iii) to make such appropriate and equitable adjustments to the terms of Share Options granted under the [REDACTED] Share Option Scheme as it deems necessary, (iv) to amend, add to and/or delete any of the provisions of the [REDACTED] Share Option Scheme, provided that no such amendment, addition or deletion shall adversely affect the rights of any grantee of the Share Options (the “**Grantee**”) in respect of any Share Options granted to such Grantee, and (v) to make such other decisions or determinations as it shall deem appropriate in the administration of the [REDACTED] Share Option Scheme.

(d) Offer and grant of Share Options

On and subject to the terms of the [REDACTED] Share Option Scheme, the Administrator is entitled to make an offer to any Eligible Participant as the Administrator may in its absolute discretion select to take up Share Options in respect of such number of Shares as the Administrator may determine at an exercise price. Share Options may be

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granted on such terms and conditions in relation to their vesting, exercise or otherwise as the Administrator may determine, provided such terms and conditions shall not be inconsistent with any other terms and conditions of the [REDACTED] Share Option Scheme.

An offer letter (the "**Offer Letter**") shall be made to an Eligible Participant in such form as the Administrator may from time to time determine to require the Eligible Participant to undertake to hold the Share Option on the terms on which it is to be granted and to be bound by the provisions of the [REDACTED] Share Option Scheme. A Grantee is not required to pay for the grant of any Share Option.

Unless otherwise approved by the Administrator, a Share Option shall be 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 Share Option or attempt so to do, except pursuant to the [REDACTED] Share Option Scheme.

(e) Term of the [REDACTED] Share Option Scheme

Unless terminated earlier, the [REDACTED] Share Option Scheme has a term of ten (10) years commencing on the adoption date of the [REDACTED] Share Option Scheme.

(f) Exercise of Share Options

Except as otherwise provided in an Offer Letter, any Share Option shall become exercisable upon vesting. Notwithstanding the foregoing, the exercise shall be conditional upon full compliance of the Grantee and the Company with all applicable laws and regulations. Each notice of exercise of a Share Option must be accompanied by a remittance for the aggregate amount of the exercise price multiplied by the number of Shares in respect of which the notice is given. Within 30 days after receipt of the notice and remittance and, where appropriate, receipt of the auditors' certificate, the Company shall allot and issue or procure the allotment and issue of the relevant Shares to the Grantee (or his or her personal representative) credited as fully paid and issue to the Grantee (or his or her personal representative) a share certificate in respect of the Shares so allotted. The Shares will be subject to the provisions of the Memorandum and Articles of the Company for the time being in force and will rank pari passu with the fully paid Shares in issue as from the date of exercise of the Share Option and in particular will entitle the holders to participate in all dividends or other distributions paid or made on or after the date of exercise of the Share Option other than any dividend or other distribution previously declared or recommended or resolved to be paid or made if the record date therefor is before the date of exercise of the Share Option subject to the [REDACTED] Share Option Scheme.

In the event the Grantee ceases to be an employee by reason of his/her death, disability or for any other reason that the Administrator considers valid, before exercising the Share Option in full, the Grantee's vested Share Option may be assigned to its representative (to the extent not already exercised).

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(g) Exercise price

The exercise price of the Share Options granted shall be approved by the Board and shall be set out in the Offer Letter.

(h) Vesting schedule

Unless otherwise approved by the Administrator and set forth in an Offer Letter, the vesting schedule of the Share Options granted shall be a 60-month vesting schedule consisting of a cliff vesting of forty percent (40%) after twenty-four (24) months from the commencement date as indicated in the Offer Letter and, thereafter, quarterly vesting of equal installments over the remaining twelve (12) quarters.

(i) Changes in capital structure

In the event of any alteration in the capital structure of the Company whilst any Share 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 or otherwise howsoever in accordance with legal requirements, other than any alteration in the capital structure of the Company as a result of an issue of Shares as consideration in a transaction to which the Company is a party or an issue of shares pursuant to, or in connection with, any share option plan, share appreciation rights plan or any arrangement for remunerating or incentivizing any employee, consultant or adviser to the Group or in the event of any distribution of the Company's capital assets to its Shareholders on a pro rata basis (whether in cash or in specie) other than dividends paid out of the net profits attributable to its Shareholders for each financial year of the Company, such corresponding alterations (if any) shall be made to (i) the number or nominal value of Shares subject to the Share Option so far as unexercised; or (ii) the exercise price of the Share Options, or any combination thereof, as an independent financial adviser or the auditors shall confirm to the Administrator in writing, provided that no such adjustments be made to the extent that a Share would be issued at less than its nominal value.

(j) Repurchase right

Unless otherwise approved by the Administrator, prior to the [REDACTED], after a Grantee's termination of employment by or services to the Group, any Shares issued by the Company as a result of the exercise of a Share Option by such Grantee or any vested Share Option held by such Grantee shall be subject to a right, but not an obligation, of repurchase by the Company and/or its assignee(s) at a price equal to the fair market value of the Shares on the date the Company exercises such repurchase right, minus the exercise price in the case of an unexercised and vested Share Option.

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(k) Amendment or termination of the [REDACTED] Share Option Scheme

The [REDACTED] Share Option Scheme may be altered in any respect by the prior approval of the Administrator, provided that no such alteration shall operate to affect adversely the terms of issue of any Share Option granted or agreed to be granted prior to such alteration, except with the consent or sanction of such majority of the Grantees as would be required of the Shareholders under the Memorandum and Articles for the time being of the Company for a variation of the rights attached to the Shares.

2. Outstanding Share Options

As at the Latest Practicable Date, our Company had granted Share Options under the [REDACTED] Share Option Scheme to 113 Grantees to subscribe for an aggregate of 4,705,302 shares (or [REDACTED] Shares as adjusted after the [REDACTED]). Share Options to subscribe for 459,950 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) had lapsed following the resignation of certain Grantees (including Share Options granted to two former consultants whereby part of their Share Options had lapsed after they ceased to be our consultants). As of the Latest Practicable Date, Share Options corresponding to 833,475 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) had been exercised (which included Share Options corresponding to 750,000 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) and 83,475 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) exercised by Ms. Xie and Mr. Lin Dianhai (林殿海), a former Director, respectively). Accordingly, as of the Latest Practicable Date, Share Options granted to 101 Grantees to subscribe for 3,411,877 shares (or [REDACTED] Shares as adjusted after the [REDACTED]) were outstanding, representing approximately [REDACTED]% of our Company’s issued share capital immediately after completion of the [REDACTED], Conversion and [REDACTED] (assuming the [REDACTED] are not exercised), which included Share Options granted to three Directors with respect to 1,161,827 underlying shares (or [REDACTED] Shares as adjusted after the [REDACTED]), two other senior management members with respect to 850,000 underlying shares (or [REDACTED] Shares as adjusted after the [REDACTED]), three other employees who have been granted Share Options to subscribe 120,000 ordinary shares of the Company (to be adjusted to [REDACTED] Shares upon [REDACTED]) or more with respect to 390,000 underlying shares (or [REDACTED] Shares as adjusted after the [REDACTED]), four existing and two former consultants with respect to 25,250 underlying shares (or [REDACTED] Shares as adjusted after the [REDACTED]), and 87 other Grantees with respect to an aggregate of 984,800 underlying shares (or [REDACTED] Shares as adjusted after the [REDACTED]). No Share Options were granted to other connected persons of the Company and no consideration was paid for the Share Options granted.

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Below is a list of Grantees of outstanding Share Options (excluding lapsed and exercised Share Options) under the [REDACTED] Share Option Scheme:

Name of Grantee	Position(s) held within our Group	Address	Exercise price as adjusted after the [REDACTED] (US\$ per share)	Date of grant	Vesting period	Number of Shares underlying the outstanding Share Options as adjusted after the [REDACTED]	Approximate percentage of shareholding interest in our Company underlying the outstanding Share Options ^(f)
DIRECTORS AND SENIOR MANAGEMENT							
Dr. Lu	Executive Director	26 Rockville Ave Lexington, MA 02421	[0.452]	February 15, 2023	Note 2	[2,635,520]	[REDACTED]%
	Chief Executive Officer	United States of America					
Ms. Xie	Executive Director	Room 214, No. 15, Sijing Road, Huangpu District, Shanghai, PRC	[0.05]	March 1, 2021, June 15, 2021 and March 31, 2022	Note 2	[2,482,750]	[REDACTED]%
	Senior vice president						
Dr. GU Xiang Ju Justin	Executive Director	10-1901, Lane 388, Chuanhe Road, Pudong New Area, Shanghai, PRC	[0.234]	January 4, 2020, March 2, 2020 and June 15, 2021	Note 2	[5,500,000]	[REDACTED]%
	Chief Scientific Officer						
			[0.452]	March 31, 2022	Note 2	[500,000]	[REDACTED]%
			[0.452]	February 15, 2023	Note 2	[500,000]	[REDACTED]%
Dr. YUE Yong	Chief Medical Officer	1 Bellewood Drive, Warren, NJ 07059, United States of America	[0.234]	August 31, 2018 and January 18, 2019	Note 3	[5,000,000]	[REDACTED]%
			[0.234]	March 2, 2020 and June 15, 2021	Note 2	[1,500,000]	[REDACTED]%
			[0.452]	March 31, 2022	Note 2	[500,000]	[REDACTED]%
Ms. WANG Liqing	Vice president	Room 406, No. 1, Lane 45, Yude Road, Shanghai, PRC	[0.05]	August 23, 2019	Note 3	[500,000]	[REDACTED]%
			[0.05]	March 2, 2020, March 1, 2021, June 16, 2021, and March 31, 2022	Note 2	[1,000,000]	[REDACTED]%
Total						[20,118,270]	[REDACTED]%

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Name of Grantee	Position(s) held within our Group	Address	Exercise price as adjusted after the [REDACTED] (US\$ per share)	Date of grant	Vesting period	Number of Shares underlying the outstanding Share Options as adjusted after the [REDACTED]	Approximate percentage of shareholding interest in our Company underlying the outstanding Share Options ⁽¹⁾
CONSULTANTS							
Peter ten DIJKE ⁽⁴⁾	External consultant	Rapenburg 73, 2311 GJ Leiden, Netherlands	0.452	March 31, 2022	Note 2	[10,000]	[REDACTED]
Counde O'YANG ⁽⁴⁾	External consultant	1420 Bellingham Way, Sunnyvale, CA 94087, United States of America	0.452	March 31, 2022	Note 2	[10,000]	[REDACTED]
Jeff PORTER ⁽⁴⁾	External consultant	27 Carriage Drive, Lexington, MA 02420, United States of America	0.452	March 31, 2022	Note 2	[20,000]	[REDACTED]%
Scott L. FRIEDMAN ⁽⁴⁾	External consultant	455 Central Park West, Apt 18B, New York, NY 10025, United States of America	0.452	October 1, 2022	Note 2	[10,000]	[REDACTED]
SHEN Haige ⁽⁵⁾	Former external consultant	301, No. 68, Lane 1705, Yangnan Road, Pudong New Area, Shanghai, PRC	0.234	July 16, 2018	Note 3	67,500	[REDACTED]%
WANG Yu ⁽⁵⁾	Former external consultant	Room 1101, No. 8, Lane 1220, Jiangning Road, Putuo District, Shanghai, PRC	0.234	July 16, 2018	Note 3	135,000	[REDACTED]%
Total						[252,500]	[REDACTED]%

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Name of Grantee	Position(s) held within our Group	Address	Exercise price as adjusted after the [REDACTED] (US\$ per share)	Date of grant	Vesting period	Number of Shares underlying the outstanding Share Options as adjusted after the [REDACTED]	Approximate percentage of shareholding interest in our Company underlying the outstanding Share Options ⁽¹⁾
OTHER EMPLOYEES BEING GRANTED SHARE OPTIONS TO SUBSCRIBE FOR 1,200,000 SHARES OR MORE							
FENG Tao	Vice president, head of CMC	No. 53, Lane 399, Xiangnan Road, Pudong New Area, Shanghai, PRC	[0.05]	March 2, 2020, March 1, 2021, June 15, 2021 and March 31, 2022	Note 2	[695,000]	[REDACTED]%
			[0.05]	August 31, 2018 and March 25, 2019	Note 3	[605,000]	[REDACTED]%
Guy ROSENTHAL	Vice president, head of corporate and business development	464 North Gardner St. Los Angeles, CA 90036, United States of America	[0.234]	June 1, 2021	Note 2	[1,000,000]	[REDACTED]%
			[0.452]	March 31, 2022	Note 2	[200,000]	[REDACTED]%
WANG Jun	Vice president, head of clinical development	53-302, Phase 4 Wanke, Wanshun Road, Wuxi, PRC	[0.05]	September 9, 2021, March 31, 2022 and January 31, 2023	Note 2	[1,400,000]	[REDACTED]%
Total						[3,900,000]	[REDACTED]%

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Name of Grantee	Position(s) held within our Group	Address	Exercise price as adjusted after the [REDACTED] (US\$ per share)	Date of grant	Vesting period	Number of Shares underlying the outstanding Share Options as adjusted after the [REDACTED]	Approximate percentage of shareholding interest in our Company underlying the outstanding Share Options ⁽¹⁾
OTHER GRANTEES							
Other Grantees			[0.03]	April 11, 2018	Note 3	[1,220,000]	[REDACTED]%
(including 83 employees and four former employees) ⁽⁶⁾				and March 1, 2021			
			[0.05]	November 1, 2019 to January 31, 2023	Note 2	[6,747,000]	[REDACTED]%
			[0.05]	July 31, 2018 to August 30, 2019	Note 3	[783,000]	[REDACTED]%
			[0.234]	March 1, 2020 to September 8, 2021	Note 2	[280,000]	[REDACTED]%
			[0.234]	July 9, 2019	Note 3	[128,000]	[REDACTED]%
			[0.452]	March 31, 2022 to January 31, 2023	Note 2	[690,000]	[REDACTED]%
Total						9,848,000	[REDACTED]%

Notes:

1. Approximate percentage of shareholding is calculated as the number of Shares underlying to the outstanding Share Options granted to a Grantee and divided by [REDACTED] Shares, being the total number of Shares in issue immediately upon completion of the [REDACTED] and the [REDACTED], but assuming the [REDACTED] is not exercised.
2. The vesting schedule for these Share Options is: (i) 40% to be vested two years from the date of grant; and (ii) 5% to be vested every quarter thereafter.
3. The vesting schedule for these Share Options is: (i) 20% to be vested one year from the date of grant; and (ii) 5% to be vested every quarter thereafter.
4. Each of Peter ten DIJKE, Counde O’YANG, Jeff PORTER and Scott L. FRIEDMAN is a member of our scientific advisory board.
5. SHEN Haige was our biostatistics management consultant and WANG Yu was our medical consultant whom have both ceased to be our consultants in November 2020. Share Options to subscribe for [REDACTED] and [REDACTED] Shares (as adjusted after the [REDACTED]) granted to SHEN Haige and WANG Yu had lapsed after they ceased to be our consultants, respectively.
6. Four former employees were granted and have vested Share Options to subscribe for an aggregate of [REDACTED] Shares (as adjusted after the [REDACTED]) during the period when they were employed by the Group.

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All the shares underlying the [REDACTED] Share Option Scheme which are unexercised have been allotted and issued and are held by the ESOP Trusts on trust prior to the [REDACTED]. Accordingly, if all the outstanding Share Options granted under the [REDACTED] Share Option Scheme are exercised, there will not be any dilution effect on the shareholdings of our Shareholders nor any impact on the earnings per share arising from the exercise of the outstanding Share Options.

E. [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 ordinary resolutions of our Shareholders on [●] is as follows.

1. Purpose

The purpose of the [REDACTED] Share Option Scheme is to incentivize and reward the Eligible Participants (as defined below) for their contribution to the Group and to align their interests with that of the Company so as to encourage them to work towards enhancing the value of the Company.

2. Who may join

The Board (which expression shall, for the purpose of this paragraph, include the Board or a duly authorized committee thereof) may, at its absolute discretion, offer to grant an option to subscribe for such number of Shares as the Board may determine to (a) an employee (whether full time or part-time) or a director of the Company or any of its subsidiaries (“**Eligible Employee(s)**”) and (b) a consultant who provides services to the Group (such as in respect of research and development, product commercialization, marketing and investor relations in investment environment of the Group) on a continuing and recurring basis in its ordinary and usual course of business which are material to the long term growth of the Group (“**Eligible Consultant(s)**”, together with the Eligible Employees referred as “**Eligible Participant(s)**”).

For the avoidance of doubt, Eligible Consultants shall exclude placing agents or financial advisers providing advisory services for fundraising, mergers or acquisitions, and any professional service providers such as auditors or valuers.

The eligibility of any Eligible Employee shall be determined by the Board from time to time on the basis of the Board’s opinion as to, among others, the participant’s individual performance, time commitment, responsibilities or employment conditions according to the prevailing market practice and industry standard, the length of engagement with the Group and the actual or potential contribution to the development and growth of the Group.

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The eligibility of any Eligible Consultant shall be determined by the Board from time to time on the basis of the Board's opinion as to, among others, the contribution to the development and growth of the Group, the prevailing market practice and industry standard, the actual degree of involvement in and/or cooperation with the Group and length of collaborative relationship the Eligible Consultant has established with the Group, and the amount of support, assistance, guidance, advice, efforts and contributions the Eligible Consultant has exerted and given towards the success of the Group, and/or whether the person is regarded as a valuable consultant of the Group, taking into account the knowledge, experience, qualification, expertise and reputation of the Eligible Consultant or other relevant factors (including without limitation technical know-how, market competitiveness, synergy between him/her and the Group and his/her strategic value).

3. Maximum number of Shares

- (i) Subject to paragraphs (iv) and (v) below, the total number of Shares which may be issued upon exercise of all options to be granted under the [REDACTED] Share Option Scheme shall not in aggregate exceed 10% of the relevant class of Shares in issue on the day on which trading of the Shares commences on the Stock Exchange (the "**Scheme Mandate Limit**"), being [REDACTED] Shares (excluding any Shares which may be issued upon the exercise of the [REDACTED]). Options lapsed in accordance with the terms of the [REDACTED] Share Option Scheme will not be counted for the purpose of calculating the Scheme Mandate Limit.
- (ii) Subject to paragraph (i) above, within the Scheme Mandate Limit, the total number of Shares which may be issued upon exercise of all options to be granted to Eligible Consultants shall not exceed [1]% of the relevant class of Shares in issue on the day on which trading of the Shares commences on the Stock Exchange, being [REDACTED] Shares (the "**Eligible Consultant Sublimit**").
- (iii) Subject to paragraph (iv) below, the Scheme Mandate Limit and the Eligible Consultant Sublimit may be refreshed at any time after three years from the date of Shareholders' approval for the last refreshment (or the date on which the [REDACTED] Share Option Scheme is adopted, as the case may be) by approval of its Shareholders in general meeting provided that (1) any controlling shareholders and their associates (or if there is no controlling shareholder, directors (excluding independent non-executive directors) and the chief executive of the Company and their respective associates) must abstain from voting in favor of the relevant resolution at the general meeting; and (2) the Company must comply with the requirements under Rules 13.39(6), 13.39(7), 13.40, 13.41 and 13.42 of the Listing Rules. The requirements under (1) and (2) of this paragraph do not apply if the refreshment is made immediately after an issue of securities by the Company to the Shareholders on a pro rata basis as set out in Rule 13.36(2)(a) of the Listing Rules such that the unused part of the scheme mandate (as a percentage of the relevant class of Shares in issue) upon refreshment is the same as the unused part of the scheme mandate immediately before the issue of securities, rounded to the nearest whole Share.

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- (iv) The total number of Shares which may be issued upon exercise of all options to be granted under the [REDACTED] Share Option Scheme and any other schemes of the Company under the scheme mandate as refreshed must not exceed 10% of the relevant class of Shares in issue as at the date of approval of the refreshed scheme mandate.
- (v) Without prejudice to paragraph (iv) above, the Company may seek separate Shareholders' approval in a general meeting to grant options beyond the Scheme Mandate Limit to participants specifically identified by the Company before such approval is sought. In such event, the Company must send a circular to its Shareholders containing a general description of the specified participants, the number and terms of options to be granted, the purpose of granting options to the specified participants with an explanation as to how the terms of the options will serve such purpose and all other information required under the Listing Rules. The date of board meeting for proposing such further grant should be taken as the date on which an option is offered to a participant for the purpose of calculating the exercise price under Rule 17.03E of the Listing Rules.

4. Maximum entitlement of a grantee

Where any grant of options to a participant would result in the Shares issued and to be issued upon exercise of all options and awards granted to such participant under the [REDACTED] Share Option Scheme and any other schemes of the Company (excluding any options lapsed in accordance with the terms of the [REDACTED] Share Option Scheme) in the 12-month period up to and including the date of such grant representing in aggregate over 1% of the relevant class of Shares in issue, such grant must be separately approved by the Shareholders in general meeting with such participant and his/her close associates (or his/her associates if the participant is a connected person) abstaining from voting. The number and terms (including the exercise price) of options to be granted to such participant must be fixed before Shareholders' approval. The date of board meeting for proposing such further grant should be taken as the date of grant for the purpose of calculating the exercise price under Rule 17.03E of the Listing Rules.

5. Grant and exercise of options

The Board or a duly authorized committee thereof may in its absolute discretion specify such event, time limit or conditions (if any) as it thinks fit when making such offer to the Eligible Participants, including, without limitation, conditions as to performance criteria (such as growth rate of revenue, earnings per share and/or total shareholders' return) to be satisfied or achieved by the Eligible Participants and/or the Company and/or the Group which must be satisfied before an option can be exercised.

An offer of the grant of an option shall be made to any Eligible Participants by letter in such form as the Board or a duly authorized committee thereof may from time to time determine specifying the number of Shares, the vesting period (subject to any acceleration of the vesting schedule at the Board's discretion, provided that any acceleration shall be subject to the minimum vesting period of 12 months, subject to a shorter vesting period as permitted

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under the Listing Rules from time to time), 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 date of grant (provided such offer shall be open for acceptance after the effective period of the [REDACTED] Share Option Scheme) and further requiring the Eligible Participants 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. An option shall be deemed to have been granted and accepted and to have taken effect when the duplicate letter comprising acceptance of the offer of the grant of the option duly signed by the grantee together with a payment to the Company and/or any of its subsidiaries of HK\$1 (or the equivalent of HK\$1 in the local currency of any jurisdiction where the Company and/or its subsidiaries operate, as the Board or a duly authorized committee thereof may in its absolute discretion determine) by way of consideration for the grant thereof is received by the Company within the time period specified in the offer of the grant of the option. Such remittance shall not be refundable.

An option shall be 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 in favor of any third party over or in relation to any option. Any breach of the foregoing by the grantee shall entitle the Company to cancel any outstanding entitlement of such grantee.

An option may be exercised in accordance with the terms of the [REDACTED] Share Option Scheme at any time during a period to be determined and notified by the Board to each grantee, which period may commence on a day after the date upon which the offer for the grant of options is accepted or deemed to be accepted but shall end in any event not later than 10 years from the date on which an option is offered to a participant, subject to the provisions for early termination under the [REDACTED] Share Option Scheme or the relevant document of grant or other notification issued by the Board. In any event, the minimum period for which an option must be held before it can be exercised shall be 12 months subject to a shorter vesting period otherwise permitted under the Listing Rules.

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 or a duly authorized committee thereof at its absolute discretion and notified to any Eligible Participant (subject to any adjustments made pursuant to paragraph 11 below), which shall be not less than the highest of:

- (i) the nominal value of a Share;
- (ii) the closing price of the Shares as stated in the Stock Exchange’s daily quotations sheet on the date of grant, which must be a business day; and
- (iii) the average closing price of the Shares as stated in the Stock Exchange’s daily quotations sheets for the five business days immediately preceding the date of grant.

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7. Options granted to connected persons

- (i) Any grant of options under the [REDACTED] Share Option Scheme to a director, chief executive or substantial shareholder of the Company or any of their respective associates must be approved by the independent non-executive Directors (excluding any independent non-executive Director who is a participant of the [REDACTED] Share Option Scheme and has accepted an offer of a grant of an option).
- (ii) Where any grant of options to an independent non-executive Director or a substantial shareholder of the Company or any of their respective associates would result in the Shares issued and to be issued in respect of all options and awards granted (excluding any options lapsed in accordance with the terms of the [REDACTED] Share Option Scheme) under the [REDACTED] Share Option Scheme and any other schemes of the Company to such person in the 12-month period up to and including the date of such grant representing in aggregate over 0.1% of the Shares in issue, such further grant of options must be approved by the Shareholders at a general meeting of the Company, with voting to be taken by way of poll. The Company shall send a circular to the Shareholders containing all information as required under the Listing Rules in this regard. The grantee, his/her associates and all core connected persons (as defined in the Listing Rules) of the Company shall abstain from voting (except where any core connected person intends to vote against the proposed grant and his/her intention to do so has been stated in the aforesaid circular). Any change in the terms of an option granted to a substantial shareholder of the Company or an independent non-executive Director or any of their respective associates is also required to be approved by Shareholders in the aforesaid manner.

8. Restriction of grant of options

No option shall be offered or granted:

- (a) to any Eligible Participant after a price sensitive event has occurred or a price sensitive matter has been the subject of a decision, until (and including) the trading day after the relevant price sensitive or inside information has been announced in accordance with the applicable provisions of law or the Listing Rules;
- (b) to any Eligible Participant during the period commencing one month immediately before the following (whichever is earlier):
 - (i) 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 the Company's annual, quarterly (if any) or half-yearly results; and
 - (ii) the deadline for the Company to publish an announcement of its annual, quarterly (if any) or half-yearly results;

and ending on the date of the results announcement. No option shall be granted during any period of delay in the publication of a results announcement.

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- (c) to any Director (except where the Subscription Price is to be determined by the Board or a duly authorized committee thereof 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
 - (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.

9. 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 expiry of the periods or the occurrence of the relevant event referred to in paragraphs 12 and 13 below;
- (c) subject provided in the [REDACTED] Share Option Scheme, the date of the commencement of the winding-up of the Company;
- (d) the date on which the grantee commits a breach of relevant clauses that rights are personal to the grantee; or
- (e) 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.

10. Voting and dividend rights

No grantee shall enjoy any of the rights of a Shareholder (including but not limited to voting rights or any other rights attached to a Share) by virtue of the grant of an option pursuant to the [REDACTED] Share Option Scheme, unless and until the registration of the grantee (or such other person as may succeed to the grantee's title by operation of applicable laws and in compliance with the terms of the [REDACTED] Share Option Scheme) as the holder thereof.

For the avoidance of doubt, the trustee holding unvested Shares under the [REDACTED] Share Option Scheme, whether directly or indirectly, shall abstain from voting on matters that require shareholders' approval under the Listing Rules, unless otherwise required by law to vote in accordance with the beneficial owner's direction and such a direction is given.

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11. Effects of alterations in the capital structure of our Company

In the event of a capitalization issue, rights issue, [REDACTED] or consolidation of Shares or reduction of capital of the Company whilst an option remains exercisable, such corresponding adjustment (if any) certified by the auditors for the time being or an independent financial advisor to the Company as fair and reasonable will be made to (a) the number of Shares to which the option relates, so far as unexercised, and/or (b) the Subscription Price of any unexercised option, provided that (i) any such alteration shall give a grantee the same proportion of the issued share capital (rounded to the nearest whole Share) to which the grantee was entitled prior to such alteration; (ii) any such adjustments shall be made on the basis that the aggregate Subscription Price payable by a grantee on the full exercise of any option shall remain as nearly as possible the same as it was before such event; and (iii) no adjustment shall be made the effect of which would be to enable a Share to be issued at less than its nominal value. In addition, in respect of any such adjustments, other than any adjustment made on a capitalization issue, such auditors or independent financial advisor must confirm to the Board in writing that the adjustments comply with the relevant provisions of the Listing Rules (or any guideline or supplementary guideline as may be issued by the Stock Exchange from time to time).

12. Rights on ceasing employment, death, or dismissal

- (i) In the event a grantee ceases to be an Eligible Participant for any reason other than death, or termination of his/her employment, directorship, office, appointment or engagement on one or more of the grounds referred to in sub-paragraph (iii) below, the grantee may exercise the option up to his/her entitlement at the date of cessation (to the extent which has become exercisable and not already exercised) within the period of one month following the date of such cessation.
- (ii) In the event a grantee ceases to be an Eligible Participant by reason of his/her death, before exercising the option in full and none of the event which would be a ground for termination of the grantee's employment, directorship, office, appointment or engagement under sub-paragraph (iii) below, his/her legal personal representative(s), or, as appropriate, the grantee may exercise the option (to the extent which has become exercisable but not already exercised) in whole or in part within a period of six months following the date of death of the grantee.
- (iii) In the event a grantee ceases to be an Eligible Participant and ceases to be an Eligible Participant by reason of summary termination of his/her employment, directorship, office, appointment or engagement on any one or more of the grounds that he/she has been guilty of misconduct or has been convicted of any criminal offence involving his/her integrity or honesty or (if so determined by the Board) on any other ground on which the relevant company in the Group would be entitled to terminate his/her employment, directorship, office, appointment or engagement

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summarily at common law or pursuant to any applicable laws or under the grantee's service contract, his/her option will lapse automatically on the date of cessation of his/her employment, directorship, office, appointment or engagement with the Group.

13. 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 declared unconditional, the grantee (or his/her legal personal representative(s)) shall be entitled to exercise the grantee's outstanding entitlement in full at any time within 14 days after the date on which such general offer becomes or is declared unconditional.

14. 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 entitlement, 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 entitlement 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 transferred 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.

15. Ranking of Shares

The Shares underlying the options 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.

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16. 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 the [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.

17. 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 at any time (but not so as to affect adversely any rights which have accrued to any grantee at that date).

Any alterations to the terms and conditions of the [REDACTED] Share Option Scheme which are of a material nature and among others, as to all such matters set out in Rule 17.03 of the Listing Rules, shall be subject to the approval of the Shareholders in general meeting and, where required under the Listing Rules, the Stock Exchange. Any change to the terms of any options granted to an Eligible Participant must be approved by the Board, the independent non-executive Directors and/or the Shareholders (as the case may be) if the initial grant of the options was approved as such (as the case may be).

18. Cancellation of options

Any cancellation of options granted may be effected on such terms as may be agreed with the relevant grantee, as the Board may in its absolute discretion sees fit and in a manner that complies with all applicable legal requirements for such cancellation. Where the Company cancels options granted to a participant and makes a new grant to the same participant, such new grant may only be made under the [REDACTED] Share Option Scheme with available Scheme Mandate Limit approved by the Shareholders. The options cancelled will be regarded as utilized for the purpose of calculating the Scheme Mandate Limit.

19. Malus and clawback

The Board may, at its absolute discretion, determine such malus and/or clawback provisions to be applied to an option or an offer of grant so as to provide, upon the occurrence of the applicable malus and/or clawback event(s) such as serious misconduct, a material misstatement in the Company's financial statements and fraud. If the Board exercises its discretion under this paragraph, it will give the relevant grantee written notice of such determination and the Board's interpretation of and determination pursuant to this paragraph shall be final, conclusive and binding.

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20. Termination

The Company by 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 prior to such termination shall continue to be valid and exercisable in accordance with the terms 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 [REDACTED].

22. General

As of the Latest Practicable Date, no option had been granted or agreed to be granted under the [REDACTED] Share Option Scheme.

Application has been made to the Listing Committee for the [REDACTED] of, and permission to deal in, the Shares which may fall to be issued pursuant to the exercise of the options to be granted under the [REDACTED] Share Option Scheme.

F. 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

So far as our Directors are aware, no litigation or claim of material importance is pending or threatened against any member of our Group.

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3. Sole Sponsor

The Sole Sponsor has 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 issued to the ESOP Trusts for the purpose of the [REDACTED] Share Option Scheme and the Shares issued upon conversion of Preferred Shares) and to be issued pursuant to (i) the [REDACTED], (ii) the [REDACTED] and (iii) the [REDACTED] Share Option Scheme.

The Sole Sponsor satisfies the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules. The Sole Sponsor will receive a fee of US\$500,000 for acting as a sponsor for the [REDACTED].

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
China International Capital Corporation Hong Kong Securities Limited	Licensed corporation to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 4 (advising on securities), Type 5 (advising on futures contracts) and Type 6 (advising on corporate finance) regulated activities as defined under the SFO
KPMG	Certified Public Accountants Public Interest Entity Auditor registered in accordance with the Accounting and Financial Reporting Council Ordinance
Jingtian & Gongcheng	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

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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.

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 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; and
 - (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.
- (b) Save as disclosed 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

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- (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.
- (c) None of our Directors or proposed Directors or experts (as named in this document) has 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.

**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 (i) a copy of the [REDACTED], (ii) the written consents referred to in “F. Other Information – 4. Consents of Experts” in Appendix IV, and (iii) copies of each of the material contracts referred to in “B. Further Information about our Business – 1. Summary of Material Contracts” in Appendix IV.

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.laekna.com during a period of 14 days from the date of this document:

- (a) the Memorandum and the Articles of our Company;
- (b) the Accountants’ Report from KPMG, the report from KPMG relating to the [REDACTED], the texts of which are set out in Appendices I and II;
- (c) the audited consolidated financial statements of our Group for the two financial years ended December 31, 2021 and 2022;
- (d) the PRC legal opinion issued by Jingtian & Gongcheng, our PRC Legal Adviser in respect of certain general corporate matters of our Group;
- (e) the letter of advice prepared by Harney Westwood & Riegels, our legal adviser on Cayman Islands law, summarizing the constitution of our Company and certain aspects of the Cayman Companies Act referred to in Appendix III;
- (f) the industry report prepared by Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.;
- (g) the material contracts referred to under the section headed “B. Further Information about our Business – 1. Summary of Material Contracts” in Appendix IV;
- (h) the service agreements and the letters of appointment with our Directors referred to in “C. Further Information about our Directors – 1. Particulars of Directors’ Service Contracts and Appointment Letters” in Appendix IV;
- (i) the written consents referred to under the section headed “F. Other Information – 4. Consents of Experts” in Appendix IV;

**APPENDIX V DOCUMENTS DELIVERED TO THE REGISTRAR
OF COMPANIES AND AVAILABLE ON DISPLAY**

- (j) the terms of the [REDACTED] Share Option Scheme; and
- (k) the terms of the [REDACTED] Share Option Scheme.

DOCUMENT AVAILABLE FOR INSPECTION

A copy of a list of grantees under the [REDACTED] Share Option Scheme, 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 10th Floor, 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.