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 14 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 174 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.

	Drug Candidate	Target Mechanism	Indications	Lead Discovery / Proof of Mechanism / CMC IND Enabling / Phase I / Phase II	Commercial Rights	Upcoming Major Milestones	Licensor/Partner
Cancer	LAE002 ★ + Paclitaxel	AKT + Chemotherapy	PROC (second- to sixth-line treatment)	MRCT (U.S. and China) | Registrational[1]	Global	NDA submission with the FDA and NMPA in 4Q 2023	NOVARTIS
	LAE002 ★ + LAE001 + Prednisone	AKT + CYP17A	mCRPC following SOC Treatment (second- to fourth-line treatment)	MRCT (U.S. and South Korea)[2]		Phase III initiation in 2H 2023	NOVARTIS
	LAE002 ★ + Sintilimab + Chemotherapy	AKT + PD-1 + Chemotherapy	PD-1/PD-L1 Resistant Solid Tumors	[3]		Phase I read-out in 4Q 2023	NOVARTIS innovent
	LAE002 ★ + LAE005 + Nab-Paclitaxel	AKT + PD-L1 + chemotherapy	TNBC (second- to third-line treatment)	[4]		Phase I read-out in 4Q 2023	NOVARTIS
	LAE002 ★ + Fulvestrant	AKT + ER	Locally Advanced or Metastatic HR+/HER2-Breast Cancer (second- to third-line treatment)	MRCT (U.S. and China) [5]		NDA submission with the FDA and NMPA in 2H 2025	NOVARTIS
	LAE001 ★	CYP17A/CYP11B2	mHSPC (first-line treatment)	[6]		Phase II read-out in 3Q 2023	NOVARTIS
	LAE102[8]	ActRIIA	Cancer			Phase I initiation in the U.S. in 1H 2024	
	LAE109	NK / T regulator	Cancer			IND application with FDA or NMPA by 4Q 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	
	LAE118	Oncogenic signaling	Cancer			IND application with FDA or NMPA by 2025	
	LAE119	Synthetic lethality	Cancer			IND application with FDA or NMPA by 4Q 2024	
	LAE120	Synthetic lethality	Cancer			IND application with FDA or NMPA by 4Q 2024	
Liver Fibrosis	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 TGFß blocker	Liver Fibrosis			IND application with FDA or TGA by 2025	
Rare Disease	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

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 completed the patient recruitment in both the U.S. and South Korea in March 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 completed the recruitment of patients for the Phase Ib study in April 2023, and plan to 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.

(8) We obtained the IND approval of LAE102 in May 2023.

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

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. As a dual CYP17A1/CYP11B2 inhibitor, LAE001 can block both androgen and aldosterone synthesis and potentially be administrated without prednisone, the short-term high dose or long-term exposure of which can lead to a variety of 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 expected 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 expected 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.

Drug Candidates	Highlights
LAE102	LAE102 is our most advanced internally discovered drug candidate for cancer treatment. It is a potentially potent and selective activin receptor type IIA (ActRIIA) monoclonal antibody (mAb) that has demonstrated anti-tumor activity and ability to increase the bodyweight of cancer-bearing animals in pre-clinical animal models. We obtained the IND approval of LAE102 in May 2023, and plan to initiate the Phase I trial in the U.S. in the first half of 2024.
LAE105	LAE105 is our most advanced internally discovered drug candidate for liver fibrosis treatment, which is expected to target 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 with or without bevacizumab or PARP inhibitor. 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 as a late line (second- to sixth-line) treatment compared with SOC of ovarian cancer that consists of debulking surgery and platinum-based chemotherapy with or without bevacizumab or PARP inhibitor.

- 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 as a second- to fourth-line treatment 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) with or without immune checkpoint inhibitors (ICIs) as first- and second-line treatment. 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 that are resistant to first- and second-line treatment therapies of endocrine/anti-estrogen therapies with CDK4/6 inhibitors for HR+/HER2- mBC or systemic therapies (chemotherapies) with or without ICIs for TNBC, LAE002 represents a potential new option as a second- to third-line treatment.

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 LAE002's preclinical data as well as with reference to the then available published clinical trial data of other AKT inhibitor candidates, 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.

	Projected addressable patient pool in 2030		
LAE002 indication	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

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 April 30, 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 HSPC (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 April 30, 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	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 Maintenance therapy of platinum-sensitive recurrent ovarian cancer Patients with BRCA-mutated metastatic castration-resistant prostate cancer	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 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	**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**	Metastatic colorectal cancer, with intravenous 5-fluorouracil–based chemotherapy for first- or second-line treatment. Glioblastoma, as a single agent for adult patients with progressive disease following prior therapy. Non-squamous non-small cell lung cancer, with platinum-based chemotherapy for first line treatment of unresectable, locally advanced, recurrent or metastatic disease Combination of atezolizumab (Tecentriq) plus bevacizumab (Avastin) for use in patients with advanced or unresectable hepatocellular carcinoma (HCC) 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 In combination with paclitaxel and cisplatin or paclitaxel and topotecan for the treatment of patients with persistent, recurrent or metastatic cervical cancer
China NRDL inclusion	Category B	Category B	Category B	Category B
China NRDL indications	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 Maintenance therapy of platinum-sensitive recurrent ovarian cancer	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 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	**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**	Metastatic colorectal cancer, with intravenous 5-fluorouracil–based chemotherapy for first- or second-line treatment. Glioblastoma, as a single agent for adult patients with progressive disease following prior therapy. Non-squamous non-small cell lung cancer, with platinum-based chemotherapy for first line treatment of unresectable, locally advanced, recurrent or metastatic disease Combination of atezolizumab (Tecentriq) plus bevacizumab (Avastin) for use in patients with advanced or unresectable hepatocellular carcinoma (HCC)
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

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	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 mHSPC PFS:NA)	14.1 (mHSPC 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, HSPC	CRPC, mHSPC	mHSPC, nmCRPC	nmCRPC, mHSPC	NA
China approval time	2003	1999	Not approved	2015	2019	2019	2021	2022
NMPA approved indications	Prostate cancer	Late stage Prostate cancer	NA	mCRPC, mHSPC	mCRPC, nmCRPC	nmCRPC, mHSPC	nmCRPC, mHSPC	mHSPC
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 (mHSPC 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 April 30, 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 April 30, 2023.

Source: NMPA, FDA, Frost & Sullivan analysis.

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	HSPC, 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 April 30, 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 April 30, 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

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) although abiraterone acetate (a CYP17A1 inhibitor) has already been approved and we do not expect to apply for the NDA of LAE001 until 2027, 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; (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

- Deep understanding into fundamental disease biology and clinical practice that empowers our internal discovery, business development and translational research

- Integrated operations 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 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 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, our most advanced internally discovered drug candidate for cancer treatment, is a potentially potent and selective ActRIIA mAb 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 is expected to target 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 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 58 employees, including 16 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.

INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we held 174 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, Kazakstan	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

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 17 registered trademarks 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.

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. 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.

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.

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.

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 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**], 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 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

The table below sets forth summary of our consolidated statements of profit or loss 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	(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)**

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**]. 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 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**
	RMB'000	*RMB'000*
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 April 30, 2023, our current assets and current liabilities were RMB234.9 million and RMB74.5 million, respectively.

We recorded net liabilities of RMB1,111.2 million and RMB1,905.1 million as of December 31, 2021 and 2022, respectively. The increase in our net liabilities was primarily due to the total comprehensive loss of RMB902.2 million, which was driven by the expanded research and development activities and fair value changes on financial instruments issued to investors, and partially offset by increased equity from shares issued upon exercise of the warrant of RMB81.8 million as well as equity settled share-based payment of RMB26.5 million. Our financial instruments issued to investors that we recorded as financial liabilities in relation to our Preferred Shares reached 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 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**
	RMB'000	*RMB'000*
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	**296,412**	**323,070**

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.

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 1.5 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 the six months ended June 30, 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 8.4 months, or, if we taking into account the estimated net [**REDACTED**] (based on the [**REDACTED**] of HK$[**REDACTED**] per [**REDACTED**]) from the [**REDACTED**], for at least 25.9 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.

Please see "Financial Information – Discussion of Certain Selected Items From the Consolidated Statements of Financial Position – Other Payables."

[**REDACTED**]

[**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.

USE OF [REDACTED]

We estimate that we will receive net [**REDACTED**] from the [**REDACTED**] of approximately HK$[**REDACTED**], after deducting [**REDACTED**] commissions, fees and estimated expenses payable by us in connection with the [**REDACTED**], at the [**REDACTED**] of HK$[**REDACTED**] per Share.

(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 our 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**]".

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.

- 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 complete response letter ("CRL") by the FDA and it may negatively affect our overseas development and commercialization of combination therapies involving sintilimab globally. For more information regarding CRL, please see "Regulatory Overview – U.S. Review and Approval Processes."

- 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.

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

- We 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**] 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, 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**]-related expenses, including [**REDACTED**] commission and other expenses, of RMB[**REDACTED**]; and (ii) non-[**REDACTED**]-related 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.

RECENT DEVELOPMENTS

Impact of the COVID-19 Outbreak

The COVID-19 pandemic and its recurrence have caused temporary disruption to our certain aspects of our operations, including clinical development, which had a negative impact on our operations during the Track Record Period. As of the Latest Practicable Date, however, COVID-19 did not impose any material adverse impact on our clinical development, daily operation, supply chain and regulatory affairs. Given that the PRC government has substantially lifted its COVID-19 prevention and control policies since December 2022, our Directors are of the view that it is unlikely that the COVID-19 pandemic will have a material adverse impact on our business going forward.

Overseas Listing

On February 17, 2023, the CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Enterprises (《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 five supporting guidelines, which became effective on March 31, 2023. Pursuant to the Overseas Listing Trial Measures, PRC domestic enterprises that directly or indirectly offer or list their securities in an overseas market, which include (i) any PRC company limited by shares, and (ii) any offshore company that conducts its business operations primarily in China and contemplates to offer or list its securities in an overseas market based on its onshore equities, assets or similar interests, are required to file with the CSRC within three business days after its application for overseas listing is submitted.

On the same date, the CSRC promulgated the Notice on the Arrangement for the Filing-based Administration of Overseas Securities Offering and Listing by Domestic Enterprises (《關於境內企業境外發行上市備案管理安排的通知》) (the "**Arrangement for Filing-based Administration**") which, among others, clarifies that (1) the domestic enterprises that have already been listed overseas before the effective date of the Overseas Listing Trial Measures (i.e., March 31, 2023) shall be deemed as existing applicants (存量企業) (the "**Existing Applicants**"). Existing Applicants 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; (2) a six-month transition period will be granted to domestic enterprises which, prior to the effective date of the Overseas Listing Trial Measures, have already passed the hearing for a contemplated offering and/or listing in Hong Kong, and such domestic enterprises complete their overseas offering and listing within such six-month transition period (i.e., before September 30, 2023), they will be deemed as Existing Applicants. Within such six-month transition period, however, if such domestic enterprises need to re-perform the overseas regulatory procedures for overseas securities offering and listing, or fail to complete their indirect overseas offering and listing, such domestic enterprises shall complete the filing procedures with the CSRC; (3) for applicants who have received approval from the CSRC for a direct overseas listing, they may continue to pursue the overseas listing during the validity period of the approval. Those who have not completed the overseas offering and listing upon the expiry of the approval period shall file with the CSRC as required.

We have passed the hearing before [**REDACTED**] and if our [**REDACTED**] can be completed before [**REDACTED**], as advised by our PRC Legal Advisor, we will not be required to file with the CSRC with respect to this [**REDACTED**]. In addition, the future [**REDACTED**] or [**REDACTED**] of our securities in an overseas market will be subject to the above-mentioned regulations, and if we fail to make the required filings, our ability to conduct such [**REDACTED**] or [**REDACTED**] will be limited. Please see "Risk Factors – Risks Relating to Doing Business in China – We may be required to complete filing procedures with the CSRC for the [**REDACTED**] and [**REDACTED**] of our Shares on the Hong Kong Stock Exchange."

Expected Loss

We expect that we will continue to incur loss for the year ending December 31, 2023, primarily from (i) increasing expenses for clinical development and pre-clinical research and (ii) [**REDACTED**] expenses. All of our Preferred Shares will be automatically and irrevocably converted into the Shares upon [**REDACTED**], after which we do not expect to recognize any further loss or gain on the fair value changes of financial instruments issued to investors.

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.