As confidentially submitted to the Securities and Exchange Commission on April 13, 2023

Registration No. 377-06518

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM F-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Adlai Nortye Ltd.

(Exact name of Registrant as specified in its charter)

Cayman Islands	**2834**	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

Adlai Nortye Ltd.
c/o PO Box 309, Ugland House
Grand Cayman, KY1-1104
Cayman Islands
Telephone: 848 230 7430

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Adlai Nortye USA INC
New Jersey Biotechnology Development Center,
685 US Hwy 1, 2nd floor, North Brunswick Township, NJ 08902
Telephone: 848 230 7430

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Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

PRELIMINARY PROSPECTUS (Subject to Completion)

Dated , 2023.

American Depositary Shares

Adlai Nortye Ltd.

Representing Class A Ordinary Shares

This is an initial public offering of American depositary shares, or ADSs, representing Class A ordinary shares of Adlai Nortye Ltd. We are offering a total of ADSs. Each ADS represents of our Class A ordinary shares, par value US$0.0001 per share. The underwriters may also purchase up to ADSs within 30 days from the date of this prospectus.

Prior to this offering, there has been no public market for the ADSs or our Class A ordinary shares. We anticipate the initial public offering price per ADS will be between US$ and US$. We intend to apply for the listing of the ADSs on the Nasdaq Stock Market under the symbol "ANL." At this time, the Nasdaq Stock Market has not yet approved our application to list the ADSs. The closing of this offering is conditioned upon the Nasdaq Stock Market 's final approval of our listing application, and there is no guarantee or assurance that the ADSs will be approved for listing on the Nasdaq Stock Market.

Immediately prior to the completion of this offering, our issued and outstanding share capital will consist of Class A ordinary shares and Class B ordinary shares. Holders of Class A ordinary shares and Class B ordinary shares have the same rights except for voting and conversion rights. Each Class A ordinary share will be entitled to one vote, and each Class B ordinary share shall be entitled to 15 votes on all matters subject to a vote at general meetings of our company. Each Class B ordinary share shall be convertible into Class A ordinary share at any time at the option of the holder thereof. Class A ordinary shares shall not be convertible into Class B ordinary shares under any circumstances.

Additionally, upon the completion of this offering, we will be a "controlled company" as defined under corporate governance rules of Nasdaq Stock Market, because Mr. Yang Lu will beneficially own % of our then-issued and outstanding Class B ordinary shares and will be able to exercise % of the total voting power of our issued and outstanding ordinary shares immediately after the consummation of this offering, assuming the underwriters do not exercise its option to purchase additional ADSs. For further information, see "Principal Shareholders" and "Risk Factors — Risks related to the ADSs — We will be a "controlled company" within the meaning of the Nasdaq Stock Market listing rules and, as a result, may rely on exemptions from certain corporate governance requirements that provide protection to shareholders of other companies."

Adlai Nortye Ltd. is not a Chinese operating company, but is a Cayman Islands holding company. Our daily operations are conducted primarily through our operating subsidiaries in the United States and mainland China. Investors purchasing the ADSs in this initial public offering are purchasing equity securities of our Cayman Islands holding company and are not purchasing equity securities of our operating subsidiaries. As a holding company, we may rely on dividends from our subsidiaries for our cash requirements, including any payment of dividends to our shareholders. The ability of our subsidiaries to pay dividends to us, however, may be restricted by the debt they incur on their own behalf and/or laws and regulations applicable to them. Unless otherwise indicated or the context otherwise requires, "we," "us," "our company," and "our" refer to Adlai Nortye Ltd., our Cayman Islands holding company and its subsidiaries, which include those in the U.S. and mainland China that conduct daily operations.

If needed, cash can be transferred between our Cayman Islands holding company and subsidiaries incorporated in the United States, mainland China and Hong Kong through equity investments and intercompany loans. Currently, there are no restrictions of transferring funds between our Cayman Islands holding company and subsidiaries in the United States and Hong Kong; however, currency exchange control measures imposed by the PRC government may restrict the ability of our subsidiaries in the PRC to transfer their cash to our Cayman Islands holding company and other subsidiaries incorporated outside the PRC through loans, advances or cash dividends. See Note 27 to our consolidated financial statements for a detailed discussion. We may also make loans and additional capital contribution to our subsidiaries or branches, subject to certain restrictions under the applicable local laws, including the laws of China. We have no plans to declare cash dividends in the near term, but as a holding company, we may depend on receipt of funds from one or more of our subsidiaries if we determine to pay cash dividends to holders of our ordinary shares and ADSs in the future. We do not have a regular dividend policy, and our Board of Directors has discretion as to whether to distribute dividends, subject to certain requirements of Cayman Islands law. As of the date of this prospectus, our Cayman Islands holding company has not declared or paid any dividends or distributions on equity to its shareholders. See "Prospectus Summary — Cash transfers and dividend distributions" for the summary of our cash transfers and dividend distributions.

Pursuant to the Holding Foreign Companies Accountable Act, or the HFCAA, the Public Company Accounting Oversight Board, or the PCAOB, issued a Determination Report in December 2021 which found that the PCAOB is unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong because of positions taken by the authorities in those jurisdictions. Our auditor, which is based in New York, is currently subject to inspection by the PCAOB at least every two years. However, our auditor's China affiliate is located in, and organized under the laws of, the PRC. On August 26, 2022, the PCAOB entered into a Statement of Protocol with the China Securities Regulatory Commission and the Ministry of Finance of the PRC and, as summarized in the "Statement on Agreement Governing Inspections and Investigations of Audit Firms Based in China and Hong Kong" published on the U.S. Securities and Exchange Commission's official website, the parties agreed to the following: (i) in accordance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the PCAOB shall have independent discretion to select any issuer audits for inspection or investigation; (ii) the PCAOB shall have direct access to interview or take testimony from all personnel of the audit firms whose issuer engagements are being inspected or investigated; (iii) the PCAOB shall have the unfettered ability to transfer information to the SEC, in accordance with the Sarbanes-Oxley Act; and (iv) the PCAOB inspectors shall have access to

complete audit work papers without any redactions, with view-only procedures for certain targeted pieces of information such as personally identifiable information. On December 15, 2022, the PCAOB issued a report that vacated its December 16, 2021 determination and removed mainland China and Hong Kong from the list of jurisdictions where it is unable to inspect or investigate completely registered public accounting firms. On December 29, 2022, legislation entitled "Consolidated Appropriations Act, 2023" (the "Consolidated Appropriations Act"), was signed into law by President Joseph Biden of the United States. The Consolidated Appropriations Act contained, among other things, an identical provision to Accelerating Holding Foreign Companies Accountable Act, which reduces the number of consecutive non-inspection years required for triggering the prohibitions under the HFCAA from three years to two. Each year, the PCAOB will determine whether it can inspect and investigate completely audit firms in mainland China and Hong Kong, among other jurisdictions. We cannot assure you that we will not be identified by the SEC under the HFCAA as an issuer that has retained an auditor that has a branch or office located in a foreign jurisdiction that the PCAOB determines it is unable to inspect or investigate completely because of a position taken by an authority in that foreign jurisdiction. In addition, there can be no assurance that, if we have a "non-inspection" year, we will be able to take any remedial measures. If any such event were to occur, trading in our securities could in the future be prohibited under the HFCAA and, as a result, we cannot assure you that we will be able to maintain the listing of the ADSs on the Nasdaq Stock Market or that you will be allowed to trade the ADSs in the United States on the "over-the-counter" markets or otherwise. Should the ADSs become not listed or tradeable in the United States, the value of the ADSs could be materially affected. See "Risk Factors — Risks relating to our operation in the People's Republic of China" for a detailed discussion.

We are an "emerging growth company" under the applicable U.S. federal securities laws and are eligible for reduced public company reporting requirements. See "Risk Factors" beginning on page 19 for factors you should consider before buying the ADSs.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

We face various legal and operational risks and uncertainties relating to our operation in China. We have substantial business operations located in mainland China and are subject to complex and evolving PRC laws and regulations. Recently, the PRC government has indicated an intent to exert more oversight and control over offerings that are conducted overseas and/or involve foreign investment in China-based issuers, and initiated a series of regulatory actions and made a number of public statements, some of which are published with little advance notice, including stringent enforcement against illegal activities in the securities market, enhancing supervision over China-based companies listed overseas, adopting new measures to extend the scope of cybersecurity reviews, and expanding efforts in anti-monopoly enforcement. We may be subject to the approval, filing or other requirements of the China Securities Regulatory Commssion, or the CSRC, or other PRC governmental authorities in connection with this Offering under current PRC laws, regulations and rules. However, we do not believe that approval of the cybersecurity review of the Cyberspace Administration of China, or the CAC is required in connection with this Offering under current PRC laws, regulations and rules at this stage, as we have not processed, and do not anticipate to process in the foreseeable future, personal information of more than one million users or persons and the data we handle in our business operations, either by its nature or in scale, does not normally trigger significant concerns over PRC national security. However, we cannot affirm that PRC regulators share the same interpretation. Because these statements and regulatory actions are new and subject to change, it is highly uncertain how quickly the legislative or administrative regulation making bodies in China will respond to them, or what existing or new laws or regulations will be amended or promulgated, if any, or the potential impact such amended or new legislation will have on our daily business operations or our ability to accept foreign investments and list on a U.S. stock exchange. For risks relating to approval of the CSRC, the oversight of the CAC, and other PRC government authorities, please refer to "Risk Factors — Risks relating to our operation in the People's Republic of China." Uncertainties in the PRC legal system and the interpretation and enforcement of PRC laws and regulations could limit the legal protections available to you and us, hinder our ability to offer or continue to offer the ADSs, result in a material adverse effect on our business operations, and damage our reputation, which might further cause the ADSs to significantly decline in value or become worthless.

PRICE US$ PER ADS

	Per ADS	Total
Initial public offering price	US$	US$
Underwriting discounts and commissions[(1)]	US$	US$
Proceeds, before expenses, to us	US$	US$

(1) See "Underwriting" for additional information regarding total underwriter compensation.

The underwriters expect to deliver the ADSs to purchasers on or about , 2023.

Cantor **CLSA**

Prospectus Dated , 2023.

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TABLE OF CONTENTS

Through and including , 2023 (the 25th day after the date of this prospectus), all dealers that effect transactions in these ADSs, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

You should rely only on the information contained in this prospectus or in any free writing prospectus that we authorize to be distributed to you. We and the underwriters have not authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you, and neither we, nor the underwriters, take responsibility for any other information others may give you. We are offering to sell, and seeking offers to buy the ADSs, only in jurisdictions where such offers and sales are permitted. The information in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or the time of any sale of the ADSs. Our business, financial condition, results of operations, and prospects may have changed since that date.

Neither we nor any of the underwriters has taken any action to permit a public offering of the ADSs outside the United States or to permit the possession or distribution of this prospectus or any filed free writing prospectus outside the United States. Persons outside the United States who come into possession of this prospectus or any filed free writing prospectus must inform themselves about and observe any restrictions relating to the offering of the ADSs and the distribution of the prospectus or any filed free writing prospectus outside the United States.

PROSPECTUS SUMMARY

The following summary is qualified in its entirety by, and should be read in conjunction with, the more detailed information and financial statements appearing elsewhere in this prospectus. In addition to this summary, we urge you to read the entire prospectus carefully, especially the risks of investing in the ADSs discussed under "Risk Factors" before deciding whether to invest in the ADSs.

Overview

We are a global clinical-stage biotechnology company focused on the discovery and development of innovative cancer therapies for patients across the spectrum of tumor types. Our mission is to transform deadly cancer into a chronic and eventually curable disease. We are now developing multiple innovative antitumor drug candidates by leveraging our deep knowledge in cancer biology, as well as significant global R&D and clinical execution capabilities. These drug candidates are currently undergoing clinical trials, and in many cases, in collaboration with multinational pharmaceutical companies to fully realize their commercialization potential on a global scale. Our combination therapy strategy is directed towards systematically activating the immune system through a combination of multiple drugs, aiming to enhance the clinical benefit by achieving superior efficacy and safety while overcoming drug resistance.

We have identified seven drug candidates and have developed a robust pipeline of drug candidates. Currently, our pipeline includes three clinical-stage drug candidates, buparlisib (AN2025), palupiprant (AN0025), and AN4005, as well as four preclinical candidates. Our most advanced program is our lead product AN2025, a pan-phosphoinositide 3-kinase ("PI3K") inhibitor that is designed to act against solid tumors. AN2025 is currently undergoing a Phase III, multi-regional, randomized, open-label clinical trial for the treatment of recurrent or metastatic head and neck squamous cell carcinomas ("HNSCC") after anti-programmed death-1 ("PD-1") or its ligand ("PD-L1") treatment in more than 180 sites in 18 jurisdictions covering North America, Europe, Asia, and South America. We believe that AN2025, if approved, has the potential to be first-to-market, and is currently the only drug candidate in active Phase III clinical trial targeting recurrent or metastatic HNSCC patients after progression on prior anti-PD-1/PD-L1 therapy, potentially addressing a global unmet medical need.

We are collaborating with MSD International GmbH, or MSD, to evaluate AN0025, a small molecule prostaglandin E receptor 4 ("EP4") antagonist. It is currently being developed to modulate the tumor microenvironment in combination with Keytruda or pembrolizumab, in a Phase Ib clinical trial for the treatment of recurrent non-small cell lung cancer ("NSCLC") and urothelial cancer after anti-PD-1/PD-L1 treatments, recurrent triple-negative breast cancer ("TNBC"), microsatellite stable colorectal cancer ("MSS CRC") and cervical cancer after standard of care treatments in the U.S. and France. In addition, a Phase I clinical trial has been initiated for a combination therapy consisting of AN2025, AN0025, and Tecentriq or atezolizumab targeting a variety of PIK3CA mutant solid tumors. The atezolizumab used in this clinical trial is supplied by F. Hoffman La Roche Ltd or Roche. This triple combination is expected to target the PI3K mediated tumorigenesis while inhibiting the immunosuppressive tumor microenvironment through multiple non-overlapping mechanisms, leading to synergistic action for tumor regression. AN4005, which is currently being studied in a Phase I clinical trial in the U.S. and China, is an internally discovered oral small molecule PD-L1 inhibitor in development to induce and stabilize PD-L1 dimerization and thereby disrupt the interaction between PD-1 and PD-L1.

Additionally, we continue to advance four in-house preclinical programs which we believe have high global commercial viability. We are performing investigational new drug ("IND") enabling studies for AN3025, an immune-stimulatory anti-tumor necrosis factor receptor 2 ("TNFR2") antibody, with a goal to submit an IND application in the second half of 2023. Our earlier preclinical candidates are: AN8025, a multifunctional antibody as T cell and antigen-presenting cell ("APC") modulator; AN1025, an oral small molecule degrader of β-catenin; and AN6025, an oral small molecule hematopoietic progenitor kinase 1 ("HPK1") inhibitor. We anticipate submitting the IND for AN8025 in the first half of 2024.

We believe the next frontier in cancer immunotherapy lies in the category of combination therapies. Our drug candidates combine an immune checkpoint inhibitor with two or more additional cancer therapies in effort to elicit synergistic anti-cancer effects and improved tolerability relative to monotherapies. As we endeavor to engender complementary and synergistic results across our portfolio, our primary consideration

is the potential interaction with our other pipeline candidates and/or currently available treatments. We strive to develop innovative antitumor candidates focusing on druggability as well as combinational strength to be leveraged in the next wave of immuno-oncology treatments, ultimately helping to shape the next-generation of cancer therapy.

Through our multi-national R&D centers established in New Jersey and Hangzhou, we execute on our global vision for drug development innovation. The geographic span of our R&D footprint empowers us to more effectively identify and develop novel early-stage programs, as well as recruit top R&D talent from the U.S. and China. We have assembled a management team and a scientific advisory board with industry leaders and influential scientists, who provide international and strategic guidance to our R&D, business development, and operational teams. In addition to building our own R&D capabilities, we continue to seek and secure partnerships with leading multi-national pharmaceutical companies such as Eisai Co., Ltd. or Eisai and Novartis Pharma AG or Novartis, to fully realize the potential of our pipeline programs. We believe our partnerships validate our clinical expertise and reflect belief in our ability to deliver on our development and commercialization capabilities across a versatile pipeline.

Our pipeline

We are advancing a robust pipeline of innovative drug candidates in various stages of development. The following chart provides an overview of the status of our drug candidates:

Abbreviations: MOA = Mechanism of Action; NDA = New Drug Application; TNBC = Triple Negative Breast Cancer; NSCLC = Non-Small Cell Lung Cancer; MSS CRC = Microsatellite Stable Colorectal Cancer; RP2D = Recommended Phase 2 Dose; IND: Investigational New Drug; PCC: Preclinical Candidate; POC: Proof of Concept.

AN2025: a pan-PI3K inhibitor aimed at becoming the vanguard for recurrent or metastatic HNSCC after anti-PD-1/PD-L1 therapy

Our lead product AN2025, the most clinically advanced drug candidate in our pipeline, is a pan-PI3K inhibitor currently undergoing a global Phase III trial. In-licensed from Novartis, we have the exclusive global rights to develop and commercialize AN2025. It is currently the only drug candidate we are aware of in active registrational clinical trial for the treatment of recurrent or metastatic HNSCC after disease progression with anti-PD-1/PD-L1 therapy. Although anti-PD-1/PD-L1 therapy is becoming first line treatment in patients with recurrent or metastatic HNSCC since its U.S. Food and Drug Administration ("FDA") approval in 2019, the current treatments are unable to meet the needs of HNSCC patients progressed on prior anti-PD-1/PD-L1 treatment. We believe that AN2025, if approved, has the potential to be the first product globally with such label to address this unmet medical need and capture the sizable addressable market.

AN2025 is a widely studied molecule with Novartis alone having sponsored 40 clinical trials on over 4,200 patients across a variety of cancers. These studies include a Phase II trial that demonstrated that the combination of AN2025 with paclitaxel achieved a superior median overall survival ("mOS"), and significant improvements in median progression-free survival ("mPFS") and overall response rate ("ORR") compared to the control group in recurrent or metastatic HNSCC after disease progression with platinum based

chemotherapy. In July 2016, AN2025 was granted Fast Track designation by the FDA for the treatment of recurrent or metastatic HNSCC with disease progression on or after platinum-based therapy. For the Phase III trial, we expect to enroll 483 patients in more than 180 sites around the world, spanning over 18 markets in North America, Europe, Asia, and South America. Leveraging the benefit of using ORR data from the planned Phase III interim analysis, we expect to submit the NDA to the FDA seeking a potential accelerated approval in the first half of 2024, followed by further marketing approval applications to National Medical Products Administration of People's Republic of China ("NMPA"), European Medicines Agency ("EMA"), Pharmaceuticals and Medical Devices Agency of Japan ("PMDA"), and other authorities.

AN0025: a tumor microenvironment modulator

AN0025, in-licensed from Eisai, is a small molecule EP4 antagonist designed to modulate the tumor microenvironment. It is designed to block the prostaglandin E2 ("PGE2")-EP4 signaling pathway to inhibit PGE2-mediated immunosuppression in cancer patients. In the CT26 murine colon cancer model, for those which are not responsive to anti-PD-1/PD-L1 therapy, AN0025 combined with an anti-PD-1 antibody treatment demonstrated stronger antitumor activity compared to each standalone compound. In June 2020, we initiated a Phase Ib clinical trial to evaluate the combination of AN0025 and pembrolizumab for the treatment of recurrent NSCLC and urothelial cancer after anti-PD-1/PD-L1 treatments, as well as recurrent TNBC, MSS CRC, and cervical cancer after standard of care treatments. As of December 31, 2022, we were in the dose expansion stage having enrolled 54 patients in the U.S. and France, and expect to obtain top-line results in the second half of 2023. We aim to identify specific cancer types sensitive to this combination based on the results and will proactively communicate with the regulatory authorities for the design of Phase II/III registrational trials.

Triple combination of AN2025, AN0025, and atezolizumab: an example of our combination therapy strategy

To fully explore the potential of AN2025 and AN0025, we initiated a study of the triple combination of AN2025, AN0025, and atezolizumab, an anti-PD-L1 antibody. This study exemplifies our combination therapy strategy to achieve synergistic effects from both targeted therapy and immunotherapy perspectives. AN2025 targets not only PI3K mediated tumorigenesis (e.g., via inhibition of PI3Kα / PIK3CA mutants) but also the immunosuppression of the tumor microenvironment (e.g., via inhibition of PI3Kδ and PI3Kγ). Leveraging the complementary and synergistic antitumor effects of our drug candidates in combination therapies, AN2025 is designed to mechanistically complement and synergize with the combination of anti-PD-1/PD-L1 and AN0025 to form an improved treatment regimen for patients with multiple advanced solid tumors. In different tumor-bearing mouse models, we have consistently observed significantly stronger antitumor activity in the triple combination of AN2025, AN0025, and atezolizumab compared with doublet combinations. In July 2021, we initiated a Phase I clinical trial to evaluate the triple combination of AN2025, AN0025, and atezolizumab, for a variety of PIK3CA mutant solid tumors. In September 2022, subsequent to the doublet arm dose-ranging studies, we initiated a dose-ranging study for the triple combination, and we expect to identify the recommended Phase II dose ("RP2D") in the second quarter of 2023.

AN4005: a backbone of our future oral combination therapies

AN4005, a drug candidate discovered in-house, is an oral small-molecule PD-L1 inhibitor designed to induce and stabilize PD-L1 dimerization and thereby disrupt the interaction between PD-1 and PD-L1. Compared to the crowded development of anti-PD-1/PD-L1 antibodies, with multiple brands already available to patients and many potential candidates in clinical trials, small-molecule PD-L1 inhibitors are underdeveloped and do not have a drug approved in any jurisdiction globally, despite advantages such as shorter half-life that may allow for dose titration and schedule modifications to minimize immune-related adverse events ("AEs") and lower production costs. In our preclinical studies, AN4005 was well tolerated and exhibited excellent tumor growth inhibition ("TGI") to an extent comparable to an approved anti-PD-L1 antibody, and promoted an adaptive immune response for antitumor activities. We received allowance to proceed under INDs from the FDA and NMPA for the treatment of advanced tumors in June 2021 and December 2021, respectively, dosed the first patient in January 2022, and expect to identify the RP2D from the Phase I clinical trial in the second half of 2023.

Our preclinical programs

We continue actively advancing four in-house preclinical programs which we believe have high global commercial viability. We are performing IND enabling studies for AN3025, an immune-stimulatory anti-TNFR2 antibody and aim to submit the IND in the second half of 2023. Our earlier preclinical candidates are: AN8025, a multifunctional antibody as T cell and APC modulator; AN1025, an oral small molecule degrader of β-catenin; and AN6025, an oral small molecule HPK1 inhibitor. We anticipate submitting the IND for AN8025 in the first half of 2024.

Our company history and team

We rebranded in 2016 as Adlai Nortye Biopharma and began development activities focusing on the discovery and development of innovative cancer therapies, after originally incorporating in 2004. We have assembled an experienced management team consisting of successful entrepreneurs and industry veterans. Largely, our success stems from management's leadership and industry expertise, covering the full spectrum of the cancer therapy development process, from design and execution of preclinical and clinical studies through the regulatory process and commercialization.

Our management team has more than 100 cumulative years of industry experience and a proven track record of innovative drug R&D, clinical development, and commercialization. Our founder, chief executive officer, and chairman of our board of directors, Mr. Yang Lu is a successful entrepreneur who brings expertise across the domains of business development, operations, and management. Our president, chief medical officer, and chief executive officer of our U.S. subsidiary, Dr. Lars Erik Birgerson, has extensive experience as a senior leader with numerous well-known companies in the biopharmaceutical industry, including Roche Pharmaceuticals, Genentech, and Bristol-Myers Squibb ("BMS"). Our senior vice president and global head of clinical operations, Dr. Kaiyang Tang, has deep experience in global clinical operations and regulatory affairs in the pharmaceutical industry, and has served as a clinical leader in a number of companies, including Generon (Shanghai) Corporation Ltd. and Hutchison MediPharma Ltd, a company triple listed on the Nasdaq, Hong Kong Stock Exchange, and Alternative Investment Market. Our senior vice president and global head of regulatory affairs, Dr. Victoria Elizabeth Demby, has over 20 years of industry experience and has served in various senior positions for several multinational pharmaceutical companies such as GSK, MSD, and BMS.

Since our inception, we have received strong support from our shareholders, including financial investors as well as several industry-leading strategic investors. This investor base is, and we expect will continue to be, aligned with our vision and strategy going forward.

Our strengths

We believe our competitive advantage is underpinned by the following competitive strengths:

- ***Multi-modality pipeline with several innovative drug candidates targeting a range of tumor indications.*** We plan to continue to leverage our expertise in drug discovery and our proficiency in executing promising collaborations and partnerships to bring innovative drugs to patients across the cancer type spectrum. Our candidates utilize a multitude of different mechanisms of action, enabling us to employ our assets on a standalone basis or in combination across tumor types and treatment combinations.
- ***Robust Phase II data laying a concrete foundation for potential registration.*** In a Phase II clinical trial of our lead asset, AN2025, for the treatment of recurrent or metastatic HNSCC on or after disease progression with platinum-based chemotherapy, the clinical data showed that the combination of AN2025 with paclitaxel achieved an mOS of over 10 months (vs. 6.5 months in the placebo plus paclitaxel group), an mPFS of 4.6 months (vs. 3.5 months in the placebo plus paclitaxel group), and a 39.2% ORR (vs. 13.9% in the placebo plus paclitaxel group). These data also showed that when AN2025 was combined with paclitaxel, grade 3-4 AEs (82% in the AN2025 plus paclitaxel group vs. 72% in the placebo group), serious adverse events ("SAEs") (57% in the AN2025 plus paclitaxel group vs. 47% in the placebo group) or on-treatment deaths (20% in the AN2025 plus paclitaxel group vs. 22% in the placebo group) is comparable to paclitaxel alone. The most frequent SAEs for AN2025 plus paclitaxel combination were pneumonia (7.89% vs. 7.69% in the placebo group), and diarrhea (5.26% vs. 0.00%

in the placebo group). The most frequent SAEs for AN2025 plus paclitaxel combination that occurred less in the placebo group were diarrhea (5.26% vs. 0.00%), hyperglycaemia (3.95% vs. 0.00%), and general physical health deterioration (3.95% vs. 0.00%). In addition, the Phase II clinical trial was designed to be a thoroughly placebo-controlled double-arm study, which provides us with further confidence in the success of the ongoing Phase III clinical trial.

- ***Targeting unmet medical need with large total addressable markets.*** AN2025 is designed to address globally urgent unmet medical demands for effective treatments in HNSCC after anti-PD-1/PD-L1 treatment. In seven major markets (the U.S., the U.K., Germany, France, Italy, Spain, and Japan), it is estimated that by 2028 there can be more than 50,000 recurrent or metastatic HNSCC patients experiencing progression after anti-PD-1/PD-L1 therapy. As the only drug candidate currently in Phase III clinical trial for the treatment of recurrent or metastatic HNSCC after anti-PD-1/PD-L1 therapy of which we are aware, we believe that AN2025, if approved, has potential to be the first product globally to address this unmet need and capture the sizable addressable market.
- ***Strong R&D capabilities***. Spanning the full spectrum from target identification to clinical development, our in-house drug discovery platforms deploy a suite of powerful and specialized techniques. They consist of two platforms, PAINT-2D^{TM} and ANEAT-Id^{TM}. PAINT-2D^{TM} provides us with a "one-stop" function for early-stage development of immuno-oncology therapies. ANEAT-Id^{TM} is a highly efficient and robust yeast display system dedicated to therapeutic antibody discovery and development.
- ***Sustainable patent portfolio in our key jurisdictions.*** As of December 31, 2022, we owned or had exclusive license rights to (i) 162 granted patents and 92 pending patent applications in jurisdictions such as the U.S., European Patent Office ("EPO"), mainland China, Japan, South Korea, Canada, Australia, Taiwan, Mexico and Brazil, and (ii) 11 patent applications under the Patent Cooperation Treaty, or PCT, that have not been nationalized. Granted patents and pending patent applications cover the key inventions for our pipeline candidates in clinical trials under IND, as well as our key technologies. Protections over potential approved use of core matters of AN2025 and AN0025 can expire in 2032 and 2036, respectively, both taking into account of the possible 5-year patent term extensions in jurisdictions where patent term extension is available, including but not limited to the U.S., Europe, China and Japan.
- ***Seasoned industry veterans and strong shareholder support***. We believe our team, with a proven track record of innovative drug R&D, clinical development, and commercialization knowledge, as well as rich expertise in business development and operational execution, can successfully drive our drug candidates to approval and clinical use on a global scale. Additionally, we are supported by the strategic guidance of a visionary scientific advisory board with members from both academia and the pharmaceutical industry. We have also received continued support from our shareholders including financial investors and several industry-leading strategic investors.

Our vision & strategy

We strive to become a global leader in the next wave of immuno-oncology therapies employing a combination therapy strategy. Our mission is to transform deadly cancer into a chronic and eventually curable disease. We intend to execute the following strategies to achieve this goal:

- ***Advance the development of and pursue regulatory approval for our lead drug candidate AN2025.*** We have advanced AN2025, in combination with paclitaxel for the treatment of recurrent or metastatic HNSCC after anti-PD-1/PD-L1 therapy into a Phase III clinical trial. We expect to enroll 483 patients across 180 sites in North America, Europe, Asia, and South America, and to submit an NDA to the FDA for a potential accelerated approval as early as the first half of 2024 leveraging the ORR data from the Phase III interim analysis, followed by further marketing approval applications to the NMPA, EMA, PMDA and other authorities.
- ***Continue advancing pipeline products through in-house development and strategic partnerships to maximize value.*** As we evaluate assets, we place a strong emphasis on first-in-class potential, combinational synergies with our current pipeline or other available therapies, as well as global development and commercialization rights. We intend to continue to develop our novel drug candidates

by leveraging our proprietary R&D platforms, our strong early and clinical stage drug discovery expertise, as well as through the support of our various global collaborators. We intend to continue building upon our existing partnership success, exploring new opportunities through strategic collaborations and potentially co-development arrangements, ultimately maximizing the clinical and commercial value of our drug candidates.

- ***Utilize manufacturing partnerships to maximize economies of scale.*** We currently work with qualified contract manufacturing organizations, or CMOs, to manufacture drug candidates for preclinical and clinical supply. In the near future, we plan to continue outsourcing the manufacturing of our drug candidates, including commercial-scale manufacturing of our approved drugs, to industry-leading, highly reputable, and qualified CMOs/contract development and manufacturing organizations, or CDMOs, globally. We have historically adopted and plan to continue to implement robust procedures to ensure that production qualifications, facilities, and processes of our CMOs/CDMOs comply with applicable regulatory requirements as well as our own internal guidelines and quality standards. We may also engage additional qualified CMOs/CDMOs in the future to ensure sufficient supply of drug candidates for our clinical trials as well as for commercial sale of our approved drugs.
- ***Assemble a world-class marketing team to accelerate the adoption of emerging next-wave immuno-oncology treatments.*** We aim to capture market share in the U.S. and gradually enter other significant markets including Europe, China, and Japan. To ensure maximum commercial value of our late-stage drug candidates globally, we intend to form our core in-house commercial leadership team by recruiting senior-level sales and marketing personnel to support commercialization of our drug candidates in the U.S. We may also consider strategic collaboration opportunities for the commercialization of our drug candidates in other countries in Europe and Asia. In particular, we may selectively out-license, establish joint ventures or consider other forms of commercialization partnerships with leading biopharmaceutical companies.
- ***Seek and nurture top talent to fuel our innovation and ingenuity.*** We place a high priority on selecting and retaining top talent. Our R&D centers in New Jersey and Hangzhou provide access to a global talent pool of highly skilled scientists and physicians. To support our continued growth, we plan to continue investing in recruiting and retaining top talent for our various operations around the world, including drug discovery, chemistry, manufacturing and controls ("CMC"), clinical development, regulatory affairs, and sales and marketing.

Summary of significant risk factors

We face various legal and operational risks and uncertainties as we have substantial operations in China. The PRC government has significant authority to exert influence on the ability of a China-based company, like us, to conduct its business, accept foreign investments or list on a U.S. stock exchange. For example, we face risks associated with regulatory approvals of offshore offerings, anti-monopoly regulatory actions, cybersecurity and data privacy, as well as the lack of inspection from the PCAOB. The PRC government may also intervene with or influence our operations as the government deems appropriate to further regulatory, political and societal goals. Any such action, once taken by the PRC government, could cause the value of such securities to significantly decline or in extreme cases, become worthless.

Investing in the ADSs involves significant risks. You should carefully consider all of the information set forth in this prospectus before making an investment in the ADSs. Below please find a summary of the principal risks and uncertainties we face, organized under relevant headings. These risks are discussed more fully in the section titled "Risk factors."

Risks relating to our operation in the People's Republic of China

Having the majority of our operations in China poses risks to investors. We face risks arising from the legal system in China, including risks and uncertainties regarding the enforcement of laws and that rules and regulations in China can change quickly with little advance notice:

- We have the majority of our operations in China, and are subject to complex and evolving PRC laws and regulations. Recently, the PRC government has indicated an intent to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers,

and initiated a series of regulatory actions and made a number of public statements, some of which are published with little advance notice. We may be subject to the approval, filing or other requirements of the CSRC or other PRC governmental authorities in connection with this Offering under current PRC laws, regulations and rules. See "Risk Factors — Risks relating to our operation in the People's Republic of China — The approval, filing, or other procedures of the CSRC or other PRC regulatory authorities may be required in connection with this offering under PRC laws, regulations, and rules."

- The CAC has recently increased oversight over data security, particularly for companies seeking to list on a foreign exchange. We believe the impact of the CAC's increasing oversight on our business is immaterial. However, there remains uncertainty as to how the CAC's regulations will be interpreted or implemented and whether CAC may adopt new regulations which may adversely affect us. See " Risk Factors — Risks relating to our operation in the People's Republic of China — The impact of the CAC's increasing oversight over data security remains highly uncertain, particularly for China-based companies seeking to list on a foreign stock exchange."
- Our substantial operations are located in mainland China. Accordingly, we may be influenced to a significant degree by political, economic and social conditions in China generally. See "Risk Factors — Risks relating to our operation in the People's Republic of China — We may be influenced by changes in the political and economic policies of the PRC government."
- Our operations in mainland China are governed by PRC laws and regulations. The uncertainties with respect to the PRC legal system could materially and adversely affect us. See "Risk Factors — Risks relating to our operation in the People's Republic of China — Uncertainties with respect to the PRC legal system, including uncertainties regarding the enforcement of laws, and sudden or unexpected changes in laws and regulations in China with little advance notice could materially and adversely affect us."
- The Chinese government may intervene or influence our operations at any time, or may exert more control over offerings conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in our operations and/or the value of our securities. See "Risk Factors — Risks Relating to our operation in the People's Republic of China — The PRC government has significant authority to exert influence on our operations in mainland China."
- Recent negative publicity surrounding China-based companies listed in the United States may negatively impact the trading price of the ADSs.
- We are also subject to other risks and uncertainties in relation to PCAOB inspection. We cannot assure you that we will not be identified by the SEC under the HFCAA, as an issuer that has retained an auditor that has a branch or office located in a foreign jurisdiction that the PCAOB determines it is unable to inspect or investigate completely because of a position taken by an authority in that foreign jurisdiction. In addition, there can be no assurance that, if we have a "non-inspection" year, we will be able to take any remedial measures. If any such event were to occur, trading in our securities could in the future be prohibited under the HFCAA and, as a result, we cannot assure you that we will be able to maintain the listing of the ADSs on the Nasdaq Stock Market or that you will be allowed to trade the ADSs in the United States on the "over-the-counter" markets or otherwise. Should the ADSs become not listed or tradeable in the United States, the value of the ADSs could be materially affected. See "Risk Factors — Risks Relating to our operation in the People's Republic of China — the ADSs may be delisted under the HFCAA if the PCAOB is unable to inspect auditors or their affiliates that are located in mainland China. The delisting of the ADSs, or the threat of such delisting, may materially and adversely affect the value of your investment. Additionally, the inability of the PCAOB to conduct inspections deprives our investors of the benefits of such inspections."
- 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 face uncertainties in the PRC with respect to indirect transfer of equity interests in our PRC subsidiaries.

Risks relating to our business

- We have a limited operating history, have incurred net losses and anticipate that we will continue to incur net losses for the foreseeable future. We may not be able to generate sufficient revenue to achieve or maintain profitability;
- Our business depends substantially on the success of our preclinical and clinical drug candidates. If we are unable to successfully develop drug candidates or experience significant delays in doing so, our business will be materially harmed;
- We have relied and will continue to rely on third parties to manufacture our drug candidates in the foreseeable future;
- We may seek and form strategic alliance, collaboration, or licensing arrangements for the development of drug candidates in the future, which may not achieve the anticipated benefits to or even negatively impact our business;
- We may rely on certain third-party collaborators for some of our clinical development activities, which could delay or limit the future development or regulatory approval of our drug candidates;
- Our success depends upon our and our business partners' ability to obtain and maintain intellectual property protection for our drug candidates and technologies;
- We may face competition from generic or biosimilar manufacturers after the patent protection is no longer valid;
- We are exposed to risks of conducting our business and operations in international markets; and
- We may face force majeure risks, including the recent COVID-19 outbreak.

Risks relating to the ADSs

- An active trading market for our ordinary shares or the ADSs may not develop and the trading price of the ADSs may be volatile regardless of our operating performance, which could result in substantial losses to you;
- ADS holders do not have the same rights as our shareholders;
- Owners or holders of the ADSs have limited recourse if we or the depositary fail to meet our respective obligations under the deposit agreement;
- As an exempted company incorporated in the Cayman Islands, we are permitted to adopt certain home country practices for corporate governance matters that differ significantly from the Nasdaq corporate governance listing standards; these practices may afford less protection to shareholders than they would enjoy if we complied fully with the corporate governance listing standards;
- We are a foreign private issuer within the meaning of the rules under the Exchange Act, and as such we are exempt from certain provisions applicable to U.S. domestic public companies; and
- We are an emerging growth company within the meaning of the Securities Act and may take advantage of certain reduced reporting requirements.
- We will be a "controlled company" within the meaning of the Nasdaq Stock Market listing rules and, as a result, may rely on exemptions from certain corporate governance requirements that provide protection to shareholders of other companies.

Recent PRC regulatory developments

On July 6, 2021, the relevant PRC government authorities issued the Opinions on Strictly Scrutinizing on Illegal Securities Activities in Accordance with the Law. These opinions call for strengthened regulation over illegal securities activities, supervision of overseas securities offerings and listings by China-based companies, and propose to take effective measures, such as promoting the development of relevant regulatory systems, to deal with perceived risks or incidents faced by China-based overseas-listed companies. As of the date of this prospectus, no official guidance and implementation rules have been issued in relation to these recently issued

opinions. Therefore, the interpretation and implementation of these opinions remain unclear at this stage. We cannot assure you we will not be required to obtain the pre-approval of the China Securities Regulatory Commission, or the CSRC, and potentially other regulatory authorities to pursue this offering.

On February 17, 2023, the China Securities Regulatory Commission, or the CSRC, released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies, or the Trial Measures, and five supporting guidelines, which took effect on March 31, 2023. Pursuant to the Trial Measures, domestic companies that seek to list overseas, both directly and indirectly, should fulfill the filing procedure and report relevant information to the CSRC. If a domestic company fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, such domestic company may be subject to administrative penalties, such as order to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines. See "Regulations — Regulations on M&A Rules and Overseas Listings." However, since the Trial Measures was newly promulgated, the interpretation, application and enforcement of Trial Measures remain unclear. If the filing procedure with the CSRC under the Trial Measures is required for any future offering or any other capital raising activities, it is uncertain whether it would be possible for us or how long it will take us to complete the filing.

The revised Measures of Cybersecurity Review as promulgated by a total of thirteen governmental departments of the PRC, including the Cyberspace Administration of China, or the CAC, came into effect on February 15, 2022. The revised Measures of Cybersecurity Review stipulated that, in addition to network products and services acquired by critical information infrastructure operators, online platform operators are also subject to cybersecurity review if they carry out data processing activities that affect or may affect national security. Moreover, online platform operators listing in a foreign country with more than one million users' personal information data must apply for a cybersecurity review with the Cybersecurity Review Office. The revised Measures of Cybersecurity Review further elaborated the factors to be considered when assessing the national security risks of the relevant activities. On July 7, 2022, the CAC promulgated the Measures on Security Assessment of Cross-border Data Transfer, or the Data Export Measures, which became effective on September 1, 2022. The Data Export Measures requires that any data processor who processes or exports personal information exceeding a certain volume threshold shall apply for a security assessment by the CAC before transferring any personal information abroad. The security assessment requirement also applies to any transfer of important data outside of China. Since our business operation is not an operator of a network platform with personal information of over one million users, we should not be required to undergo the cybersecurity review for this offering and the listing of the ADSs under the revised Measures of Cybersecurity Review. However, as the aforementioned measures were issued recently, there are uncertainties regarding how they would be interpreted and enforced, and to what extent they may affect us.

On February 24, 2023, the CSRC, jointly with other relevant governmental authorities, promulgated the Provisions on Strengthening Confidentiality and Archives Management of Overseas Securities Issuance and Listing by Domestic Enterprises, or the Confidentiality and Archives Management Provisions, which took effect on March 31, 2023. The Confidentiality and Archives Management Provisions outline obligations of issuers listed in overseas markets with operations in mainland China when they provide information involving state secrets or sensitive information to their securities service providers (such as auditors) and overseas regulators. In addition, under the Confidentiality and Archives Management Provisions, such issuers will also be required to obtain approval from the CSRC and other authorities in mainland China before accepting any investigation or inspection by overseas regulators. As the Confidentiality and Archives Management Provisions were recently promulgated, there are uncertainties with respect to their interpretation and implementation. For further details, see "Regulation — Regulations relating to information security and data privacy."

Industry and market data

We include statements and information in this prospectus concerning our industry ranking and the markets in which we operate, including our general expectations and market opportunity. We obtained the industry, market, and similar data set forth in this prospectus from our internal estimates and research and from academic and industry research, publications, surveys, and studies conducted by third parties, including governmental agencies. In some cases, we do not expressly refer to the sources from which this data is derived.

Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information.

Projections, assumptions and estimates of the future performance of the industry in which we operate and our future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

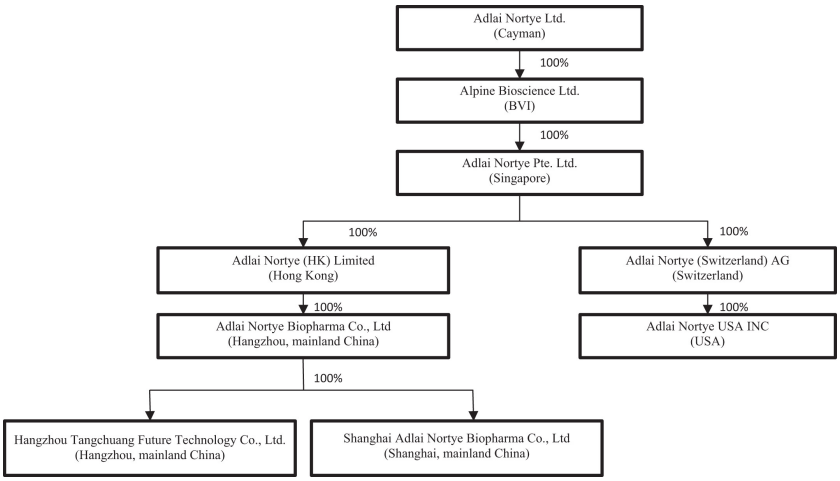
Corporate history and structure

We commenced our business in mainland China in 2004 through Adlai Nortye Biopharma Co., Ltd., which we refer to as our operating subsidiary in the PRC. We initially focused primarily on generic pharmaceuticals and polypeptide intermediate, until 2016 when our founders Mr. Yang Lu and Mr. Donghui Yang led our strategic transition to become a R&D-driven pharmaceutical company, focusing on the discovery and development of innovative cancer therapies.

Our ultimate holding company was incorporated in the Cayman Islands in May 2018 to facilitate offshore financing activities, and our daily operations are conducted primarily through our operating subsidiaries in the United States and mainland China. Between January 2018 and June 2022, Alpine Bioscience Ltd., Adlai Nortye Pte. Ltd., Adlai Nortye (HK) Limited, and Adlai Nortye (Switzerland) AG were incorporated in the British Virgin Islands, Singapore, Hong Kong, and Switzerland as our intermediary holding entities. In March 2019, Adlai Nortye (HK) Limited acquired entire equity interests in the Adlai Nortye Biopharma Co., Ltd. from its then shareholders and Adlai Nortye Biopharma Co., Ltd. became a wholly owned subsidiary of our ultimate holding company.

In order to conduct clinical trials in the U.S., Adlai Nortye USA INC was incorporated under the laws of the State of Delaware in the U.S. in January 2018. In June 2022, as a part of a reorganization, Adlai Nortye (Switzerland) AG acquired all its shares and Adlai Nortye USA INC become a wholly owned subsidiary of our ultimate holding company.

The chart below sets forth our corporate structure and identifies our subsidiaries and their subsidiaries, as of the date of this prospectus:



Cash transfers and dividend distributions

Adlai Nortye Ltd. is not a Chinese operating company, but is a Cayman Islands holding company. We maintain our bank accounts and balances primarily in licensed banks in the United States, mainland China

and Hong Kong. If needed, cash can be transferred between our Cayman Islands holding company and subsidiaries incorporated in the United States, mainland China and Hong Kong through equity investments, dividends and intercompany loans, and there are currently no restrictions of transferring funds between our Cayman Islands holding company and subsidiaries in the United States and Hong Kong. We may also make loans and additional capital contribution to our mainland China, subject to certain restrictions under the applicable local laws.

Adlai Nortye Ltd., our Cayman Islands holding company, has not declared or made any dividends or other distributions to its shareholders since its inception. U.S. investors will not be subject to Cayman Islands taxation on dividend distributions, and no withholding will be required on the payment of dividends or distributions to them while they may be subject to U.S. federal income tax. Adlai Nortye Ltd. may be classified as a "resident enterprise" of China. This classification could result in unfavorable tax consequences to us and our non-PRC shareholders and dividends paid by us may be subject to PRC withholding tax. See "Taxation — United States federal income tax considerations — Dividends."

We have no plans to declare cash dividends in the near term, but as a holding company, we may depend on receipt of funds from one or more of our subsidiaries if we determine to pay cash dividends to holders of our ordinary shares in the future.

Our subsidiaries incorporated in the United States and Hong Kong are permitted, under the respective laws, to provide funding to Adlai Nortye Ltd. through dividend distributions without restrictions on the amount of the funds. The ability of our PRC subsidiaries to distribute dividends to us will be limited by foreign exchange restrictions under the PRC law. The restrictions on currency exchanges in the PRC may limit our ability to freely convert RMB to fund any future business activities outside the PRC or other payments in U.S. dollars, and capital control measures imposed by the Chinese government may limit our ability to use capital from our PRC subsidiaries for business purposes outside of the PRC. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and trade and service-related foreign exchange transactions, cannot be made in currencies other than RMB without complying with certain procedural requirements of State Administration of Foreign Exchange, or SAFE. Specifically, approval from or registration with appropriate government authorities is required where RMB is to be converted into another currency and remitted out of China to pay capital expenses, such as the repayment of loans denominated in currencies other than RMB. As a result, we may need to obtain SAFE approval to use cash generated from the operations of our PRC subsidiaries in the future to pay off its debt in a currency other than RMB owed to entities outside the PRC, or to make other capital expenditure payments outside the PRC in a currency other than RMB. Additionally, the PRC Enterprise Tax and its implementation rules provide that a withholding tax rate of up to 10% will be applicable to dividends payable by Chinese companies to non-PRC-resident enterprises unless otherwise exempted or reduced according to treaties or arrangements between the PRC central government and governments of other countries or regions where the non-PRC-resident enterprises are incorporated. The following table sets forth the amount of the cash transfers for the periods presented. Further details are contained in Note 27 of our consolidated financial statements included elsewhere in this prospectus.

	For the Year Ended December 31,		
	2020	2021	2022
	US$	US$	US$
	(in thousands)		
Capital Contribution			
Capital contributions from Adlai Nortye Ltd. (Cayman) to Adlai Nortye Pte Ltd.(Singapore)	—	—	17
Capital contributions from Adlai Nortye Ltd. (Cayman) to Adlai Nortye (Switzerland) AG (Swiss)	—	—	113
Capital contributions from Adlai Nortye Ltd. (Cayman) to Adlai Nortye USA Inc.(United States)	14,163	18,670	24,035
Capital contributions from Adlai Nortye (HK) Limited (Hong Kong) to its mainland China subsidiaries	35,840	33,960	19,394
Capital contributions from Adlai Nortye (HK) Limited (Hong Kong) to its non-mainland China subsidiaries	—	—	—

	For the Year Ended December 31,		
	2020	2021	2022
	US$	US$	US$
	(in thousands)		
Intercompany Loan			
Intercompany loans from Adlai Nortye Ltd. (Cayman) to Adlai Nortye (HK) Limited (Hong Kong)	42,565	46,794	10,900
Intercompany loans from Adlai Nortye (HK) Limited (Hong Kong) to its mainland China subsidiaries	—	—	—
Intercompany loans from Adlai Nortye (HK) Limited (Hong Kong) to its non-mainland China subsidiaries	—	—	—
Intercompany loans from Adlai Nortye (HK) Limited (Hong Kong) to Adlai Nortye Pte Ltd.(Singapore)	—	—	750
Intercompany loans from Adlai Nortye Ltd. (Cayman) to our mainland China subsidiaries	2,755	257	—
Intercompany loans from Adlai Nortye Ltd. (Cayman) to Adlai Nortye USA Inc.(United States)	55	84	—
Intercompany loans from Adlai Nortye Ltd. (Cayman) to our non- mainland China subsidiaries	—	—	—
Intercompany loans from our mainland China subsidiaries to Adlai Nortye USA Inc.(United States)	—	150	—
Intercompany loans from Adlai Nortye Biopharma Co.,Ltd to Shanghai Adlai Nortye Biopharma Co.,Ltd	—	—	1,640
Intercompany loans repaid by Adlai Nortye (HK) Limited (Hong Kong) to Adlai Nortye Ltd. (Cayman)	—	—	—
Intercompany loans repaid by our mainland China subsidiaries to Adlai Nortye (HK) Limited (Hong Kong)	—	—	18
Intercompany loans repaid by our non-mainland China subsidiaries to Adlai Nortye (HK) Limited (Hong Kong)	—	—	—
Intercompany loans repaid by our mainland China subsidiaries to Adlai Nortye Ltd. (Cayman)	—	—	—
Intercompany loans repaid by our non-mainland China subsidiaries to Adlai Nortye Ltd. (Cayman)	—	—	—
Intercompany loans repaid by Adlai Nortye USA Inc.(United States) to our mainland China subsidiaries	—	—	—
Dividend Distribution			
Dividend distribution from our mainland China subsidiaries to Adlai Nortye (HK) Limited (Hong Kong)	—	—	—
Dividend distribution from our non-mainland-China subsidiaries to Adlai Nortye (HK) Limited (Hong Kong)	—	—	—
Dividend distribution from Adlai Nortye (HK) Limited (Hong Kong) to Adlai Nortye Ltd. (Cayman)	—	—	—
Dividend distribution from Adlai Nortye USA Inc.(United States) to Adlai Nortye Ltd. (Cayman)	—	—	—

Implication of being an emerging growth company and a foreign private issuer

As a company with less than US$1.07 billion in revenue for our last fiscal year, we qualify as an "emerging growth company" pursuant to the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other requirements compared to those that are otherwise applicable generally to public companies. These provisions include exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002 in the assessment of the emerging growth company's internal control over financial reporting. The JOBS Act also provides that an emerging growth company does not need to comply with any new or revised financial accounting standards until such date that a private company is otherwise required to comply with such new or

revised accounting standards. Pursuant to the JOBS Act, we have elected to take advantage of the benefits of this extended transition period for complying with new or revised accounting standards. As a result, our operating results and financial statements may not be comparable to the operating results and financial statements of other companies who have adopted the new or revised accounting standards.

We will remain an emerging growth company until the earliest of (a) the last day of the fiscal year during which we have total annual gross revenues of at least US$1.07 billion; (b) the last day of our fiscal year following the fifth anniversary of the completion of this offering; (c) the date on which we have, during the preceding three-year period, issued more than US$1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of the ADSs that are held by non-affiliates exceeds US$700 million as of the last business day of our most recently completed second fiscal quarter. Once we cease to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above.

Upon consummation of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions in the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents, or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events.

Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

Implication of being a controlled company

We will be a "controlled company" as defined under the Nasdaq Stock Market Listing Rules because Mr. Yang Lu, our founder, chairman and the chief executive officer, will hold % of our total issued and outstanding ordinary shares and will be able to exercise % of the total voting power of our issued and outstanding share capital upon the completion of this offering, assuming that the underwriters do not exercise their option to purchase additional ADSs, or % of our total issued and outstanding ordinary shares and % of the total voting power of our issued and outstanding share capital upon the completion of this offering, assuming that the underwriters exercise their option to purchase additional ADSs in full. As a result, Mr. Yang Lu will have the ability to control or significantly influence the outcome of matters requiring approval by shareholders. As long as we remain as a "controlled company," we are permitted to elect not to comply with certain corporate governance requirements, including an exemption from the rule that a majority of our board of directors must be independent directors. We may also rely on the exemption available for foreign private issuers to follow our home country governance practices. As a result, you will not have the same protection afforded to shareholders of companies that are subject to these corporate governance requirements. For details, see "Risk Factors — Risks Related to the ADSs — We will be a "controlled company" within the meaning of the Nasdaq Stock Market listing rules and, as a result, may rely on exemptions from certain corporate governance requirements that provide protection to shareholders of other companies."

Corporate information

Adlai Nortye Ltd. was incorporated in the Cayman Islands on May 9, 2018 as an exempted company with limited liability. The address of our registered office in Cayman Islands and our principal executive office

is at c/o PO Box 309, Ugland House, Grand Cayman KY1-1104, Cayman Islands. Our telephone number is +1 848-230-7430. The United States and China are two important markets and locations for our operations. In addition to our principal executive office in the Cayman Islands, we also have two regional headquarters at (i) New Jersey Biotechnology Development Center, 685 US Hwy 1, 2nd floor, North Brunswick Township, NJ 08902, the United States and (ii) Building 6 & 8, 1008 Xiangwang Street, Yuhang District, Hangzhou, Zhejiang, People's Republic of China.

Investor inquiries should be directed to us at the address and telephone number of our principal executive offices set forth above. Our website address is *https://www.adlainortye.com*. Our website and the information contained on our website do not constitute a part of this prospectus. Our agent for service of process in the United States is Adlai Nortye USA INC, with the address at New Jersey Biotechnology Development Center, 685 US Hwy 1, 2nd floor, North Brunswick Township, NJ 08902.

Conventions that apply to this prospectus

Unless otherwise indicated or the context otherwise requires, references in this prospectus to:

- "ADRs" are to the American depositary receipts that may evidence the ADSs;
- "ADSs" are to the American depositary shares, each of which represents our Class A ordinary shares;
- "BVI" are to the British Virgin Islands;
- "CAGR" are to the compound annual growth rate;
- "China" or the "PRC" are to the People's Republic of China, including Hong Kong and Macau; and only in the context of describing PRC rules, laws, regulations, regulatory authority, and any PRC entities or citizens under such rules, laws and regulations and other legal or tax matters in this prospectus, excludes Taiwan, Hong Kong and Macau;
- "Class A ordinary shares" are to our Class A ordinary shares, par value US$0.0001 per share;
- "Class B ordinary shares" are to our Class B ordinary shares, par value US$0.0001 per share;
- "Hangzhou Adlai" is to Adlai Nortye Biopharma Co., Ltd, our wholly foreign-owned enterprise incorporated in the PRC;
- "RMB" or "Renminbi" are to the legal currency of China;
- "shares" or "ordinary shares" are to prior to the completion of this offering, our pre-offering ordinary shares, and upon and after the completion of this offering, are to our Class A ordinary shares and Class B ordinary shares;
- "US$," "U.S. dollars," "$," and "dollars" are to the legal currency of the United States; and
- "we," "us," "our company," and "our" are to Adlai Nortye Ltd., our Cayman Islands holding company and its subsidiaries, which include those in the U.S. and mainland China that conduct daily operations.

Unless the context indicates otherwise, all information in this prospectus assumes no exercise by the underwriters of their option to purchase additional ADSs from us.

	The offering
Offering price	We currently estimate that the initial public offering price will be between US$ and US$ per ADS.
ADSs offered by us	ADSs (or ADSs if the underwriters exercise their option to purchase additional ADSs in full).
ADSs outstanding immediately after this offering	ADSs (or ADSs if the underwriters exercise their option to purchase additional ADSs in full).
Ordinary shares issued and outstanding immediately after this offering	Class A ordinary shares (or Class A ordinary shares if the underwriters exercise their option to purchase additional ADSs) and Class B ordinary shares. [This excludes shares issuable upon exercise of outstanding options with an average exercise price of US$ per share.]
The ADSs	Each ADS represents Class A ordinary shares, par value US$0.0001 per share. The depositary will hold in custody Class A ordinary shares underlying your ADSs. You will have rights as provided in the deposit agreement among us, the depositary and owners and holders of ADSs from time to time. We do not expect to pay dividends in the foreseeable future. If, however, we declare dividends on our ordinary shares, the depositary will pay you the cash dividends and other distributions it receives on our Class A ordinary shares after deducting its fees and expenses in accordance with the terms set forth in the deposit agreement. You may surrender your ADSs to the depositary for cancellation to receive the underlying Class A ordinary shares. The depositary will charge you fees for any cancellation. We may amend or terminate the deposit agreement without your consent. If you continue to hold your ADSs after an amendment to the deposit agreement, you agree to be bound by the deposit agreement as amended. To better understand the terms of the ADSs, you should carefully read the “Description of American Depositary Shares” section of this prospectus. You should also read the deposit agreement, which is filed as an exhibit to the registration statement that includes this prospectus.
Option to purchase additional ADSs	We have granted to the underwriters an option, exercisable within 30 days from the date of this prospectus, to purchase up to an aggregate of additional ADSs.
Use of proceeds	We expect that we will receive net proceeds of approximately US$ million from this offering, assuming an initial public offering price of US$ per

	ADS, which is the midpoint of the estimated range of the initial public offering price, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use approximately US$ million of the net proceeds for the ongoing and future R&D activities, including planned preclinical studies, clinical trials, and future commercialization of our drug candidates; approximately US$ million of the net proceeds for the expansion of our drug portfolio through a combination of internal R&D activities and external business development efforts; and the remaining US$ million for our general working capital and general corporate purposes. See "Use of Proceeds" for more information.
Lock-up	We [and each of our officers, directors, and existing shareholders and holders of share-based awards] have agreed with the underwriters, subject to certain exceptions, not to sell, transfer or otherwise dispose of any ADSs, ordinary shares or similar securities for a period of 180 days after the date of this prospectus. See "Shares Eligible for Future Sale" and "Underwriting" for more information.
Listing	We intend to apply to have the ADSs listed on the Nasdaq Stock Market under the symbol "ANL." At this time, the Nasdaq Stock Market has not yet approved our application to list the ADSs. The closing of this offering is conditioned upon the Nasdaq Stock Market's final approval of our listing application, and there is no guarantee or assurance that the ADSs will be approved for listing on the Nasdaq Stock Market.
Payment and settlement	The underwriters expect to deliver the ADSs against payment therefor through the facilities of the Depository Trust Company on , 2023.
Depositary	[The Bank of New York Mellon.]

The number of ordinary shares that will be outstanding immediately after this offering:

- 97,983,414 ordinary shares issued and outstanding on an as-converted basis as of the date of this prospectus, assuming (1) the re-designation of 16,990,000 shares beneficially owned by Archer Future Limited into Class B ordinary shares on a one-for-one basis immediately prior to the completion of this offering; (2) the re-designation of all of our remaining issued and outstanding 80,993,414 ordinary shares into Class A ordinary shares on a one-for-one basis immediately prior to the completion of this offering; and
- Class A ordinary shares in the form of ADSs that we will issue and sell in this offering, assuming the underwriters do not exercise their option to purchase additional ADSs.

Summary Consolidated Financial and Operating Data

The following summary consolidated statements of operations and comprehensive loss for the years ended December 31, 2020, 2021 and 2022, summary consolidated statements of financial position as of December 31, 2020, 2021 and 2022, and summary consolidated statements of cash flows for the years ended December 31, 2020, 2021 and 2022 have been derived from our audited consolidated financial statements

included elsewhere in this prospectus. Our consolidated financial statements are prepared and presented in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. None of our consolidated financial statements were prepared in accordance with U.S. GAAP. Our historical results are not necessarily indicative of results expected for future periods. You should read this Summary Consolidated Financial Data section together with our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

The following table sets forth a summary of our consolidated statements of operations and comprehensive loss for the years ended December 31, 2020, 2021, and 2022.

	For the Year Ended December 31,		
	2020	2021	2022
	US$	US$	US$
		(in thousands)	
Selected consolidated statements of operations and comprehensive loss:			
Revenue	—	45,726	—
Other operating income, net	50	183	259
Administrative expenses	(6,524)	(12,450)	(13,039)
Research and development expenses	(21,146)	(42,105)	(54,490)
Total operating loss	**(27,620)**	**(8,646)**	**(67,270)**
Other income and gains	559	213	2,079
Other expenses	(69)	(70)	(1,395)
Investment income	18	32	550
Fair value gain on financial assets at FVTPL	—	40	484
Fair value (loss)/gain on financial liabilities at FVTPL	(35,839)	(46,910)	7,195
Finance costs	(1,797)	(1,337)	(433)
Loss before tax	**(64,748)**	**(56,678)**	**(58,790)**
Income tax expense	—	—	—
Loss for the year	**(64,748)**	**(56,678)**	**(58,790)**
Attributable to:			
Ordinary equity holders of the parent	(64,748)	(56,678)	(58,790)

The following table sets forth a selected consolidated statements of financial position as of December 31, 2020, 2021, and 2022.

	As of December 31,		
	2020	2021	2022
	US$	US$	US$
	(in thousands)		
Selected consolidated statements of financial position:			
ASSETS			
Current assets:			
Cash and cash equivalents	24,261	64,131	42,758
Financial assets at FVTPL	—	53,809	21,287
Prepayments, other receivables and other assets	5,502	6,604	2,258
Total current assets	**29,763**	**124,544**	**66,303**
Total non-current assets	**7,873**	**7,141**	**6,291**
Total assets	**37,636**	**131,685**	**72,594**
LIABILITIES			
Current liabilities:			
Trade payables	2,000	2,981	13,098
Other payables and accruals	2,464	3,224	3,877
Interest-bearing bank and other borrowings	8,296	10,457	4,307
Lease liabilities	794	834	1,001
Financial liabilities at FVTPL	74,697	—	290,368
Total current liabilities	**88,251**	**17,496**	**312,651**
Total non-current liabilities	**81,427**	**299,617**	**1,236**
Total liabilities	**169,678**	**317,113**	**313,887**
Total shareholders' deficit	**(132,042)**	**(185,428)**	**(241,293)**
Total liabilities and shareholders' equity	**37,636**	**131,685**	**72,594**

The following table sets forth a consolidated statements of cash flows for the years ended December 31, 2020, 2021, and 2022.

	For the Year Ended December 31,		
	2020	2021	2022
	US$	US$	US$
	(in thousands)		
Net cash used in operating activities	(32,851)	(3,034)	(43,223)
Net cash (used in)/generated from investing activities	(2,032)	(54,857)	28,376
Net cash from/(used in) financing activities	53,071	97,200	(6,780)
Net increase/(decrease) in cash and cash equivalents	**18,188**	**39,309**	**(21,627)**
Cash and cash equivalents at the beginning of the year	6,006	24,261	64,131
Effect of foreign exchange rate changes, net	67	561	254
Cash and cash equivalents at the end of the year	**24,261**	**64,131**	**42,758**

RISK FACTORS

Investing in the ADSs involves a high degree of risk. You should carefully consider the following risks and uncertainties and all other information contained in this prospectus before investing in the ADSs. Our business, financial condition, results of operations, or prospects could also be harmed by risks and uncertainties not currently known to us or that we currently do not believe are material. If any of the risks actually occur, our business, financial condition, results of operations, and prospects could be adversely affected. In that event, the market price of the ADSs could decline, and you could lose part or all of your investment. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See the section titled "Special Note Regarding Forward-Looking Statements."

Risks related to our business

Our business depends substantially on the success of our preclinical and clinical drug candidates. If we are unable to successfully develop drug candidates or experience significant delays in doing so, our business will be materially harmed.

Our business will depend on the successful development, regulatory approvals, and commercialization of our drug candidates. Our drug candidates are still in preclinical and clinical development. We cannot guarantee that we will be able to obtain regulatory approvals for our drug candidates in a timely manner, or at all. None of our drug candidates has been approved for marketing in the U.S., Europe, China, or any other jurisdiction. Each of our drug candidates will require additional clinical development, regulatory approvals, development of manufacturing supply and capacity, substantial investment, and significant marketing efforts before we generate any revenue from product sales. Further, we are not in control of any clinical trials conducted by our licensors or sublicensors for obtaining regulatory clearance and they may be driven by strategical goals or concerns that do not align with ours. If our licensors or sublicensors fail to obtain regulatory approvals for those drug candidates in jurisdictions where they reserve their rights, if any, it would be more difficult for us to obtain regulatory approvals from the regulatory authorities in other jurisdictions where we have exclusive rights for to develop the drug candidates for regulatory approvals.

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

- completion of preclinical studies as well as completion of clinical trials, including successful enrollment of patients;
- favorable safety and efficacy data from our clinical trials and other studies;
- obtaining sufficient supplies of any drug products that are used in combination with our drug candidates, competitor drugs or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- receipt of regulatory allowances or approvals from applicable regulatory authorities for planned clinical trials;
- establishing sufficient commercial manufacturing capabilities by making arrangements with third-party manufacturers;
- the performance by CROs or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining, maintaining, and enforcing patent, trademark, trade secret, and other intellectual property protection and regulatory exclusivity for our drug candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defend against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- receipt of marketing approvals from applicable regulatory authorities;
- successfully launching commercial sales of our drug candidates, if and when approved;

- obtaining and maintaining favorable reimbursement from third-party payors for drugs, if and when approved;
- competition with other drug candidates and drugs; and
- continued acceptable safety profiles of our drug candidates following regulatory approvals.

If we do not achieve one or more of these in a timely manner or at all, we could experience significant delays in our ability to obtain approval for our drug candidates, which would materially harm our business and may prevent us from generating sufficient revenues and cash flows to continue our operations.

The clinical trial results of our drug candidates may fail to satisfy regulatory authorities or might not produce positive results.

We must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans to obtain regulatory approvals for the sale of our drug candidates. Clinical and preclinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials or preclinical studies will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the trial or study process. Despite promising preclinical or clinical results, any drug candidate can unexpectedly fail at any stage of clinical development. The historical failure rate for drug candidates in our industry is high, particularly in the earlier stages of development.

The results from preclinical studies or clinical trials of a drug candidate or a competitor's candidate in the same class may not predict the results of later clinical trials of our drug candidate, and interim, top-line, or preliminary results of a clinical trial are not necessarily indicative of final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on earlier clinical trials and preclinical studies, many candidates fail in clinical trials despite very promising early results, and a number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Based upon negative or inconclusive results, we or any future collaborator may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, which would cause us to incur additional operating expenses. As a result, we cannot be certain that our ongoing and planned clinical trials and preclinical studies will be successful.

We may also experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to obtain regulatory approvals or commercialize our drug candidates, including but not limited to:

- we may be unable to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- regulators, institutional review boards, or IRBs, or ethics committees not authorizing us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- regulators may disagree as to the design or implementation of our clinical trials;
- manufacturing issues relating to our third-party CMOs, 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;
- clinical sites may deviate from trial protocols or drop out of trials;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;

- 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.

Clinical trials are expensive and difficult to design and implement and can take many years to complete, and their outcomes are inherently uncertain. Our research and development expenses amounted to US$21.1 million, US$42.1 million, and US$54.5 million in 2020, 2021, and 2022, respectively. With our further exploration of potential new drug candidates and indication expansion of our current drug candidates, we may need more capital to support our R&D activities. If we are unable to obtain sufficient capital resources in a timely manner, our clinical process may be adversely impacted. We could also face difficulties due to any number of reasons including, but not limited to, regulatory delay, complexities of analytical testing technology, shortage of clinical trial material supply, and health epidemics, such as the recent COVID-19 pandemic. For a detailed discussion about the impact from COVID-19 on our clinical development, see "— We may face force majeure risks, including the recent COVID-19 outbreak."

Clinical trials must be conducted in accordance with applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where the clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by applicable regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by applicable regulatory authorities foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our drug candidates.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, or 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 approvals for our drug

candidates; (ii) not obtain regulatory approvals at all; (iii) obtain approval for indications that are not as broad as intended; (iv) have the drugs removed from the market after obtaining regulatory approvals; (v) be subject to additional post-marketing testing requirements; (vi) be subject to restrictions on how the drugs are distributed or used; or (vii) be unable to obtain reimbursement for the use of the drugs.

Significant clinical trial delays may also increase our development costs, shorten the commercialization periods enjoyed by our drug candidates, or allow our competitors to bring drugs to market before we do.

We may seek and form strategic alliance, collaboration, or licensing arrangements for the development of drug candidates in the future, which may not achieve the anticipated benefits to or even negatively impact our business.

We have in the past formed and may in the future continue to seek and form strategic alliances, collaboration, and/or licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our current and future drug candidates. Any of these relationships may require us to increase our near and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business.

Our strategic collaboration with partners involves various risks. If and when we collaborate with a third party for development and commercialization of a drug candidate, we may have to relinquish some or all of the control over the future success of that drug candidate to the third party. 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 time frame. Also, the synergies from our collaboration with partners may be offset by other costs incurred in the collaboration, increases in other expenses, operating losses, or problems in the business unrelated to our collaboration. As a result, there can be no assurance that we will be able to achieve our expected benefits and synergies from these collaborations, if at all.

We may rely on certain third parties for some of our clinical development activities, which could delay or limit the future development or regulatory approval of our drug candidates.

We collaborate with third parties for clinical development activities from time to time. For example, we reached a supply agreement with MSD to evaluate the combination of AN0025 and pembrolizumab in patients with solid tumors in a Phase Ib clinical trial, and also a supply agreement with Roche to evaluate the triple combination of AN2025, AN0025, and atezolizumab for a variety of PIK3CA mutant solid tumors in a Phase I clinical trial. We cannot guarantee that MSD, Roche, or other third parties will not diminish the amount of supply of the relevant compounds, or terminate the agreements altogether. Disputes arising between us and these third parties 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. In such cases, we may need to reevaluate our approaches with respect to these combination trials, and potentially find other compounds with combination potential 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 doing so.

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

We have relied on and plan to continue to rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development, manufacture, or commercialization of some of our drug candidates. Pursuant to these license agreements, our licensors may also provide us with clinical data required for NDA filings in our licensed territories, besides many other types of support. However, some of the licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use and in all territories where we may wish to develop or commercialize our drug candidates and the underlying patents may fail to provide the intended exclusivity. As a result, we may not be able to develop, export, or sell our drug candidates outside of the territories stipulated by the license agreements or prevent competitors from developing and commercializing competitive drug candidates in the markets that we hope to address. In addition, our licenses may not include rights to all intellectual property relevant to these drug candidates, and as a result, we may need to obtain additional licenses from our existing

licensors, which may not be available on an exclusive basis or commercially reasonable terms. Otherwise, we will need to spend significant time and resources to redesign our drug candidates or the methods for manufacturing them. Moreover, we do not own the background intellectual property rights related to these drug candidates invented prior to the licenses. If our licensors breach our license agreements, we may lack bargaining power to enforce such agreements or obtain adequate remedies.

Over time, we may seek additional rights to intellectual property from our licensors and, in connection with the related negotiations, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses.

We may not have the rights to handle patent management related to the in-licensed drug candidates.

We may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the drug candidates that we in-license from third parties. We also have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our current or future licensors or collaboration partners fail to prosecute, maintain (including by failing to pay the relevant fees), enforce, and defend patents licensed to us that are material to our business, the exclusivity associated with the relevant drug candidate may be reduced or eliminated, and as a result, our ability to prevent competitors from developing or commercializing the same drug candidates could be adversely affected. In addition, even if we have the right to control patent prosecution and maintenance of patents and patent applications licensed to us, we may still be adversely affected or prejudiced by actions or inactions of our licensors, the inventors, third-party collaborators, and their respective counsel that took place either before or after the date upon which we assumed that control.

Pursuant to the terms of our license agreements, the licensors may have the right to control enforcement of our in-licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. Even if we are permitted to enforce or defend these patents, this will require the cooperation of our licensors and any other relevant patent owners, and we cannot be certain that such cooperation will be provided to us. We also cannot be certain that our licensors will allocate sufficient resources or prioritize their enforcement of such patents or defense of such claims to protect our interests. An adverse outcome in any of these matters, regardless of whether we are a party or otherwise participating, could significantly harm our business if we are relying on the patents for exclusivity or material technology or we are subject to damages or other restrictions on our business activities.

The in-licensed patent rights may be encumbered.

Our licensors may have relied on third party consultants or collaborators or on funds, resources, or expertise from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market equivalent or substantially equivalent drug candidates and technologies. In addition, if our licensors have not obtained adequate rights and licenses from these third parties, we may need to obtain additional rights from these third parties or we could be prevented from developing and commercializing the related drug candidates or face competition.

If we fail to comply with our obligations in the licensing agreements or experience disruptions to our business relationships with our licensors, we could lose license rights or be required to pay monetary damages.

We are required to make various payments to our licensors in exchange for in-licensing of certain drug candidates, including upfront payments, milestone payments, tiered royalties based on commercial sales and other payments. Our license and intellectual property-related agreements also require us to comply with other obligations, such as to use commercially reasonable efforts in developing and commercializing the drug candidates, provide certain information regarding our activities and maintain the confidentiality of information we receive from our licensors. In certain of our license agreements, we also are required to achieve

certain developmental and commercial milestones by specific deadlines. We cannot be certain that we will be able to fulfill all such obligations. In particular, some of the milestone payments that we are obligated to pay under these agreements are payable upon our drug candidates reaching development milestones before we have commercialized or received any revenue from sales of such drug candidate, and we cannot guarantee that we will have sufficient resources to make such milestone payments.

In addition, drug development is an uncertain process and even if we have such resources, we cannot be certain that such milestones will be met within the timeline required by our license agreements. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements and, upon the effective date of such termination, may have the right to terminate our exclusive rights or all of our rights and acquire rights to certain of our intellectual property. If any of our licensors terminate any license we rely upon, we might not be able to develop, manufacture, or market any drug candidate related to the intellectual property licensed under these agreements and we may face other additional penalties. In such case, we may have to negotiate new agreements or terms with less favorable terms to us, if we are able to do so at all. We may also face claims for monetary damages or other penalties. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach we commit if permitted, and otherwise seek to preserve our rights under the intellectual property rights licensed and sublicensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all.

Disputes may arise from the license agreements between us and our collaborating parties, which may have negative impacts on the scope of our rights.

The license agreements under which we in-license intellectual property or technology from third parties are complex, and disputes may arise regarding these agreements, including:

- the scope of rights granted under the license agreement;
- the extent to which the conduct of our business, including any relevant technology and processes, infringe, misappropriate, or otherwise violate intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other rights under the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by us, our partners, and our licensors; and
- the priority right of the patents or patent applications of inventions.

The resolution of any dispute could narrow what we understand to be the scope of our rights to the relevant intellectual property or technology, or increase what we understand to be our financial or other obligations under the relevant license agreement. Moreover, if disputes over intellectual property that we have in-licensed prevent or impair our ability to use the intellectual property or otherwise maintain our current licensing arrangements on commercially acceptable terms, we may not be able to successfully develop and commercialize the affected drug candidates.

We may face significant competition and fail to establish a partnership with a third party.

We may face significant competition from other pharmaceutical or biotechnology companies, even ones with greater resources or capabilities than us, in seeking appropriate strategic partners. Moreover, we may fail to establish a strategic partnership or other alternative arrangements with a third party especially when the drug candidate is in the early developmental stage, due to the fact that the third party may believe our drug candidates lacking potentials to commercial viability.

We may lose our relationships with CROs and they may not successfully carry out their contractual duties.

We have relied on and plan to continue to rely on third-party CROs to generate, monitor, and manage data for certain of our ongoing clinical programs. We also expect to rely on third parties to assist in conducting

certain preclinical studies that we may carry out in the future. Our CROs have the right to terminate their agreements with us in the event of an unrectified material breach. If any of our relationships with our third-party CROs is terminated, we may not be able to enter into arrangements with alternative qualified CROs or do so on commercially reasonable terms; or meet our desired clinical development timelines. There is a natural transition period when a new CRO commences work, and the new CRO may not provide the same type or level of services as the original provider, and as a result, we cannot assure you that data from our clinical trials may not be compromised. There is also a need for relevant technology to be transferred to the new CRO, which may take time and further delay our development timelines.

Furthermore, except for remedies available to us under our agreements with our CROs, we cannot control whether or not our CROs devote sufficient time and resources to our ongoing clinical, nonclinical, and preclinical programs. If our CROs fail to successfully carry out their contractual duties or obligations or meet expected deadlines, or if the accuracy of the clinical data obtained by CROs is compromised due to their 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 approvals for or successfully commercialize our drug candidates.

If CROs fail to comply with applicable protocol, laws, regulations, or scientific standards, our clinical development plan can be delayed.

As we rely on CROs for the execution of certain of our clinical trials, we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of the studies sponsored by us is conducted in accordance with the applicable protocol, legal, and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We, our CROs for our clinical programs and our clinical investigators are required to comply with good clinical practice, or GCP, and other regulatory regulations and guidelines enforced by the FDA and other comparable regulatory authorities for all of our drug candidates in clinical development. Regulatory authorities enforce these GCP or other regulatory requirements through periodic inspections of trial sponsors, investigators, and trial sites. If we or any of our CROs or clinical investigators fail to comply with applicable GCP or other regulatory requirements, the relevant clinical data generated in our clinical trials may be deemed unreliable and the FDA and other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP requirements. In addition, our clinical trials must be conducted with drug candidates produced under GMP requirements. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There may be information disclosure risks associated with using CROs.

The use of CROs requires us to disclose proprietary information to these third parties, which could increase the risk that such information will be misappropriated or disclosed. We currently have a small number of employees, which limits our ability to identify and monitor the activities of CROs. To the extent we are unable to identify and successfully manage the performance of CROs in the future, our business may be adversely affected.

Our success depends upon our and our business partners' ability to obtain and maintain intellectual property protection for our drug candidates and technologies.

We have and will apply for our own patents with claims covering our technologies, processes, and drug candidates. Additionally, we have also licensed patent rights from third parties for some of our pipeline products, including AN2025 from Novartis and AN0025 from Eisai. There can be no assurance that each patent eligible subject matter has been or will be applied for patent protection, the claims of any existing or future patent application that we or our partners file will be issued as a patent, or that the protection scope of a patent will be broad enough to exclude others from making, using, or selling our existing or future drug candidates or drugs similar or identical to those drug candidates. There is also no guarantee that the patent protection scope of a subject matter will be the same in all jurisdictions where patent applications have been filed. We also rely on trade secrets to protect aspects of our business, especially where we or our partners do

not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect and even with trade secret protection, companies may be able to independently develop equivalent knowledge, methods, and know-how. As a result, in countries where we or our partners have not sought and do not seek patent protection, third parties may be able to manufacture and sell products we commercialize in the future without our permission, and we may not be able to stop them from doing so, even if our products are protected by trade secrets.

The patent portfolio to which we have rights may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours. With respect to issued patents in certain jurisdictions, we or our partners may be entitled to obtain a patent term extension to extend the patent expiration date provided we or our partners meet the applicable requirements for obtaining such patent term extensions. For example, patents protecting core matters of AN2025 and AN0025 will expire in 2027 and 2031 respectively. Our partners may be entitled to extend the term of those patents in jurisdictions where patent term extension is adopted, including U.S., EU, China, and Japan. However, the applicable authorities may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we or our partners may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to the expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, any period during which we have the right to exclusively market our drug candidates will be shorter than we would otherwise expect. As such, the patent terms of AN2025 and AN0025 may not be successfully extended to 2032 and 2036 respectively, or at all.

We may face competition from generic or biosimilar manufacturers after the patent protection is no longer valid.

Even if patent protection for our approved drug candidates is successfully obtained, we may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may also challenge the scope, validity, or enforceability of the patents to which we have right 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. The applied and issued patents of our licensing partners for our drug candidates are expected to expire on various dates as described in paragraphs headed "Business — Intellectual Property" in this prospectus. Upon the expiration or invalidation of these and our future applied and issued patents, we will not be able to assert such patent rights against potential competitors.

We may face risks related to compulsory licensing

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

Our owned and in-licensed patents and patent applications may be subject to priority disputes, inventorship disputes, and similar proceedings.

While we are not currently aware of any pending challenges, we or our licensing partners may be subject to claims brought by former employees, collaborators, or other third parties who have an interest in our owned or in-licensed patents or other intellectual property or become involved in opposition, revocation, 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 to which our owned 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. Particularly, 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.

Any such event may require us to obtain and maintain licenses from third parties, including parties involved in such proceedings or disputes. Those licenses may not be available to us 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 from using or commercializing similar or identical drug products. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

We may face future patent claims or alike against our drug candidates or the exploitation of our products.

Our commercial success depends in significant part upon our ability to develop, manufacture, market, and sell our drug candidates without infringing, misappropriating, or otherwise violating the intellectual property rights of third parties. There is no assurance that our drug candidates or the sale or use of our future products do not and will not in the future infringe third-party patents or other intellectual property rights. Numerous issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing drug candidates. The risk increases as patent offices issue more patents to third parties or accept and examine more patent applications filed by them.

Third parties may also allege that we 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 or development, or with respect to the sale, use or manufacture of the compounds we have developed, in-licensed, or are developing. Such third parties might resort to litigation against us or our licensors or other parties we have agreed to indemnify based on either existing intellectual property or intellectual property that arises in the future.

We may fail to identify potential intellectual property related risks and take precautions.

It may be possible that we or our licensors failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Because patent applications can take many years to issue, there may be pending patent applications that we are not aware of and which may later result in issued patents that our drug candidates may infringe. In addition, third parties may obtain patents in the future and claim that development or commercialization of our drug candidates infringes upon these patents. We or our licensors also may incorrectly conclude that third party patents are invalid or that our activities do not infringe, misappropriate, or otherwise violate a third party's intellectual property.

If a competent court holds that our drug candidates, their manufacturing process, or any intermediate products during the manufacturing process falls into the protection scope of a patent owned by a third party, the patent holder may be able to prevent us from manufacturing such drug candidate unless we obtain a license under the applicable patents, design around the patent, or until such patents expire or they are held invalid or unenforceable. Similarly, if a competent court holds that our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods fall within the protection scope of a patent owned by a third party, the patent holder may be able to block the development and commercialization of the applicable drug candidate unless we obtain a license, limit our uses, design around the patent, or until such patent expires or is held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property.

If we were found liable for intellectual property infringement or misappropriation, we may be obligated to pay substantial damages.

In the event of a successful claim of infringement or misappropriation against us, we may have to pay substantial damages, including, in the U.S., triple damages, and attorneys' fees in the case of willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing drug candidates, which may be impossible or require substantial time and monetary expenditure. Third parties who

bring successful claims against us for infringement of their intellectual property rights may obtain injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights, regardless of merit, would involve substantial expense and be time-consuming, regardless of the outcome, and our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Claims that we misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect.

We may face legal proceedings or disputes before regulatory authorities related to our patents and other intellectual property, which can be unpredictable, expensive and time-consuming.

Notwithstanding measures we or our licensors may take, now or in the future, to obtain and maintain patent and other intellectual property rights with respect to drug candidates we plan to develop, our intellectual property rights could be challenged or invalidated in courts or before regulatory authorities.

The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or otherwise interpreted narrowly. 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 defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our or our licensor's ability to enforce such claims against the defendant and others. Additionally, during an intellectual property litigation, there will be substantial amount of discovery required in connection with the litigation. As a result, there is a risk that some of our confidential information could be compromised by disclosure.

Litigation and other proceedings in connection with any of the foregoing claims can be expensive and time-consuming and, even if resolved in our favor, may cause us to incur significant expenses and could distract management and our scientific and technical personnel from their normal responsibilities. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and defend their intellectual property rights than we can. Thus, we or our licensors may not have sufficient funds to defend against any such claims or may otherwise decide not to defend them for commercial or other reasons. Moreover, the damages or other remedies awarded, if any, may not be commercially meaningful.

Even if we obtain patent protection, a competent court may nevertheless find that a potentially infringing technology does not fall within protection scope of our patent protection scope.

Even if we or our licensors obtain patent protections, a competent court may still find that an alleged infringing technology does not fall within the protection scope of our or our licensor's patent protection scope. The scope of a patent can be reinterpreted after its issuance and changes pursuant to either the patent laws or interpretation of the patent laws in the U.S. and other applicable jurisdictions. If the protection scope is interpreted narrowly, it may diminish the value of the patents we hold or in-license. Issuance is not conclusive as to its scope and any patents that we hold or in-license rights may be challenged by third parties in the courts or patent offices in the U.S., China, or other applicable jurisdictions. We cannot predict whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. If a court determines that the actual protection scope of our or our licensor's patent is narrower than the scope based on its literal meaning, the court will hold that the alleged infringer does not infringe the patent at issue and will refuse to stop the alleged infringer from using the technology at issue on the grounds that our patents do not cover the technology in question.

Our current or any future patent applications may not be successfully granted into patents, or if granted, the protection scope may not be broad enough to cover our technology.

The patent positions of biotechnology and pharmaceutical companies, including our patent position, involve complex legal and factual questions. Therefore, the issuance of any patent applicants to which we have

rights or may obtain rights cannot be predicted with certainty. Our pending and future patent applications may not result in the issuance of patents at all. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other applicable jurisdictions are typically not published until 18 months after filing or in some cases, as in the U.S., until they are issued as a patent. Therefore, we cannot be certain that we or our current or future licensors, licensees, or collaborators were the first to make or file on the inventions claimed in our owned or licensed patents or pending patent applications. There is also no assurance that all of the potentially relevant prior art relating to the patents and patent applications covering our drug candidates has been identified and disclosed to the relevant patent office, during the prosecution of the related patent application, and such prior art could be used by a third party to prevent a patent from being issued from a pending patent application.

Even if our current or future licensors', licensees', or collaborators' patent applications are issued 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. The coverage claimed in a patent application can be significantly reduced before the patent is issued. 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 sufficiently covering our technology in any particular jurisdiction.

Intellectual property litigation may lead to unfavorable publicity which may harm our reputation.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard any such announcements as negative, the perceived value of our drug candidates, future drugs, programs, or intellectual property could be diminished. Accordingly, the market price of the ADSs may decline. Such announcements could also harm our reputation or the market for our drug candidates, which could have a material adverse effect on our business. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, in-license needed technology, or enter into strategic partnerships that would help us bring our drug candidates to market.

Our patent protection could be reduced or eliminated if we or our licensors do not comply with patent administration authorities' relevant requirements.

In several stages over the lifetime of a patent and patent application, periodic maintenance fees, renewal fees, annuity fees and various other governmental fees are due to be paid to the United States Patent and Trademark Office, or the USPTO, the China National Intellectual Property Administration, or the CNIPA, and other patent offices and agencies. The USPTO, the CNIPA and various comparable governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and maintenance process. In certain circumstances, we may be required to rely on our licensors to take the necessary action to comply with these requirements with respect to patents or other intellectual property they have licensed to us. While 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 noncompliance, which could include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents, 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.

Changes in patent law of the U.S., China, or other jurisdictions could diminish the value of our patents in general.

Changes in either the patent laws or their interpretation in the U.S., China, or other applicable 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.

Certain recently enacted U.S. laws have changed the procedures through which patents may be obtained and by which the validity of patents may be challenged. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. Particularly, in March 2013, the U.S. changed from first to invent to first to file rule, meaning the applicant who files a patent

application first is entitled to the patent 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 patent applications in the U.S. and the enforcement or defense of patents issued to us or our licensors. 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. Furthermore, 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. Similar changes in the laws could happen in other applicable jurisdictions.

In China, intellectual property laws are constantly evolving and efforts have been made to improve intellectual property protection. For example, on October 17, 2020, the Standing Committee of the National People's Congress of PRC promulgated the amended Patent Law of the PRC (2020 Revision), which took effect since June 1, 2021. It regulates a patent linkage for pharmaceutical patents and approves the patent term extension for eligible innovative pharmaceutical patents. However, it lacks an implementing rule for how to obtain and how to calculate patent term extension, and thus we may not be able to successfully secure sufficient patent term extensions or at all for our patents or patents we in-licensed. Also, if a third party obtains patent term extension for its patent and our drug candidates fall within the protection scope, we are required to delay commercialization for an extended period of time. Therefore, we cannot guarantee that these changes or any future changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

We may be unable to protect our trade secrets.

In addition to patent rights, we currently rely on and plan to continue to 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 trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, our collaborators, sponsored researchers, contract manufacturers, consultants, advisers, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. 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 likely to be unpredictable. In addition, if any trade secrets that we rely on were to be lawfully obtained or independently developed by a competitor or other third party, we may have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed. In addition, while we typically require our employees, consultants, and contractors who may be involved in the 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, 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. Our partners who have granted rights to trade secrets or other confidential information also may not take all such precautions or may be exposed to other risk that could result in the loss of trade secrets or rights in confidential information that we rely upon.

We may be subject to claims that we have wrongfully used or disclosed alleged trade secrets of others or claims asserting ownership of what we regard as our own or our partners' intellectual property.

Some of our employees, consultants, and advisers, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential

competitors. Some of these employees, consultants, and advisers, including members 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 they do not use the proprietary information or know-how of others in their work for us, we cannot be certain that we or our partners take enough precautions, and we may be subject to claims that we, our partners 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 such disclosures, or threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future, there can be litigation where we need to defend against such claims. If we fail in defending any such claims, in addition to possibly paying monetary damages, we may lose valuable intellectual property rights, or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. In addition, we may lose personnel or even important ones 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. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Moreover, 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.

We may not be able to enjoy additional protection over drug-related patents in the U.S.

In the U.S., the Federal Food Drug and Cosmetic Act, as amended by the law generally referred to as "Hatch-Waxman", provides the opportunity for limited patent term extension, which can compensate for patent term lost due to FDA's regulatory review. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval; only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. Even then, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we fail to obtain patent term extensions or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration.

Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Moreover, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the U.S. to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the U.S. Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where the FDA designates the drug candidate as an orphan drug and the drug is approved for the designated orphan indication. However, we may not be able to enjoy those benefits if we fail to apply for them according to the FDA's relevant requirements.

Our drugs may not share the same level of protection in China as in the U.S.

The Patent Law of the PRC (2020 Revision) provides a patent linkage system, pursuant to which the patent holder or a party of interest can resolve potential patent infringement disputes before a follow-on drug

receives marketing approval. Depending on the outcome of the disputes, NMPA will decide whether to delay approval of such follow-on applications. There are certain implementation rules and interpretations for the patent linkage system, such as Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial) published by NMPA and the CNIPA and took effect from July 4, 2021, and Provisions on Several Issues Concerning the Application of Law in the Trial of Patent Civil Cases Involving Drug Marketing Review and Approval of Patent (Draft for Solicitation of Comments) published by Supreme People's Court on October 29, 2020. Currently, the patent linkage system has been established in China. However, the enforcement of laws and regulations to some extent remain uncertain in China. In addition, there is no currently effective law or regulation providing data exclusivity in China (referred to as regulatory data protection). Although Implementation Rules for Drug Regulatory Data Protection (Trial) (Draft for Solicitation of Comments was published by NMPA on April 25, 2018), no updates or progress have been reported on this legislation. In view of the uncertainty of the newly established patent linkage system and also the lack of data protection, a lower-cost generic drug can emerge onto the market much more quickly than in the U.S.

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 and unregistered trademarks or trade names that we own or in-license are valuable assets and may be challenged, infringed, circumvented, declared generic, lapsed, or determined to infringe on or dilutive of other marks. We may not be able to protect and maintain our rights to these trademarks and trade names, which may be necessary to build name recognition among potential collaborators or customers in our markets of interest. Sometimes, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. As of December 31, 2022, we had trademarks in the progress of registration and are subject to the risk of limited trademark protection. If we delay or fail to complete the registration of our trademarks, 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 trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names against us. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights, or other intellectual property may be ineffective, incur substantial costs and divert our resources.

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

Legislation that the U.S. Congress has passed is likely to expand the jurisdiction and powers of the Committee on Foreign Investment in the U.S., or the CFIUS, the U.S. interagency committee that conducts national security reviews of foreign investment. President Trump signed the Foreign Investment Risk Review Modernization Act or 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 U.S. export controls and certain "emerging and foundational technology," a term that is still being defined but is expected to include a range of U.S. biotechnology. If an investment by a foreign entity in a U.S. business dealing in "critical technology" meets certain thresholds, a filing with the CFIUS is mandatory. While the FIRRMA currently grants CFIUS jurisdiction on only controlling and certain non-controlling investments made by foreign persons in U.S. businesses in research and development in biotechnology, the CFIUS's jurisdiction may be further expanded in the future, which may place additional limitations on strategic collaborations with our

current or future 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.

Intellectual property rights do not necessarily address all potential threats.

Intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. Thus, the degree of future protection afforded by our intellectual property rights is uncertain. The following examples are illustrative:

- 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 in-license now or in the future;
- we or any of our licensors might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or exclusively in-license, which could result in the patents applied for not being issued or being invalidated after issuing;
- we or any of our licensors might not have been the first to file patent applications covering certain of our or their inventions;
- pending patent applications may not lead to issued patents;
- we may obtain or in-license patents for certain compounds many years before we receive NDA approval for drugs containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related drugs, the commercial value of our patents may be limited;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating, or otherwise violating our intellectual property rights;
- 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 rights to patents and then use the information learned from such activities to develop competitive products for commercialization in our major markets;
- we may fail to develop or acquire rights to additional proprietary technologies that are patentable;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate;
- third parties may gain unauthorized access to our intellectual property due to potential lapses in our information systems;
- the patents of others may materially and adversely affect our business, for example by preventing us from commercializing one or more of our drug candidates for one or more indications; 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.

We may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may later prove to be more profitable, or for which there is a greater likelihood of success.

As there are many potential drug candidates to choose from, our research programs to identify drug candidates that we may wish to in-license require substantial technical, financial, and human resources. We may focus our efforts and resources on research programs or drug candidates that ultimately prove to be unsuccessful. Moreover, because we have limited financial and managerial resources, we focus on clinical development programs and drug candidates for specific indications. As a result, we may forego or delay pursuit

of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may result in failure to capitalize on viable commercial products or profitable market opportunities, which could materially and adversely affect our future growth and prospects.

We may not be able to identify, discover, or in-license new drug candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval, and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to identify, license in, discover, develop, or commercialize additional drug candidates. Our research programs or licensing efforts may fail to identify, discover or in-license new drug candidates for clinical development and commercialization for a number of reasons, including, without limitation, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential drug candidates;
- our potential drug candidates may be shown to have harmful side effects or may have other characteristics that may make the drug candidates unmarketable or unlikely to receive marketing approval; and
- 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, thereby limiting our ability to diversify and expand our product portfolio.

Certain of our drug candidates may be limited to those patients who are ineligible for or have failed prior treatments and the relevant market may be relatively small.

Certain of our drug candidates are mainly targeted for treatment of patients who are ineligible for or have failed prior treatments. Our lead product buparlisib or AN2025 is used for treatment of recurrent or metastatic HNSCC after anti-PD-1/PD-L1 therapy. Also, our product AN0025 is developed in combination with Keytruda or pembrolizumab for the treatment of NSCLC and bladder cancer after anti-PD-1/PD-L1 treatments and TNBC, MSS CRC, and cervical cancer after standard of care treatments. As such drug candidates are targeting late-line patients, the relevant market may be relatively small.

We may encounter difficulties enrolling patients in our clinical trials.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients in the clinical trials. We may fail or experience significant delays to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, NMPA, EMA, or similar regulatory authorities, or the patient enrolment is delayed. 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.

Patient enrollment for our clinical trials may be affected by many factors. For example, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in the clinical trials of our competitors' drug candidates. Other factors include:

- severity of the disease under investigation;
- total size and nature of the relevant patient population;
- design and eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the drug candidate under study;
- our resources to facilitate timely enrollment in clinical trials;
- the ability to obtain and maintain informed consents;

- the risk that enrolled patients will not complete a clinical trial;
- clinicians' and patients' perceptions as to the potential advantages and risks of the candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any candidates under development;
- patient referral practices of physicians;
- our investigators' or clinical trial sites' efforts to screen and recruit eligible patients;
- proximity and availability of clinical trial sites for prospective patients; and
- epidemics.

The outbreak of epidemics and the resulting government actions may adversely impact our planned and ongoing clinical trials. Clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff, and patient enrollment may be delayed due to the prioritization of hospital resources towards combating the COVID-19 pandemic. For further details, see "Risk Factors — Risks related to our business — We may face force majeure risks, including the recent COVID-19 outbreak."

AEs or undesirable side effects caused by our drug candidates could interrupt, delay, or halt clinical trials, delay or prevent regulatory approvals, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approvals.

As is the case with biopharmaceuticals generally, it is likely that there may be adverse side effects associated with pipeline products or our future drug candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of expected or unexpected side effects or unexpected characteristics. Undesirable side effects caused by our drug candidates when used alone or in combination with approved or investigational drugs could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label, or lead to the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities.

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

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

In addition, some of our drug candidates are still considered as emerging and relatively novel therapeutics for treating cancer. 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 FDA, NMPA, EMA, 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.

Interim, "top-line" or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose top-line or preliminary data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line or preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Disclosure of interim data by us or by our competitors could also result in volatility in the price of the ADSs after this offering.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product and our stock. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and investors or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our drug candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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 worldwide. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability, or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug

candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in significant negative consequences, including but not limited to:

- 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; and
- the inability to commercialize any approved drug candidate.

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

If a product fails to demonstrate safety and efficacy in one clinical trial, we may have to execute additional clinical trials or even terminate clinical trials of such drug candidate.

During clinical trials, there can be numerous unexpected events that could cause one or more of our drug candidates to fail to demonstrate safety and efficacy in humans in accordance with our current clinical development plans, including but not limited to: clinical trials of our drug candidates may produce negative or inconclusive results, and additional clinical trials may be required. Examples include lack of clinical response or other unexpected characteristics, participants are being exposed to unacceptable health risks, and the cost of clinical trials of our drug candidates is greater than we anticipate. If any of these events occurs and a product fails a clinical trial, we cannot guarantee that we would be able to effectively develop alternative clinical plans in time or at all and we may have to terminate clinical trials of the drug candidate.

We may in the future conduct additional clinical trials for our drug candidates outside the United States and/or China, and FDA, NMPA and similar foreign regulatory authorities may not accept data from such trials.

We have conducted clinical trials for our drug candidates in France and China, and may in the future conduct clinical trials for our drug candidates outside the U.S., including in Europe, Australia, China or other foreign jurisdictions. The acceptance of trial data from clinical trials conducted outside the U.S. by the FDA may be subject to certain conditions. In cases where data from clinical trials conducted outside the U.S. are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Otherwise, for studies that are conducted at sites outside of the U.S. and not subject to an IND and which are intended to support a marketing application (but which are not intended to serve as the sole basis for marketing approval), the FDA requires the clinical trial to have been conducted in accordance with GCP requirements and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many regulatory bodies, such as

NMPA, have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, NMPA, or any similar foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA, NMPA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our drug candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

We have relied and will continue to rely on third parties to manufacture our drug candidates in the foreseeable future.

We currently work with qualified CMOs to manufacture drug candidates for preclinical and clinical supply. In the near future, we plan to continue outsourcing the manufacturing of our drug candidates, including commercial-scale manufacturing of our approved drugs, to CMOs/CDMOs globally and in China. The facilities used by third-party manufacturers to manufacture our drug candidates must be approved for such manufacture by the FDA and any comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit an NDA to the FDA or any comparable submission to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with GMP requirements for manufacture of products. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance ("QA") and qualified personnel. If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for such drug candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our reliance on third-party CMOs exposes us to certain additional risks, such as:

- due to the limited number of qualified CMOs, we may not be able to locate a sufficient number of qualified CMOs at all times and on acceptable terms;
- substantial training is required for CMOs to manufacture a new drug candidate. We cannot ensure that the CMOs can acquire the technology and know-how in the manufacturing of our drug candidates in a timely manner, if at all;
- the CMOs may not always be able to fully perform our obligations, including timely manufacture and deliver our drug candidates in quantity and quality to meet our clinical and commercial needs;
- the CMOs are subject to ongoing periodic unannounced inspections by NMPA and other comparable regulatory authorities to ensure strict compliance with GMP and other government regulations and requirements. We have limited control over these matters for our CMOs and thus cannot assure you that our CMOs will comply with these regulations and requirements at all times;
- if the CMOs fail to properly obtain, protect, maintain, defend, or enforce our or our licensors' intellectual property rights, or otherwise use our or our licensors' 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, our business may be materially harmed;
- we may not own, or may have to share, the intellectual property rights to any improvements made by the third-party manufacturers in the manufacturing process for our drug candidates; and
- products and components from our or our licensors' overseas third-party manufacturers may be subject to additional customs and import charges, which may cause us to incur delays or additional costs as a result.

If the CMOs were to encounter any of these difficulties or fail to comply with their contractual obligations, our ability to supply our drug candidates in clinical trials and to deliver drugs for commercial sales in the future would be jeopardized.

We may encounter problems in manufacturing our drug candidates or our future drug products through CMOs.

The manufacturing of biopharmaceutical products is highly complex. We currently work with qualified CMOs to manufacture drug candidates for preclinical and clinical supply. In the near future, we plan to continue outsourcing the manufacturing of our drug candidates, including commercial-scale manufacturing of our approved drugs, to CMOs/CDMOs globally and in China. Problems may arise during the course of manufacturing for a variety of reasons, such as:

- equipment malfunction;
- failure to follow specific protocols and procedures;
- changes in product specification;
- low quality or insufficient supply of raw materials;
- delays in the construction of new facilities or the expansion of existing manufacturing facilities of third-party manufacturers 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 cause, 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 may experience delay in clinical trials or commercialization due to manufacturing problems.

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

We may also encounter problems with achieving adequate or clinical-grade products that meet the FDA, NMPA, EMA, or other comparable regulatory authority standards or specifications, and maintaining consistent and acceptable production costs. In such events, we may be required to locate alternative suitable CMOs, and we cannot guarantee that we will be able to secure temporary, alternative manufacturers for our drug candidates with the terms, quality, and costs acceptable to us, or at all. It could delay our clinical trials and/or the availability of our future drug products for commercial sale.

CMOs that we collaborate with now or in the future may fail to exercise effective quality control and quality assurance.

The quality of our future drug products, including drug candidates manufactured for research and development purposes and, in the future, drugs manufactured for commercial use, depends in significant part on the effectiveness of the quality control and quality assurance, which in turn depends on factors such as the

production processes used in the manufacturing facilities, the quality and reliability of equipment used, the quality of the staff and related training programs of our cooperative CMOs. However, we cannot assure you that the employees of CMOs will always adhere to the quality control and QA protocol, and that such quality control and QA procedures will be effective in consistently preventing and resolving deviations from pre-agreed quality standards. Any significant failure or deterioration of the quality control and QA protocol could render our future drug 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.

We may be unable to meet the increasing demand for our existing drug candidates and future drug products due to insufficient manufacturing or shipping capabilities.

Manufacturers of 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 elimination of contamination. These problems include problems in logistics and shipping, difficulties in managing production costs and increasing yields, and potential issues related to quality control, including stability of the product, product testing, operator error, availability of qualified personnel and compliance with strictly-enforced regulations. For example, if contaminants are discovered in our supply of our drug candidates or in the manufacturing facilities of our contract manufacturers, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. If our contract manufacturers encounter unanticipated delays and expenses as a result of any of these difficulties, we may not be able to manufacture sufficient quantities of our drug candidates in the time frame we expect or at all.

To produce our drug candidates in the quantities that we understand to be required to meet anticipated market demand for our drug candidates, if approved, our contract manufacturers will need to significantly increase, or "scale up," the production process over the initial level of production. If our contract manufacturers are unable to meet the quantity requirements, or if we cannot find a sufficient number of quality third-party suppliers, we may not be able to produce our approved drug candidates in a sufficient quantity to meet future demand.

Our suppliers may fail to provide us with sufficient quantities of the raw materials or fail to do so at acceptable quality levels or prices.

We currently rely on and expect to continue to rely on third parties to supply raw materials for us to manufacture the approved drugs in the future. However, raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material defects or prices. Such risks could delay or prevent R&D activities, result in higher costs, or adversely impact commercialization of our future approved drug candidates.

Our drug candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

Our future approved drug candidates, if any, may fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community, who may prefer other drugs to ours. If our future approved drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from sales of such drug candidates and may not become profitable.

The degree of market acceptance of our future approved drug candidates, if and when they are approved for commercial sale, will depend on a number of factors, including but not limited to:

- product labeling or package insert requirements of the FDA, NMPA, EMA or other comparable regulatory authorities, including the clinical indications for which our drug candidates are approved and limitations or warnings contained in the labeling;
- physicians, hospitals, cancer treatment and patients considering our drug candidates to be safe and effective;

- whether our drug candidates have achieved first-in-class or best-in-class status and the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- timing of the launch of our drug candidates as well as competitive drugs;
- cost of treatment in relation to alternative treatments;
- availability of adequate coverage and reimbursement under the National Reimbursement Drug List (the "NRDL") and provincial reimbursement drug lists in China, or from third-party payors and government authorities in other applicable jurisdictions;
- willingness of patients to pay any out-of-pocket expenses in the absence of coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared with alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

Even if our 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 and render our drug candidates obsolete.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours.

The biotechnology and pharmaceutical industries are subject to intense competition and rapid and significant technological change. We face competition with respect to our current drug candidates, and we will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future. Our competitors include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are developing our drug candidates in competition with a number of large biopharmaceutical companies that currently market and sell drugs or are pursuing the development of drugs for the same target indications as ours. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Many of our competitors have substantially greater financial, technical, and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approvals from the FDA, NMPA, EMA or other comparable regulatory authorities more rapidly than we are able to and may be more effective in selling and marketing their products as well. For example, recently NMPA has accelerated market approval of drugs for diseases with high unmet medical needs, and may review and approve drugs that have gained regulatory market approval in the U.S., the European Union or Japan within the previous ten years without requiring further clinical trials in China. This may lead to increased competition from drugs which have already obtained approval in other jurisdictions.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring, or licensing products that are more effective or less costly than any future drug product that we may develop, or achieve earlier patent protection, regulatory approvals, product commercialization, and market penetration than we do. Additionally, technologies developed by our competitors may render our future drug products uneconomical or obsolete, and we may not be successful in marketing our future drug products against competitors.

We have no experience in launching and marketing drug candidates. We may not be able to effectively build and manage our sales network, or benefit from third-party collaborators' sales network.

We currently have no sales, marketing or commercial product distribution capabilities and have no experience in marketing drugs. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. If we are unable or decide not to establish internal sales, marketing and commercial distribution capabilities for any or all of the drugs we develop, we will likely pursue collaborative arrangements regarding the sales and marketing of our drugs. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or, if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend on the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts of our drug candidates. There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

Our future approved drug candidates may not receive reimbursement in the U.S., Europe, China, or other countries, and we may be subject to unfavorable pricing regulations.

The regulations governing regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approvals for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and reduce the revenues we are able to generate from the sale of the drug in that country.

Our ability to successfully commercialize any future approved drug candidates will depend in part on the extent to which reimbursement for such drug candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide the medications they will pay for and establish reimbursement levels. If our future approved drug candidates failed to be included in the reimbursement programs or did not receive a favorable reimbursement level, our drug candidates may lose advantages in pricing compared to the competitor drugs.

Obtaining reimbursement for our future 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.

Reimbursement of our future approved drug candidates may not be immediately available or may be limited in the U.S., Europe, China, or other countries.

There may be significant delays in obtaining reimbursement for our future approved drug candidates, and coverage may be more limited than the approved indications. Inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any future approved drug candidates could have a material adverse effect on our business, operating results, and financial condition. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent.

Our revenue may be negatively affected whether our future approved drug candidates are included in reimbursement programs or not.

A primary trend in the global healthcare industry is cost containment. In recent years, government authorities and third-party payors, such as private health insurers and health maintenance organizations have

attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. As a result, our revenue may be negatively affected whether our future approved drug candidates are included in reimbursement programs or not.

For example, if the Ministry of Human Resources and Social Security of the People's Republic of China or any of its local counterparts accepted our application for the inclusion of our future approved drug candidates in the NRDL or the Provincial Reimbursement Drug List (the "PRDL"), our potential revenue from the sales of such drug candidates could decrease as a result of the significantly lowered prices we may be required to charge for the products to be included in the NRDL or the PRDL. If we failed in our efforts to have our future drug products included in the NRDL or the PRDL but were able to successfully launch commercial sales of our future approved drug candidates, our revenue from commercial sales would be highly dependent on patient self-payment, which can make our future approved drug candidates less competitive.

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

The illegal importation of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates, which may adversely affect our sales and profitability in the U.S., China, and other applicable jurisdictions where we commercialize our future approved drug candidates. Unapproved foreign imports of prescription drugs are illegal under the current laws of the U.S., China, and other applicable jurisdictions. However, illegal imports occur and may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets, known as parallel imports, into higher-priced markets could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as China, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our future drug products. Since counterfeit pharmaceutical products in many cases are very similar in appearance to the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products could quickly erode the demand for our future approved drug candidates.

In addition, counterfeit pharmaceutical products are unlikely to meet our or our collaborators' rigorous manufacturing and testing standards. A patient who receives a counterfeit pharmaceutical product may be at risk for a number of dangerous health consequences. Our reputation and business could suffer as a result of counterfeit pharmaceutical products sold under our or our collaborators' brand name(s). In addition, thefts of improperly stored inventory at warehouses or plants or while in transit which are sold through unauthorized channels could also adversely impact patient safety, our reputation, and our business.

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

All jurisdictions in which we intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We intend to conduct our activities spanning over 18 significant markets in North America, Europe, and Asia. These jurisdictions 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 that make for a more complex and costly regulatory compliance burden for a company like ours that plans to operate in these regions.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process and approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include refusal to approve pending applications, withdrawal of an approval, revocation of a license, a hold on clinical trials,

voluntary or mandatory recalls of products, the seizure of products, total or partial suspension of production, or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or other civil or criminal penalties.

We are subject to stringent privacy laws, information security policies, and contractual obligations related to data privacy and security.

We routinely receive, collect, generate, store, process, transmit, and maintain medical data treatment records and other personal details of subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, national, and international data protection and privacy laws, directives, regulations, and standards that apply to the collection, use, retention, protection, disclosure, transfer, and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by customers, and other affected individuals, damage to our reputation and loss of goodwill.

Such data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the patients' private or medical records without their consent, they will be held liable for damage caused thereby. We have taken measures to maintain the confidentiality of the medical records and personal data of patients 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 patients' 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 use medical data and subject us to liability for the use of such data for previously permitted purposes.

The regulatory approval processes of the FDA and other comparable regulatory authorities are uncertain and time-consuming and may evolve over time.

The time required to obtain the approval from the FDA, NMPA, EMA, and other comparable regulatory authorities is inherently uncertain and depends on numerous factors, including the substantial discretion of the regulatory authorities. Generally, such approvals take many years to obtain following the commencement of preclinical studies and clinical trials. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. We cannot guarantee that we will be able to obtain regulatory approvals for our existing drug candidates or any drug candidates we may discover, in-license, or acquire and seek to develop in the future.

Our drug candidates could fail to receive the regulatory approvals from the FDA, NMPA, EMA, or a comparable regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective for its proposed indication;
- failure of our clinical trial results to meet the level of statistical significance required for approval;
- failure of our clinical trial process to pass relevant GCP and inspections;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;

- insufficient data collected from the clinical trials of our drug candidates to support the submission and filing of a NDA, or other submissions or to obtain regulatory approvals;
- failure of our drug candidates to pass current GMP inspections during the regulatory review process or across the production cycle of our drug;
- failure of our clinical sites to pass audits carried by out by the FDA, NMPA, EMA, or comparable regulatory authorities, resulting in a potential invalidation of our research data;
- findings by the FDA, NMPA, EMA, or comparable regulatory authorities of deficiencies related to the manufacturing processes or the facilities of third-party manufacturers with whom we contract for clinical and commercial supplies;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval; and
- failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations.

The FDA, NMPA, EMA, or a comparable regulatory authority may require more information, including additional preclinical, clinical, or chemistry, manufacturing, and control data, to support approval, which may delay or prevent approval and our commercialization plans. Based on the feedback we received from the FDA, we are able to submit ORR data from the Phase III interim analysis for the potential accelerated approval of AN2025 in combination with paclitaxel for the treatment of recurrent or metastatic HNSCC after anti-PD-1/PD-L1 therapy. However, if the FDA believes that ORR is not good enough to support approval, we will need to wait to obtain and submit OS, which may at least cause delays in receiving the marketing approval. Even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials, or approve a drug candidate with an indication that is not desirable for the successful commercialization of that drug candidate.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified drugs from being developed, approved or commercialized in a timely manner or at all.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels. Statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to licensed biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the Covid-19 pandemic, in March, 2020, the FDA postponed most inspections of foreign and domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. In July 2021, the FDA resumed standard inspectional operations of domestic facilities. Since that time, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the Covid-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions.

We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We may in the future seek an accelerated approval for AN2025 in combination with paclitaxel for the treatment of recurrent or metastatic head and neck squamous cell carcinomas ("HNSCC") after anti-PD1/PD-L1 therapy. Under the accelerated approval program, the FDA may grant accelerated approval to a drug candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the drug candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verity and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for any of our drug candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an IND or BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our drug candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our drug candidate would result in a longer time period to commercialization of such drug candidate, could increase the cost of development of such drug candidate and could harm our competitive position in the marketplace.

A fast track designation by the FDA, even if granted for any of our drug candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our drug candidates will receive marketing approval.

We have received fast track designation for AN2025 the treatment of recurrent or metastatic HNSCC with disease progression on or after platinum-based therapy. We may seek additional designation for some or all of our other drug candidates. If a drug or biologic is intended for the treatment of a serious condition and demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA fast track designation. The sponsor of a fast track drug candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA or NDA is submitted, the application may be eligible for priority review. A fast track drug candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA or NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA or NDA, the FDA agrees to accept sections of the BLA or NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the

BLA or NDA. The FDA has broad discretion on whether or not to grant this designation. Even if we believe a particular drug candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that statutory criteria for granting such designation are no longer met.

If we are unable to obtain NMPA approval for our drug candidates to be eligible for an expedited registration pathway as innovative drug candidates, the time and cost we incur to obtain regulatory approvals may increase.

NMPA has mechanisms in place for expedited review and approval for drug candidates that are innovative drug applications, provided such drug or drug candidate has a new and clearly defined structure, pharmacological property, and apparent clinical value and has not been marketed anywhere in the world. However, there is no assurance that an innovative drug designation will be granted by NMPA for any of our drug candidates. Moreover, an innovative drug designation, which is typically granted only towards the end of a drug's developmental stage, does not increase the likelihood that our drug candidates will receive regulatory approvals on a fast-track basis, or at all.

Further, there have been recent regulatory initiatives in China regarding clinical trial approvals, the evaluation and approval of certain drugs and medical devices and the simplification and acceleration of the clinical trial process. For further details, see "Regulation — PRC laws and regulations — PRC drug regulatory regime" in this prospectus.

The regulatory environment in China has substantially changed in recent years and may change further in the future in unpredictable ways. Any future policies, or changes to current policies, that NMPA approves might require us to change our planned clinical study design or otherwise spend additional resources and effort to obtain approval of our drug candidates. In addition, policy changes may contain significant limitations related to use restrictions for certain age groups, warnings, precautions, or contraindications, or may be subject to burdensome post-approval study or risk management requirements.

Even if we receive regulatory approvals for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review.

If the FDA, NMPA, EMA, or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements on pharmacovigilance. These requirements include submissions of safety and other post-marketing information and reports, registration, random quality control testing, adherence to any chemistry, manufacturing, and controls, specifications, continued compliance with current GMPs, and GCPs and potential post-approval studies for the purposes of license renewal. Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies.

In addition, once a drug is approved by the FDA, NMPA, EMA, or a comparable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug products, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters, or holds on our clinical trials;
- refusal by the FDA, NMPA, EMA, or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us;
- suspension or revocation of existing drug license approvals;
- refusal by the FDA, NMPA, EMA, or comparable regulatory authorities to accept any of our other IND approvals or NDAs;

- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative, or criminal penalties.

Any government investigation of alleged violations of law could require us to spend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit, or delay regulatory approvals of our drug candidates. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability.

Failure by us or other parties to obtain or renew certain approvals, licenses, permits, and certificates required for our business, or any failure to comply with applicable regulations and industry standards may materially and adversely affect our reputation, business, financial condition, and results of operations.

Pursuant to the relevant laws, regulations, and relevant regulatory practice by governmental authority, we and/or other parties related to our operations, such as landlords or managers of premises on or local science parks in which we operate, are required to obtain and maintain various approvals, licenses, permits, and certificates (e.g., drainage permits) from relevant authorities to operate our business. Some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew any approvals, licenses, permits, and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities causing operations to cease, and may include corrective measures requiring capital expenditure or remedial actions. There is also no assurance that the relevant authorities would not take any enforcement action against us.

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

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our drug candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA, NMPA, EMA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our drug candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for any of our drug candidates, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of any of our drug candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. Even though the FDA, NMPA, EMA, and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains the risk that our product is subject to off-label drug use and is prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our

products less effective or entirely ineffective and may cause adverse drug reactions. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may also ultimately result in failure to obtain regulatory approvals for our drug candidates.

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 FDA, NMPA, EMA, or another comparable regulatory agency revokes or denies its approval of one component drug, in either the clinical design, clinical administration, therapy approval or commercialization stage, we will be forced to terminate or redesign the clinical trials for the combination therapy, and 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.

We may be restricted from transferring our scientific data abroad.

In March 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data , which provide a broad definition of scientific data and relevant rules for the management of scientific data. According to this new regulation, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. If and to the extent our research and development of drug candidates will be subject to this new rule and any relevant laws as required by the relevant government authorities, we cannot guarantee that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad. 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. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under this new regulation, we may be subject to fines and other administrative penalties imposed by those government authorities.

We have a limited operating history, have incurred net losses and anticipate that we will continue to incur net losses for the foreseeable future. We may not be able to generate sufficient revenue to achieve or maintain profitability.

Investment in the development of biopharmaceutical products is highly speculative as it entails substantial upfront capital expenditures and significant risks that a drug candidate may fail to demonstrate sufficient efficacy or safety to gain regulatory or marketing approvals or become commercially viable. Previously, we have financed our activities primarily through proceeds from private equity and debt financings. We have not generated any revenue from commercial product sales, and continue to incur significant upfront licensing fees, milestone payments, and other fees under existing in-license agreements, as well as research and development expenses and other expenses related to our ongoing operations. In addition, we issued a series of preferred shares to investors and recorded these financial instruments as financial liabilities at FVTPL. As a result, we are not profitable currently and have incurred net losses. In 2020, 2021, and 2022, our net loss for the year was US$64.7 million, US$56.7 million, and US$58.8 million, respectively. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and losses for the foreseeable future, and that these expenses and losses will increase as we carry out certain activities relating to our development, such as:

- acquiring or in-licensing other intellectual property, drug candidates, and technologies and payment of milestones and other fees under existing in-license agreements;
- conducting preclinical studies and clinical trials of our existing and new drug candidates;

- manufacturing clinical trial materials and commercial supplies through contract manufacturing organizations in and out of China; seeking regulatory approvals for our drug candidates;
- commercializing those of our drug candidates for which we have obtained marketing approval;
- hiring additional clinical, operational, financial, quality control, and scientific personnel;
- granting equity-settled awards to our employees under our share incentive schemes;
- obtaining, maintaining, expanding, and protecting our intellectual property portfolio; and
- creating additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

We expect that it could take multiple years to develop a new drug from discovery, clinical development to commercialization. During the process, we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend partially on the rate of the future growth of our expenses, our ability to generate revenues, and the timing and amount of milestone payments and other payments that we make to third parties. If any of our drug candidates fails during clinical trials or does not gain regulatory approvals, or, even if approved, fails to achieve market acceptance, our business may not become profitable.

We may need to obtain additional financing to fund our drug development programs and commercialization efforts, which may not be available to us on acceptable terms, or at all.

Our operations have consumed substantial amounts of cash. We recorded net cash outflow from operating activities of US$32.9 million, US$3.0 million, and US$43.2 million in 2020, 2021, and 2022, respectively.

We believe our available financial resources, including cash and cash equivalents and the estimated net proceeds from this offering will be sufficient to meet our anticipated cash needs for the next 12 months. We may, however, from time to time experience net cash outflows from our operating activities for the foreseeable future, and require additional cash resources to meet our continued operating cash requirements in the future. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance the clinical development of our drug candidates, initiate additional clinical trials of these and other future drug candidates, and seek regulatory approvals for them.

In addition, if we obtain regulatory approvals for any of our drug candidates, we expect to incur significant commercialization expenses relating to product manufacturing, marketing, sales and distribution and post-approval commitments to continue monitoring the efficacy and safety data of those products we may have on the market. In particular, costs that may be required for the manufacture of any drug candidate that has received regulatory approvals may be substantial as we mainly rely on third party contract manufacturing organizations and/or our partners to manufacture such drug candidates. We may also incur expenses as we create additional infrastructure to support our operations as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts.

We had a working capital deficiency in 2020 and 2022 as well as accumulated deficits in 2020, 2021, and 2022.

We cannot assure you that we will not experience working capital deficiencies or accumulated deficits in the future, which could expose us to liquidity risks. We had net current liabilities of US$58.5 million in 2020 and US$246.3 million in 2022. In addition, we had net liabilities of US$132.0 million, US$185.4 million, and US$241.3 million in 2020, 2021, and 2022, respectively. Our net current liabilities position and deficit position were in part due to the accounting treatment of our preferred shares, which were classified as financial liabilities in accordance with IFRSs. Such preferred shares will automatically convert into shares upon completion of this offering, at which time we expect to reclassify them from liabilities to equity and, accordingly, turn into net current asset position and net asset position. However, there can be no assurance that we will not experience liquidity problems in the future. If we fail to maintain sufficient cash and financing,

we may not have sufficient cash flows to fund our business, operations and capital expenditure and our business and financial position will be adversely affected.

Our results of operations, financial conditions, and prospects may be adversely affected by fair value changes and credit risk associated with our financial assets at FVTPL.

As of December 31, 2021, we recorded financial assets at FVTPL of US$53.8 million. Our financial assets at FVTPL represented wealth management products purchased from commercial banks in the PRC and Hong Kong. As these wealth management products were not traded in active markets, their fair values were determined based on the expected rate of return on our investment. The valuation involves the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs. As a result, such treatment of carrying amounts of our financial assets measured at FVTPL may cause significant volatility in or materially and adversely affect our financial condition and results of operations.

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

We adopted employee incentive plans for the benefit of our employees as remuneration for their services provided to us to incentivize and reward the eligible persons who have contributed to the success of our company. For the years ended December 31, 2020, 2021, and 2022, we incurred share-based payment expenses of US$2.3 million, US$3.4 million, and US$6.1 million, respectively. To further incentivize our 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 material and adverse effect on our financial performance.

Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

Global economies could suffer dramatic downturns as the result of a deterioration in the credit markets and related financial crisis as well as a variety of other factors including, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. In the past, governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If these actions are not successful, the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all.

In addition, there is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies adopted by the central banks and financial authorities of some of the world's leading economies, including the U.S. and China. There have been concerns over unrest and terrorist threats in the Middle East, Europe and Africa and over the conflicts involving Ukraine, Syria and North Korea. There have also been concerns on the relationship among China and other Asian countries, which may result in or intensify potential conflicts in relation to territorial disputes or the trade related disputes between the U.S. and China.

If we fail to implement and maintain an effective system of internal controls to remediate our material weaknesses over financial reporting, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud, and investor confidence in our company and the market price of the ADSs may be materially and adversely affected.

Prior to this offering, we have been a private company with limited reporting and accounting personnel and other resources with which to address our internal control over financial reporting. In connection with the audits of our consolidated financial statements included in this prospectus, we and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting. As defined in the standards established by the U.S. Public Company Accounting Oversight Board, or PCAOB, a "material weakness" is a deficiency, or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. For details of these material weaknesses, see "Financial Information — Internal control over financial reporting". We are in the process of implementing a number of measures to address the material weaknesses and deficiencies that have been identified. See

"Management's Discussion and Analysis of Financial Condition and Results of Operations." However, we cannot assure you that these measures will fully address the material weaknesses and deficiencies in our internal control over financial reporting or that we may conclude that they have been fully remediated.

Upon completion of this offering, we will become subject to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. Section 404 of such Act will require that we include a report from management on the effectiveness of our internal control over financial reporting in our annual report on Form 20-F beginning with our second annual report on Form 20-F after becoming a public company. In addition, once we cease to be an "emerging growth company" as such term is defined in the JOBS Act, our independent registered public accounting firm must attest to and report on the effectiveness of our internal control over financial reporting. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue an adverse opinion on the effectiveness of internal control over financial reporting because of the existence of a material weakness if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, after we become a public company, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation testing and any required remediation.

During the course of documenting and testing our internal control procedures, in order to satisfy the requirements of Section 404, we may identify other weaknesses and deficiencies in our internal control over financial reporting. If we fail to maintain the adequacy of our internal control over financial reporting, as these standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. Generally speaking, if we fail to achieve and maintain an effective internal control environment, it could result in material misstatements in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis. As a result, our business, financial condition, results of operations and prospects, as well as the trading price of the ADSs, may be materially and adversely affected. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the stock exchange on which we list, regulatory investigations and civil or criminal sanctions. We may also be required to restate our financial statements from prior periods.

We may be contractually obligated to make significant payments for in-licensed drug candidates which may eventually not be approved for sale or which we find that we are unable to commercialize successfully.

Our research and development engine runs on both in-house discovery and external licensing of highly innovative products. Leveraging our global clinical development capability, deep understanding of relevant molecules, and proficiency in clinical trial designs, we are able to identify and secure suitable and promising compounds ahead of our competitors. We are developing two clinical-stage drug candidates which were secured from in-licensing agreements with third parties. Pursuant to the license agreements, we are required to make various payments to the licensors, including an upfront payment at the time when the relevant license agreement is signed, milestone payments for the achievements of specified clinical, regulatory and commercial milestones, and royalties calculated as a specified percentage of the annual net sales of the products covered by the license. Royalties are often structured so that the percentage increases in tiers as net sales increase. Please refer to the paragraphs headed "Business — License and collaboration agreements" in this prospectus for more details.

When we negotiate our license agreements, we must estimate the probability of success for the drug's development and the potential size of the eventual market for the drug product. We may have to make significant upfront payments to secure the rights to attractive drug candidates, and there is no guarantee that we will ever be able to recoup those expenses. Milestone or other non-royalty payments also become due on a drug candidate before we can obtain regulatory approvals for it or commercialize it, and we may not have sufficient funds available to make these payments when they come due. If and when we obtain regulatory approvals to market a drug, our profits from any sales will be reduced by the royalties that we agreed to pay under the license agreement. If we make significant payments under our license agreements for drug candidates

that never reach market, or if we misjudge the potential size of the market for our drug candidates and overpay for the rights that we license, our financial condition and financial performance may be materially and adversely affected.

Raising additional capital may cause dilution to the interests of our shareholders, restrict our operations, or require us to relinquish rights to our technologies or drug candidates.

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

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

We are exposed to risks of conducting our business and operations in international markets.

Global markets are a crucial component of our growth strategy. If we fail to obtain licenses or enter into collaboration arrangements with third parties in such markets, or if third-party collaborators are not successful, our revenue-generating growth potential will be adversely affected. Risks associated with global operation include, but are not limited to:

- changes in a specific country or region’s political and cultural climate or economic condition;
- differing regulatory requirements for drug approvals and marketing internationally;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements, as well as trade-protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- unexpected detention of cargos by customs, including raw material, equipment, reagents, and drug candidates;
- economic weakness, including inflation or political instability;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country;
- workforce uncertainty and labor unrest;
- failure of our employees and contracted third parties to comply with Office of Foreign Assets Control rules and regulations and the Foreign Corrupt Practices Act of the U.S., and other applicable rules and regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes, and fires.

On September 12, 2022, the President of the United States issued an "Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy", launching a national biotechnology and biomanufacturing initiative in the United States. This initiative will be comprised of various efforts by the U.S. government, including investments, programs and partnerships to advance research and development in biotechnology, and biomanufacturing, as well as efforts to secure and protect the U.S. bioeconomy. This executive order may lead to potential changes to U.S. policies affecting the biotechnology and biomanufacturing industries, however, it is unknown at this time whether and what specific policies and actions will be adopted by the U.S. government. Our business and operations in the U.S. primarily involve conducting research and development. We therefore expect that this executive order will have no immediate impact on our activities in the United States. Nevertheless, if the U.S. government were to adopt any policies that adversely impact transnational companies with business operating in China conducting research and development activities in the United States, our business and results of operations could be adversely affected.

Our international operations may require us to comply with various trade restrictions, such as economic sanctions and export controls.

Our international operations may be subject to various trade restrictions, including economic sanctions and export controls, imposed by governments around the world with jurisdiction over our operations. Such trade restrictions may prohibit or restrict transactions involving certain persons and certain designated countries or territories. Our failure to successfully comply with applicable trade restrictions may expose us to legal, business or reputational harm. Investigations of alleged violations can be expensive and disruptive.

For example, the United States continues to expand economic sanctions targeting Russian financial institutions in response to Russia's military action against Ukraine. Such sanctions on Russian financial institutions may interfere with our ability to make payment to Russian CROs in US dollars and may force us to choose another settlement currency, limit or stop our collaboration with Russian CROs. We are currently engaging a Russian CRO for conducting one clinical trial in Russia.

We endeavor to conduct our activities in compliance with applicable trade restrictions. However, we cannot guarantee that our existing compliance policies and procedures will be effective in preventing violations, which could adversely affect our business, reputation, financial condition and results of operations. Further, we cannot predict the nature, scope or effect of future regulatory requirements, including changes that may impose additional restrictions on our international operations.

We may face force majeure risks, including the recent COVID-19 outbreak.

Our operations may be under threat of numerous natural disasters such as floods, earthquakes, sandstorms, snowstorms, fire, or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, or other events, such as power, water or fuel shortages, failures, malfunction, and breakdown of information management systems, unexpected maintenance, or technical problems, or are susceptible to unforeseen catastrophic events such as potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets, and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network, and destroy our markets. For example, our business could be adversely impacted by the ongoing geopolitical tensions related to Russia's actions in Ukraine, resulting sanctions imposed by the United States and other countries and retaliatory actions taken by Russia in response to such sanctions; or other catastrophic events. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition, and results of operations.

The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments in China or elsewhere in the world could materially disrupt our business and operations. These factors could cause delay of clinical trials, regulatory submissions, and required approvals of our drug

candidates, and could cause us to incur additional costs. For example, since the end of December 2019, the outbreak of COVID-19 has affected many people globally, caused temporary suspension of productions and shortage of labor and raw materials in affected regions, and disrupted local and international travel and economy. The exacerbation, continuance or reoccurrence of COVID-19 has already caused and may continue to cause an adverse and prolonged impact on the economic, geopolitical, and social conditions in China and other affected countries. The existing clinical trials and the commencement of new clinical trials could be substantially delayed or prevented by any delay or failure in patient recruitment or enrollment in our or our collaborators' trials as a result of elevated public health safety measures. If our employees or employees of our business partners are suspected of being infected with an epidemic disease, our operations may be disrupted if we or our business partners must quarantine some or all of the affected employees or disinfect the operating facilities.

The market opportunities for our drug candidates can be smaller than we estimate or the approvals that we obtain may be based on a narrower definition of the patient population.

We make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our drug development strategy, including acquiring or in-licensing drug candidates and determining indications on which to focus in preclinical or clinical trials.

These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance by the medical community, patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations, and prospects.

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

We are heavily dependent on the expertise of our senior management and other key employees and consultants, as well as our scientific teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. In addition, we do not maintain key-person insurance for any of our executives or other key personnel.

Recruiting and retaining qualified management, 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 take an extended period of time due to the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, obtain regulatory approvals of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain, or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biopharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. To compete effectively, we may need to offer higher compensation and other benefits.

If we or our suppliers, CROs or CMOs fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs.

We are subject to various 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 guarantee that we will be able to obtain all the regulatory approvals or complete all the required procedure for our construction projects in a timely manner, or at all. Delays or failures in obtaining all the requisite regulatory approvals or completing all the required procedure for our construction projects may affect our business operation. Furthermore, 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.

While we attempt to comply with such laws and regulations, we cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our or third-parties' facilities during the process of discovery, testing, development and manufacturing of biopharmaceuticals. In the event of such accident, we could be held liable for damages and clean-up costs which, to the extent not covered by existing insurance or indemnification. Other adverse effects could result from such liability, including reputational damage. We or our collaborators may also be forced to close or suspend operations at certain of the affected facilities temporarily, or permanently due to any accidental contamination, biological or chemical hazards or personal injury. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

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

We are exposed to the risk of fraud, misconduct or other illegal activities by our employees, management, service providers, independent contractors, principal investigators, consultants, commercial partners, vendors, CROs and CMOs. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to:

- comply with the laws of the FDA, NMPA, EMA, and other comparable regulatory authorities;
- provide true, complete and accurate information to the FDA, NMPA, EMA, and other comparable regulatory authorities;
- comply with manufacturing standards that we have established in the future;
- comply with laws in the U.S., Europe, China, and similar fraudulent misconduct laws in other applicable jurisdictions; or
- report financial information or data accurately or to disclose unauthorized activities to us.

If we obtain approval of any of our drug candidates and begin commercializing those drugs in the U.S., Europe, China, or other applicable jurisdictions, our potential exposure under the laws of such jurisdictions will increase considerably and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as future sales, marketing, and educational programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws and regulations designed 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, structuring and commissions, certain customer incentive programs, and other business arrangements generally. 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. It is not always possible to identify and deter misconduct by employees and other parties, 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 comply with these 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.

In addition, our employees, management, directors, independent contractors, commercial partners, and vendors may be subject to legal, regulatory, and administrative proceedings. The existence of legal, regulatory, and administrative proceedings against any of our employees, management, directors, independent contractors, commercial partners, and vendors, even if they do not involve our company, may harm our reputation, and adversely affect our business and operations.

We may be involved in lawsuits, claims, administrative proceedings, or other legal proceedings against us, which could adversely affect our business, financial condition, results of operations, and reputation.

From time to time, 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. In addition, as we are under the progress of inspection and acceptance of one of our completed construction projects, we are subject to risks of administrative penalty if we delay or fail to obtain relevant approvals. 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 litigation, 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, provide sufficient payments to cover all of the costs to resolve one or more such claims, or 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 condition, and reputation.

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

Our reputation and business prospects could be adversely affected by any negative publicity concerning us, our affiliates, our employees, or any entity that shares the “Adlai Nortye” name, even if untrue. Therefore, we cannot assure you that negative publicity about us or any of our affiliates or any entity that shares the “Adlai Nortye” name would not damage our brand image or have a material adverse effect on our business, results of operations and financial condition. In addition, referrals and word of mouth have significantly contributed to our ability to establishing new partnerships. As a result, any negative publicity about us or any of our affiliates or any entity that shares the “Adlai Nortye” name could adversely affect our ability to maintain our existing collaboration arrangements or attract new partners. A recent example of negative publicity relates to a blog published in August 2021, alleging us paying RMB2.87 million bribes for our Series C financing purposes. Although the local police concluded that the bribery allegation had no factual basis and issued a Notice of Dismissal of Accusation, and the blog post was removed after we issued a warning letter to the blogger for potential defamation, we still suffered reputational damages associated with this blog post. We cannot assure you that similar events or negative publicity will not repeat in the future.

Our business operations and current or future relationships with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency and other healthcare laws and regulations.

Healthcare providers, physicians, and others play a primary role in recommending and prescribing any products for which we obtain regulatory approvals. If we obtain the FDA, NMPA, EMA, PMDA, or other comparable regulatory authorities’ approval for any of our drug candidates and begin commercializing those drug products in the U.S., China, Europe, Japan or other applicable jurisdictions, our operations may be subject to various fraud and abuse laws of such jurisdictions, including, without limitation, the PRC Anti-Unfair Competition Law, the PRC Criminal Law, the Federal Anti-Kickback Statute, the Federal False Claims Act, and transparency laws and regulations with respect to drug pricing and transfers of value made to

physicians and other licensed healthcare professionals. These laws may impact, among other things, our proposed sales, marketing, and education programs. In the U.S., such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives), and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by such healthcare professionals and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives; and state medical privacy laws.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and

may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government-funded healthcare programs.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses.

We are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. In addition, although currently our primary operating business is in China, we are subject to the Foreign Corrupt Practices Act or the FCPA. The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Although we have policies and procedures designed to ensure that we, our employees, and our agents comply with anti-bribery laws, there is no assurance that such policies or procedures will prevent our agents, employees, and intermediaries from engaging in bribery activities.

Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations, and liquidity.

Recently enacted and future legislation in the United States and other countries may affect the prices we may obtain for our drug candidates and increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates.

In the U.S. and many other countries, rising healthcare costs have been a concern for governments, patients and the health insurance sector, which resulted a number of changes to laws and regulations, and may result in further legislative and regulatory action regarding the healthcare and health insurance systems that could affect our ability to profitably sell any drug candidates for which we obtain marketing approval.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, was enacted in the U.S. in March 2010 with the stated goals of containing healthcare costs, improving quality and expanding access to healthcare, and includes measures to change health care delivery, increase the number of individuals with insurance, ensure access to certain basic health care services, and contain the rising cost of care.

In addition, other federal health reform measures have been proposed and adopted in the U.S. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions through 2031, unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 also introduced a quality payment program under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. Payment adjustments for the Medicare quality payment program began in 2019. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Further, there has been heightened governmental scrutiny in the U.S. of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional

inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products. Most recently, the Inflation Reduction Act of 2022, or IRA, included a number of significant drug pricing reforms, which include the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services, or HHS (beginning in 2026) that requires manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers under Medicare Parts B and D to penalize price increases that outpace inflation (first due in 2023), and a redesign of the Part D benefit, as part of which manufacturers are required to provide discounts on Part D drugs (beginning in 2025). The IRA permits the HHS Secretary to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Additional drug pricing proposals could appear in future legislation. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

These new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drug candidates, if approved.

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 PRC laws and regulations as well as insurance based on our assessment of our operational needs and industry practice. Our principal insurance policies cover losses arising from liabilities in our human clinical trials for the development of our clinical-stage drug candidates in the United States, United Kingdom, Poland, and France. We have elected not to maintain certain types of insurances, such as business interruption insurance or key-man insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. 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 internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Notwithstanding the implementation of security measures, our internal computer systems, and those of our partners and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access.

In the ordinary course of our business, we collect and store sensitive data, and manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. Shutdowns, or service disruptions at us or vendors that provide information systems, networks, or other services to us could have an adverse impact on

us and our business, including loss of data and damage to equipment and data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues.

In addition, we could be subject to risks caused by misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss of information maintained in the information systems and networks of us and our vendors. Moreover, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we may experience threats to our data and systems, including malicious codes and viruses, phishing, and other cyberattacks. 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, our reputation and credibility could be damaged, and significant amounts of money and other resources could be required to expend on the repair or replacement of information systems or networks. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices, and other data privacy laws and regulations. The development and maintenance of systems and controls for preventing, identifying, and mitigating threats are costly and requires ongoing monitoring and updating. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely.

Cyber-security incidents, including data security breaches or computer viruses, could harm our business by disrupting our delivery of services, damaging our reputation or exposing us to liability.

We receive, process, store and transmit, often electronically, the data of our clinical trial and others, much of which is confidential. Unauthorized access to our computer systems or stored data could result in the theft, including cyber-theft, or improper disclosure of confidential information, and the deletion or modification of records could cause interruptions in our operations. These cyber-security risks increase when we transmit information from one location to another, including over the internet or other electronic networks. Despite the security measures we have implemented, our facilities, systems and procedures, and those of our third-party service providers, may be vulnerable to security breaches, acts of vandalism, software viruses, misplaced or lost data, programming or human errors or other similar events which may disrupt our operations. Any security breach involving the misappropriation, loss or other unauthorized disclosure or use of confidential information, whether by us or a third party, could (i) subject us to civil and criminal penalties, (ii) have a negative impact on our reputation, or (iii) expose us to liability to third parties or government authorities. We are not aware of such breaches to date. Any of these developments could have a material adverse effect on our business, financial condition and results of operations.

We are subject to changing law and regulations regarding regulatory matters, corporate governance, and public disclosure that have increased both our costs and the risk of non-compliance.

The oncology drug market is subject to influence of relevant regulations. Recently, there is a trend of enhanced regulations. On November 19, 2021, the Center for Drug Evaluation issue the Clinical Value-Oriented Anti-tumor Drug Clinical Research and Development Guidelines with the purpose to better address the needs of patients and to promote the clinical value-oriented R&D of anti-tumor drugs. Such regulations expose our R&D of oncology drugs to higher requirements. According to the Guidelines, when clinical trials of innovative drugs are designed to choose controlled drugs, the best supportive treatment should be preferred over placebo. Also, if an indication already has the current best drug recommendation in the treatment guidelines, the new drug should be compared with the existing drug.

The Guidelines aim to select more high-quality first-in-class drugs. As AN2025 has the potential to be the first treatment globally for recurrent or metastatic HNSCC patients after disease progression with anti-PD-1/PD-L1 therapy, this new focus of regulatory policies promoting value-oriented research and development activities in China is in line with our development strategies and may further facilitate our clinical trials and studies. To the best of our knowledge, we are currently in compliance with the relevant requirements in the Guidelines. However, we cannot assure you that there will be no adverse regulatory changes in the implementation of Guidelines in the PRC, or other regulatory changes in the PRC that will have a negative impact on our business going forward.

Moreover, because these laws, regulations, and standards are subject to disparate interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these regulations and any subsequent changes, we may be subject to penalties and our business may be harmed.

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

Any tensions and political concerns between China and the relevant foreign countries or regions may adversely affect our business, financial condition, results of operations, cash flows, and prospects. The U.S. government has recently made statements and taken certain actions that may lead to potential changes to the U.S. and international policies with regard to China. It is unknown whether and to what extent other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry. While we have not started commercialization of drug candidates, any unfavorable international government policies, such as capital controls or tariffs, may affect the demand for our future approved drug products, the competitive position of our future approved drug products, the hiring of scientists and other research and development personnel, the use and transfer of clinical data, and import or export of raw materials in relation to drug development, or prevent us from selling our future approved drug products in certain countries. If any new legislation and/or regulations are implemented, or in particular, if the U.S. government takes retaliatory actions due to the recent U.S.-China tension, such changes could have an adverse effect on our business, financial condition, and results of operations.

It also remains unclear what actions, if any, the U.S. government will take with respect to other existing international trade agreements. If the U.S. were to withdraw from or materially modify certain international trade agreements to which it is a party, especially with respect to intellectual properties transfer, our business, financial condition, and results of operations could be negatively impacted.

Our business benefits from certain financial incentives and discretionary 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 mainland China granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local business. We recorded government grants of US$0.5 million, US$2,000, and US$2.1 million for the years ended December 31, 2020, 2021, and 2022, respectively. The local governments have 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.

Risks relating to our operation in the People's Republic of China

The approval, filing, or other procedures of the CSRC or other PRC regulatory authorities may be required in connection with this offering under PRC laws, regulations, and rules.

On July 6, 2021, the General Office of the State Council, together with another regulatory authority, jointly promulgated the Opinions on Strictly Combating Illegal Securities Activities in Accordance with the Law, which calls for, among others, enhanced administration and supervision of overseas-listed China-based companies, proposes to revise the relevant regulation governing the overseas issuance and listing of shares by such companies, and clarifies the responsibilities of competent domestic industry regulators and government authorities.

On February 17, 2023, the CSRC, released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies, or the Trial Measures, and five supporting guidelines, which took effect on March 31, 2023. Pursuant to the Trial Measures, domestic companies that seek to list overseas, both directly and indirectly, should fulfill the filing procedure and report relevant information to the CSRC. If a domestic company fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, such domestic company may be subject to administrative penalties, such as order to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines. See "Regulations — Regulations on M&A Rules and Overseas Listings." However, since the Trial Measures was newly promulgated, the interpretation, application and enforcement of Trial Measures remain unclear. If the filing procedure with the CSRC under the Trial Measures is required for any future offering or any other capital raising activities, it is uncertain whether it would be possible for us or how long it will take us to complete the filing.

On February 24, 2023, the CSRC jointly with other relevant governmental authorities, promulgated the Confidentiality and Archives Management Provisions, which took effect on March 31, 2023. According to the Confidentiality and Archives Management Provisions, domestic companies, whether offering and listing securities overseas directly or indirectly, must strictly abide the applicable laws and regulations when providing or publicly disclosing, either directly or through their overseas listed entities, documents and materials to securities services providers such as securities companies and accounting firms or overseas regulators in the process of their overseas offering and listing. If such documents or materials contain any state secrets or government authorities work secrets, domestic companies must obtain the approval from competent governmental authorities according to the applicable laws, and file with the secrecy administrative department at the same level with the approving governmental authority. Furthermore, the Confidentiality and Archives Management Provisions provide that securities companies and securities service providers shall fulfill the applicable legal procedures when providing overseas regulatory institutions and other relevant institutions and individuals with documents or materials containing any state secrets or government authorities work secrets or other documents or materials that, if divulged, will jeopardize national security or public interest. Since the Confidentiality and Archives Management Provisions were promulgated recently, substantial uncertainties still exist with respect to the interpretation and implementation of such provisions and how they will affect us.

If it is determined that we are subject to the approval of the CSRC for this Offering, we may fail to obtain such approval, filing or meet such requirements in a timely manner or at all, or completion could be rescinded. Any failure to obtain or delay in obtaining such approval, filing or completing such procedures for this Offering, or a rescission of any such approval or filing obtained by us, would subject us to sanctions by the CSRC or other PRC regulatory authorities. These regulatory authorities may impose fines and penalties on our operations in China, limit our ability to pay dividends outside of China, limit our operating privileges in China, delay or restrict the repatriation of the Offering or future capital raising activities into China, or take other actions that could materially and adversely affect our business, financial condition, results of operations and prospects, as well as this offering and the listing of the ADSs.

The CSRC or other PRC regulatory authorities may also take actions requiring us, or making it advisable for us, to halt this Offering or future capital raising activities before settlement and delivery of the ADS we are offering hereby. Consequently, if you engage in market trading or other activities in anticipation of and prior to settlement and delivery, you do so at the risk that settlement and delivery may not occur. In addition, if the CSRC or other regulatory authorities later promulgate new rules or explanations requiring that we obtain their approvals or accomplish the required filing or other regulatory procedures for this Offering or future capital raising activities, we may be unable to obtain a waiver of such approval requirements, if and when procedures are established to obtain such a waiver. Such procedures for obtaining the waiver remain unclear. Any uncertainties or negative publicity regarding such approval, filing or other requirements could materially and adversely affect our business, prospects, financial condition, reputation, and this offering and the listing of the ADSs.

The impact of the CAC's increasing oversight over data security remains highly uncertain, particularly for companies with substantial China operations seeking to list on a foreign stock exchange.

In January 2022, the CAC amended Measures of Cybersecurity Review, or the Revised CAC Measures, which came into effect on February 15, 2022. Pursuant to the Revised CAC Measures, critical information

infrastructure operators procuring network products and services, and online platform operators (as opposed to "data processors" in the Draft Management Regulation) carrying out data processing activities which affect or may affect national security, shall conduct a cybersecurity review pursuant to the provisions therein. In addition, online platform operators possessing personal information of more than one million users seeking to be listed in foreign country must apply for a cybersecurity review.

As of the date of this prospectus, we have not received any notice from any PRC regulatory authority identifying us as a "critical information infrastructure operator," "online platform operator" or "data processor," or requiring us to go through the cybersecurity review procedures pursuant to the Revised CAC Measures and the Draft Management Regulations. According to the Revised CAC Measures, we do not expect ourselves to become subject to cybersecurity review by the CAC for this offering, given that: (i) the data we handle in our business operations, either by its nature or in scale, do not normally trigger significant concerns over PRC national security and (ii) we have not processed, and do not anticipate to process in the foreseeable future, personal information of more than one million users or persons. Based on the above and the information currently available, we believe the impact of the CAC's increasing oversight over data security on our business is immaterial as of the date of this prospectus.

However, there remains uncertainty as to how the Revised CAC Measures will be interpreted or implemented and whether the PRC regulatory authorities may adopt new laws, regulations, rules, or detailed implementation and interpretation in relation, or in addition to the Revised CAC Measures. While we intend to closely monitor the evolving laws and regulations in this area and take all reasonable measures to mitigate compliance risks, we cannot guarantee that our business and operations will not be adversely affected by the potential impact of the Revised CAC Measures or other laws and regulations related to privacy, data protection and information security.

We may be influenced by changes in the political and economic policies of the PRC government.

A very substantial portion of our assets and operations are currently located in mainland China. Accordingly, we may be influenced to a significant degree by political and social conditions in China generally. The Chinese economy differs from the economies of most developed countries in many respects, including the level of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the Chinese government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the government. In addition, the Chinese government continues to play a significant role in regulating industry development by imposing industrial policies. The Chinese government also exercises significant control over China's economic growth through allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, and providing preferential treatment to particular industries or companies. While the Chinese economy has experienced significant growth over past decades, growth has been uneven, both geographically and among various sectors of the economy. Any adverse changes in economic conditions in China, in the policies of the Chinese government or in the laws and regulations in China could have a material adverse effect on the overall economic growth of China. Such developments could adversely affect our business and results of operations, lead to a reduction in demand for our future products and adversely affect our competitive position.

Uncertainties with respect to the PRC legal system, including uncertainties regarding the enforcement of laws, and sudden or unexpected changes in laws and regulations in China with little advance notice, could materially and adversely affect us.

Our operations in mainland China are governed by PRC laws and regulations. Our operating subsidiary in the PRC, Hangzhou Adlai, is a foreign-invested enterprise, or FIE, and is subject to laws and regulations applicable to foreign investment in China and, in particular, laws applicable to FIEs. 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 do not have binding authority. There are substantial uncertainties regarding the interpretation and application of PRC laws and regulations including, but not limited to, the laws and regulations governing our business and the enforcement and performance of our business arrangements in certain circumstances. The laws and regulations are sometimes vague and may be subject to future changes, and their official

interpretation and enforcement could be unpredictable, with little advance notice. The effectiveness and interpretation of newly enacted laws or regulations, including amendments to existing laws and regulations, may be delayed, and our business may be affected if we rely on laws and regulations which are subsequently adopted or interpreted in a manner different from our current understanding of these laws and regulations. New laws and regulations that affect existing and proposed future businesses may also be applied retroactively. We cannot predict what effect the interpretation of existing or new PRC laws or regulations may have on our business.

Since late 1970s, the PRC government has been developing a comprehensive system of laws and regulations governing economic matters in general. The overall effect of legislation over the past several decades has significantly enhanced the protections afforded to various forms of foreign investments in China. However, China has not developed a fully integrated legal system, and recently enacted laws and regulations may not sufficiently cover all aspects of economic activities in China. In particular, because these laws and regulations are relatively new, and because of the limited volume of published decisions and their nonbinding nature, the interpretation and enforcement of these laws and regulations involve uncertainties. In addition, the PRC legal system is based in part on government policies and internal rules, some of which may not be published on a timely basis or at all, and some of which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until sometime after the violation. Any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. However, 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 in more developed legal systems. These uncertainties may also impede our ability to enforce the contracts we have entered into. As a result, these uncertainties could materially and adversely affect our business and results of operations.

The PRC government has significant authority to exert influence on our operations in mainland China.

The PRC government has significant authority to exert influence on our operations in mainland China. Therefore, uncertainties in the PRC legal system and the interpretation and enforcement of PRC laws and regulations could limit the legal protection available to you and us, hinder our ability to offer or continue to offer the ADSs, result in a material adverse effect on our business operations, and damage our reputation, which might further cause the ADSs to significantly decline in value or become worthless. Changes in China's economic, political or social conditions, or government policies could materially and adversely affect our business, financial condition, and results of operations.

The economic, political and social conditions in the PRC differ from those in more developed countries in many respects, including structure, government involvement, level of development, growth rate, control of foreign exchange, capital reinvestment, allocation of resources, rate of inflation and trade balance position. Before the adoption of its reform and opening up policies in 1978, the PRC was primarily a planned economy. In recent years, the PRC government has been reforming the PRC economic system and government structure. For example, the PRC government has implemented economic reform and measures emphasizing the utilization of market forces in the development of the PRC economy in the past three decades. These reforms have resulted in significant economic growth and social prospects. Economic reform measures, however, may be adjusted, modified or applied inconsistently from industry to industry or across different regions of the country.

We cannot predict whether the resulting changes will have any adverse effect on our current or future business, financial condition or results of operations. Despite these economic reforms and measures, the PRC government continues to play a significant role in regulating industrial development, allocation of natural and other resources, production, pricing and management of currency, and there can be no assurance that the PRC government will continue to pursue a policy of economic reform or that the direction of reform will continue to be market friendly. Our ability to successfully expand business operations in the PRC depends on a number of factors, including macro-economic and other market conditions. Demand for our future products in the Chinese market and our business, financial condition and results of operations may be materially and adversely affected by the following factors:

- political instability or changes in social conditions of the PRC;

- changes in laws, regulations, and administrative directives or the interpretation thereof;
- measures which may be introduced to control inflation or deflation; and
- changes in the rate or method of taxation.

These factors are affected by a number of variables which are beyond our control.

Recent negative publicity surrounding China-based companies listed in the United States may negatively impact the trading price of the ADSs.

We believe that recent negative publicity surrounding companies with operations in China that are listed in the United States have negatively impacted the stock prices of these companies. Certain politicians in the United States have publicly warned investors to shun China-based companies listed in the United States. The SEC and the PCAOB, also issued a joint statement on April 21, 2020, reiterating the disclosure, financial reporting and other risks involved in the investments in companies that are based in emerging markets as well as the limited remedies available to investors who might take legal action against such companies.

Furthermore, various equity-based research organizations have recently published reports on China-based companies after examining their corporate governance practices, related party transactions, sales practices and financial statements, and these reports have led to special investigations and listing suspensions on U.S. national exchanges. Any similar scrutiny on us, regardless of its lack of merit, could cause the market price of the ADSs to fall, divert management resources and energy, cause us to incur expenses in defending ourselves against rumors, and increase the premiums we pay for director and officer insurance.

The ADSs may be delisted under the HFCAA if the PCAOB is unable to inspect auditors or their affiliates that are located in mainland China. The delisting of the ADSs, or the threat of such delisting, may materially and adversely affect the value of your investment. Additionally, the inability of the PCAOB to conduct inspections deprives our investors of the benefits of such inspections.

The HFCAA was enacted on December 18, 2020. The HFCAA states if the SEC determines that we have filed audit reports issued by a registered public accounting firm that has not been subject to inspection by the PCAOB for three consecutive years beginning in 2021, the SEC shall prohibit our shares or ADSs from being traded on a national securities exchange or in the over the counter trading market in the U.S.

Our auditor, the independent registered public accounting firm that issued the audit report in the prospectus, as auditor of companies that are traded publicly in the United States and as a firm registered with the PCAOB is subject to laws in the United States pursuant to which the PCAOB conducts regular inspections to assess its compliance with the applicable professional standards. Our auditor, which is based in New York, is currently subject to inspection by the PCAOB at least every two years. However, our auditor's China affiliate is located in, and organized under the laws of, the PRC, which is a jurisdiction where the PCAOB has been unable to conduct inspections without the approval of the Chinese authorities.

On March 18, 2021, the SEC adopted on an interim basis rules disclosure requirements for companies with PCAOB member auditors whom the PCAOB has determined that it cannot inspect their operations within a foreign jurisdiction, or the Covered Issuers. Covered Issuers are required to disclose in their annual reports on Form 20-F: (i) that, during the period covered by the form, the registered public accounting firm has prepared an audit report for the issuer; (ii) the percentage of the shares of the issuer owned by governmental entities in the foreign jurisdiction in which the issuer is incorporated or otherwise organized; (iii) whether governmental entities in the applicable foreign jurisdiction with respect to that registered public accounting firm have a controlling financial interest with respect to the issuer; (iv) the name of each official of the Chinese Communist Party who is a member of the board of directors of the issuer or the operating entity with respect to the issuer; and (v) whether the articles of incorporation of the issuer (or equivalent organizing document) contains any charter of the Chinese Communist Party, including the text of any such charter. Furthermore, on June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act, or the AHFCAA, which would amend the HFCAA and require the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years instead of three. On September 22, 2021, the PCAOB adopted rules governing its procedures for making determinations as to its inability to inspect or investigate registered firms headquartered

in a particular foreign jurisdiction or which has an office in a foreign jurisdiction, or a PCAOB-Identified Firm. Promptly after the effective date of this rule, the PCAOB will make determinations under the HFCAA to the extent such determinations are appropriate. Thereafter, the PCAOB will consider, at least annually, whether changes in facts and circumstances support any additional determinations. The PCAOB will make additional determinations as and when appropriate, to allow the SEC on a timely basis to identify covered issuers pursuant to the SEC rules. The rule became effective when the SEC approved the rule on November 4, 2021. On December 2, 2021, the SEC finalized its rules regarding disclosure by Covered Issuers. In addition, the release discussed the procedures the SEC will follow in implementing trading prohibitions for Covered Issuers. A foreign company would have to be designated a Covered Issuer three years in a row to be subject to a trading prohibition on that basis. The trading suspension would prohibit trading of the Covered Issuer's securities on any exchange or in the over-the-counter markets.

The trading prohibition will be terminated if the Covered Issuer certifies to the SEC that the issuer has retained a registered public accounting firm that the PCAOB has inspected to the satisfaction of the SEC and files financial statements that include an audit report signed by the non-PCAOB-Identified Firm. The SEC is not required to engage in rulemaking to implement the trading prohibition provisions of the HFCAA. Neither the Act nor the SEC's release create an obligation for an exchange to delist the Covered Issuer, but the SEC noted that under existing listing rules of the exchanges, a trading prohibition would be grounds for delisting. On December 16, 2021, the PCAOB issued a report on its determinations that it is unable to inspect or investigate completely PCAOB-registered public accounting firms headquartered in mainland China and in Hong Kong because of positions taken by PRC authorities in those jurisdictions.

On August 26, 2022, the PCAOB entered into a Statement of Protocol with the China Securities Regulatory Commission and the Ministry of Finance of the PRC and, as summarized in the "Statement on Agreement Governing Inspections and Investigations of Audit Firms Based in China and Hong Kong" published on the U.S. Securities and Exchange Commission's official website, the parties agreed to the following: (i) in accordance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the PCAOB shall have independent discretion to select any issuer audits for inspection or investigation; (ii) the PCAOB shall have direct access to interview or take testimony from all personnel of the audit firms whose issuer engagements are being inspected or investigated; (iii) the PCAOB shall have the unfettered ability to transfer information to the SEC, in accordance with the Sarbanes-Oxley Act; and (iv) the PCAOB inspectors shall have access to complete audit work papers without any redactions, with view-only procedures for certain targeted pieces of information such as personally identifiable information. On December 15, 2022, the PCAOB issued a report that vacated its December 16, 2021 determination and removed mainland China and Hong Kong from the list of jurisdictions where it is unable to inspect or investigate completely registered public accounting firms. On December 29, 2022, legislation entitled "Consolidated Appropriations Act, 2023" (the "Consolidated Appropriations Act"), was signed into law by President Joseph Biden of the United Sates. The Consolidated Appropriations Act contained, among other things, an identical provision to the AHFCAA, which reduces the number of consecutive non-inspection years required for triggering the prohibitions under the HFCAA from three years to two.

The auditor of our PRC-based subsidiaries is located in mainland China and the auditor is an affiliate of our New York based auditor that signs our audit report. Given the current question as to how "retain" should be understood for purposes of the HFCA Act, we cannot assure you that we will not be identified by the SEC as an issuer that has retained an auditor that has a branch or office that is located in a foreign jurisdiction that the PCAOB determines it is unable to inspect or investigate completely because of a position taken by an authority in that foreign jurisdiction as a result of the fact that the auditor of our China affiliates is located in, and organized under the laws of, the PRC. In addition, there can be no assurance that, if we have a "non-inspection" year, we will be able to take remedial measures in response thereto. If any such event were to occur, trading in our securities could in the future be prohibited under the HFCAA, so we cannot assure you that we will be able to maintain the listing of the ADSs on the Nasdaq or that you will be allowed to trade the ADSs in the United States on the "over-the-counter" markets or otherwise. Should the ADSs not be listed or tradeable in the United States, the value of the ADSs could be materially affected.

This lack of PCAOB inspections in China prevents the PCAOB from fully evaluating audits and quality control procedures of our independent registered public accounting firm. As a result, we and investors in the ADSs are deprived of the benefits of such PCAOB inspections. The inability of the PCAOB to conduct

inspections of auditors in China makes it more difficult to evaluate the effectiveness of our independent registered public accounting firm's China affiliate's audit procedures or quality control procedures as compared to auditor outside of China that are subject to PCAOB inspections, which could cause investors and potential investors in the ADSs to lose confidence in our audit procedures, reported financial information and the quality of our financial statements.

PRC regulation of loans to, and direct investments in, PRC entities by offshore holding companies may delay or prevent us from making loans or additional capital contributions to our PRC subsidiaries and thereby prevent us from funding our business.

As an offshore holding company with PRC subsidiaries, we may transfer funds to our PRC subsidiaries by means of loans or capital contributions. Any loans to our operating subsidiary in the PRC, Hangzhou Adlai, which is a foreign-invested enterprise, cannot exceed statutory limits based on the difference between the amount of our investments and registered capital in such subsidiary, and shall be registered with SAFE, the PRC State Administration of Foreign Exchange, or its local counterparts. Furthermore, at this stage, any capital increase contributions we make to Hangzhou Adlai, which is a foreign-invested enterprise, shall be registered with the SAMR or its local counterparts, and reported to the Ministry of Commerce or its local counterparts. In addition, the PRC government also restricts the convertibility of foreign currencies into RMB and use of the proceeds. Furthermore, SAFE promulgated a series of rules and regulations, including Notice on Reforming the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises, the Circular on Reforming and Regulating Policies on the Management of Foreign Exchange Settlement of Capital Accounts, and the Circular to Further Facilitating Cross-border Trade and Investment, to further regulate the all foreign-invested companies to use RMB converted from foreign currency-denominated capital for equity investments in China.

In light of the various requirements imposed by PRC regulations on loans to, and direct investment in, PRC entities by offshore holding companies, we may not be able to obtain these government registrations or approvals on a timely basis, if at all, with respect to future loans to our PRC subsidiaries or future capital contributions by us to our PRC subsidiaries. If we fail to receive such registrations or approvals, our ability to provide loans or capital to increase contributions to our PRC subsidiaries may be negatively affected, which could adversely affect their liquidity and our ability to fund and expand their business.

Our business may be negatively affected by the potential obligations to make additional social insurance and housing fund contributions.

We are required by PRC labor laws and regulations to make registrations for social insurance and housing funds, and to pay various statutory employee benefits, including pensions insurance, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance, and housing funds, to designated government agencies for the benefit of our employees. The relevant government agencies may examine whether we are in compliance with the relevant labor laws and regulations. Failure to make full payment of the requisite statutory employee benefits and any potential non-compliance may subject us to late payment fees, fines, and/or other penalties. If the relevant PRC authorities determine that we shall make supplemental social insurance and housing fund contributions or that we are subject to fines and legal sanctions in relation to our failure to make social insurance and housing fund contributions in full for our employees, our business, financial condition, and results of operations may be adversely affected.

It may be difficult for overseas regulators to conduct investigations or collect evidence within the PRC.

Shareholder claims or regulatory investigation that are common in the United States generally are difficult to pursue as a matter of law or practicality in China. For example, in China, there are significant legal and other obstacles to providing information needed for regulatory investigations or litigation initiated outside China. Although the authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such cooperation with the securities regulatory authorities in the Unities States may not be efficient in the absence of a mutual and practical cooperation mechanism. Furthermore, according to Article 177 of the PRC Securities Law, which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the territory of the PRC; no

organization or individual is allowed to provide documents and information related to securities business activities to overseas securities regulators without the consent of the securities regulatory authority under the State Council and the relevant competent department under the State Council; and according to the Data Security Law, no organization or individual within the territory of the PRC may provide foreign judicial or law enforcement authorities with data stored within the territory of the PRC without the approval of the competent authorities of the PRC. While detailed interpretation of or implementation rules under these regulations have yet to be promulgated, the inability of an overseas securities regulator to directly conduct investigation or evidence collection activities within China may further increase difficulties faced by you in protecting your interests.

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, and we may rely principally 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 and service any debt we may incur. If our PRC subsidiaries incur debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other distributions to us.

Under PRC laws and regulations, our operating subsidiary in the PRC, Hangzhou Adlai, as a wholly foreign-owned enterprise in the PRC, may pay dividends only out of their accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise, such as Hangzhou Adlai, is required to set aside at least 10% of its accumulated after-tax profits after making up the previous year's accumulated losses each year, if any, to fund statutory reserve funds, until the aggregate amount of such fund reaches 50% of its registered capital. It may allocate a portion of its after-tax profits based on PRC accounting standards to discretionary reserve funds according to its shareholder's decision. These statutory reserve funds and discretionary reserve funds are not distributable as cash dividends.

In addition, the PRC Enterprise Income Tax Law, and its implementation rules provide that withholding tax rate of 10% will be applicable to dividends payable by PRC companies to non-PRC-resident enterprises unless otherwise exempted or reduced according to treaties or arrangements between the PRC central government and governments of other countries or regions where the non-PRC-resident enterprises are incorporated.

Any limitation on the ability of our PRC subsidiaries to pay dividends or make other distributions to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends, or otherwise fund and conduct our business.

We may be deemed to be a PRC resident enterprise under the Enterprise Income Tax Law, and be subject to the PRC taxation on our worldwide income, which may significantly increase our income tax expenses and materially decrease our profitability.

Under the PRC Enterprise Income Tax Law, enterprises established outside of China whose "de facto management bodies" are located in China are considered to be "resident enterprises" and will generally be subject to a uniform 25% corporate income tax on their global income (excluding dividends received from "resident enterprises"). In addition, a circular issued by State Administration of Taxation, or the SAT, on April 22, 2009 and amended on January 29, 2014 sets out certain standards for determining whether the "de facto management body" of an offshore enterprise funded by Chinese enterprises as controlling shareholders is located in China. Although this circular applies only to offshore enterprises funded by Chinese enterprises as controlling shareholders, rather than those funded by Chinese or foreign individuals or foreign enterprises as controlling shareholders, the determining criteria set forth in the circular may reflect SAT's general position on how the "de facto management body" test should be applied in determining the tax resident status of offshore enterprises, regardless of how they are funded. Although our company is not funded by Chinese enterprises as controlling shareholders, substantial uncertainties remain as to whether our company or any of our other non-PRC entities will be deemed a PRC resident enterprise for the Enterprise Income Tax purposes.

If we or any of our subsidiaries registered outside the PRC are to be deemed a "resident enterprise" under the PRC Enterprise Income Tax Law, our income tax expenses may increase significantly, and our profitability could decrease materially.

We face uncertainties in the PRC with respect to indirect transfer of equity interests in our PRC subsidiaries.

The indirect transfer of equity interest in PRC enterprises by a non-resident enterprise, is potentially subject to income tax in China at a rate of 10% on the gain if such transfer is considered not to have a commercial purpose and is carried out for tax avoidance. We also face uncertainties as to the reporting and other implications of certain past and future transactions where PRC taxable assets are involved, such as offshore restructuring, sale of the shares in our offshore subsidiaries or investments. Our company may be subject to filing obligations or taxed if our company is transferor in such transactions, and may be subject to withholding obligations if our company is transferee in such transaction. For transfer of shares in our company by investors that are non-PRC resident enterprises, our PRC subsidiaries may be requested to assist in investors' tax filing in China. As a result, we may be required to expend valuable resources to comply with SAT Circular 7 and SAT Circular 37 or to request the relevant transferors from whom we purchase taxable assets to comply with these publications, or to establish that our company should not be taxed under these publications, which may have a material adverse effect on our financial condition and results of operations.

Failure to comply with PRC regulations regarding the registration requirements for employee stock ownership plans or share option plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

Under the applicable regulations and SAFE rules, PRC citizens who participate in an employee stock ownership plan or a stock option plan in an overseas publicly listed company are required to register with SAFE and complete certain other procedures. Pursuant to the rules related to stock options by SAFE, if a PRC resident participates in any stock incentive plan of an overseas publicly listed company, a qualified PRC domestic agent must, among other things, file on behalf of such participant an application with SAFE to conduct the SAFE registration with respect to such stock incentive plan and obtain approval for an annual allowance with respect to the purchase of foreign exchange in connection with the exercise or sale of stock options or stock such participant holds. Such participating PRC residents' foreign exchange income received from the sale of stock and dividends distributed by the overseas publicly listed company must be fully remitted into a PRC collective foreign currency account opened and managed by the PRC agent before distribution to such participants. We and our PRC resident employees who have been granted stock options or other share-based incentives of ours will be subject to these rules when our company becomes an overseas listed company upon the completion of this offering. If we or our PRC resident participants fail to comply with these regulations, we and/or our PRC resident participants may be subject to fines and legal sanctions. In addition, SAT has issued certain circulars concerning employee share options and restricted shares. Under these circulars, our employees working in China who exercise share options and/or are granted restricted shares in the future will be subject to PRC individual income tax. Our PRC subsidiaries have obligations to file documents related to employee share options and/or restricted shares with tax authorities and to withhold individual income taxes of those employees who exercise their share options. If our employees fail to pay or we fail to withhold their income taxes according to laws and regulations, we may face sanctions imposed by the tax authorities or other PRC government authorities.

Conversion of RMB to and from other currency may be subject to governmental control in China

Currently, the RMB cannot be freely converted into any foreign currency. 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 the availability of foreign currency may restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to pay dividends or other payments to us, or otherwise satisfy their foreign currency dominated obligations. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments, and expenditures from trade-related transactions, can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, for most capital account items, approval from or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of bank loans denominated in foreign

currencies. The PRC government may also at its discretion restrict access in the future to foreign currencies for current account transactions. If the foreign exchange control system prevents us from obtaining sufficient foreign currency to satisfy our currency demands, we may not be able to pay dividends in foreign currencies to our shareholders, including holders of the ADSs.

Risks relating to the ADSs

An active trading market for our ordinary shares or the ADSs may not develop and the trading price of the ADSs may be volatile regardless of our operating performance, which could result in substantial losses to you.

Prior to this initial public offering, there has been no public market for our ordinary shares or the ADSs. We intend to apply for the listing of the ADSs on the Nasdaq Stock Market. Our ordinary shares will not be listed on any exchange or quoted for trading on any over-the-counter trading system. If an active trading market for the ADSs does not develop after this offering, the market price and liquidity of the ADSs will be materially and adversely affected.

The trading price of the ADSs may be volatile and could fluctuate widely due to factors beyond our control. This may happen because of broad market and industry factors, including the performance and fluctuation of the market prices of other companies with business operations located mainly in China that have listed their securities in the United States. The securities of some of these companies have experienced significant volatility since their initial public offerings, including, in some cases, substantial trading price declines. In addition, any negative news or perceptions about inadequate corporate governance practices or fraudulent accounting, corporate structure or matters of other companies with substantial operations in China may also negatively affect the attitudes of investors towards similar companies in general, including us, regardless of whether we have conducted any inappropriate activities.

In addition to market and industry factors, the price and trading volume for the ADSs may be volatile for factors specific to our own operations, including the following:

- the commencement, enrollment or results of our planned and future clinical trials;
- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;
- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States, China, and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes in the structure of healthcare payment systems;
- changes to our relationships with collaborators, manufacturers or suppliers;
- announcements concerning our competitors or the pharmaceutical industry in general;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions, financing, collaborations or other corporate transactions;
- the trading volume of the ADSs on the Nasdaq;
- sales of the ADSs or ordinary shares by us, members of our senior management and directors or our shareholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States or China; and
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry.

In addition, the share price of a number of companies involved in initial public offerings, particularly among companies with relatively smaller public floats, has experienced extreme price and volume fluctuations

that have often been unrelated or disproportionate to the operating performance of these companies. Such rapid and substantial price volatility, including any share price run-up, may be unrelated to our actual or expected operating performance and financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of the ADSs. This volatility may prevent you from being able to sell your securities at or above the price you paid for your securities. If the market price of the ADSs after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

Our dual-class share structure with different voting rights will limit your ability to influence corporate matters and could discourage others from pursuing any change of control transactions that holders of our Class A ordinary shares and ADSs may view as beneficial.

We expect to have a dual-class share structure after the completion of this offering such that our ordinary shares will consist of Class A ordinary shares and Class B ordinary shares. In respect of matters requiring the votes of shareholders, holders of Class A ordinary shares will be entitled to one vote per share, while holders of Class B ordinary shares will be entitled to 15 votes per share based on our proposed dual-class share structure. We will sell Class A ordinary shares represented by the ADSs in this offering. Each Class B ordinary share is convertible into one Class A ordinary share at any time by the holder thereof, while Class A ordinary shares are not convertible into Class B ordinary shares under any circumstances.

Upon the completion of this offering, our founder, Mr. Yang Lu will beneficially own all of our issued Class B ordinary shares. These Class B ordinary shares will constitute approximately % of our total issued and outstanding share capital immediately after the completion of this offering and % of the aggregate voting power of our total issued and outstanding share capital due to the disparate voting powers associated with our dual-class share structure, assuming the underwriters do not exercise their over-allotment option. As a result of the dual-class share structure and the concentration of ownership, the holder of our Class B ordinary shares will have considerable influence over matters such as decisions regarding mergers, consolidations and the sale of all or substantially all of our assets, election of directors and other significant corporate actions. They 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 ADSs. 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 holders of Class A ordinary shares and ADSs may view as beneficial.

Our dual-class voting structure may render the ADSs representing our Class A ordinary shares ineligible for inclusion in certain stock market indices, and thus adversely affect the trading price and liquidity of the ADSs.

We cannot predict whether our dual-class share structure with different voting rights will result in a lower or more volatile market price of the ADSs, adverse publicity, or other adverse consequences. Certain index providers have announced restrictions on including companies with multi-class share structures in certain of their indices. For example, S&P Dow Jones and FTSE Russell have changed their eligibility criteria for inclusion of shares of public companies on certain indices, including the S&P 500, to exclude companies with multiple classes of shares and companies whose public shareholders hold no more than 5% of total voting power from being added to such indices. As a result, our dual-class voting structure may prevent the inclusion of the ADSs representing our Class A ordinary shares in such indices, which could adversely affect the trading price and liquidity of the ADSs representing our Class A ordinary shares. In addition, several shareholder advisory firms have announced their opposition to the use of multiple class structure and our dual-class structure may cause shareholder advisory firms to publish negative commentary about our corporate governance, in which case the market price and liquidity of the ADSs could be adversely affected.

Because we do not have a regular dividend policy yet, you may need to rely on price appreciation of the ADSs for return on your investment.

We currently intend to retain most, if not all, of our available funds and any future earnings after this offering to fund the development and growth of our business. As a result, we do not expect to pay any cash

dividends in the foreseeable future. Therefore, you should not rely on an investment in the ADSs as a source for any future dividend income.

Our board of directors has complete discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law, namely that our company may only pay dividends out of profits or share premium account, and provided always that in no circumstances may a dividend be paid out of share premium if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business. In addition, our shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our board of directors. Even if our board of directors 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 of directors. Accordingly, the return on your investment in the ADSs will likely depend entirely upon any future price appreciation of the ADSs. There is no guarantee that the ADSs will appreciate in value after this offering or even maintain the price at which you purchased the ADSs. You may not realize a return on your investment in the ADSs and you may even lose your entire investment in the ADSs.

Because our initial public offering price is substantially higher than our net tangible book value per share, you will experience immediate and substantial dilution.

If you purchase ADSs in this offering, you will pay more for your ADSs than the amount paid by existing shareholders for their Class A ordinary shares on a per ADS basis. As a result, you will experience immediate and substantial dilution of US$ per ADS, representing the difference between (i) our pro forma as adjusted net tangible book value per ADS as of December 31, 2021, after giving effect to this offering, and (ii) the initial public offering price per share of US$ per ADS. In addition, you may experience further dilution to the extent that our Class A ordinary shares are issued upon the exercise of share options. Substantially all of the Class A ordinary shares issuable upon the exercise of currently outstanding share options will be issued at a purchase price on a per ADS basis that is less than the initial public offering price per ADS in this offering. See “Dilution” for a more complete description of how the value of your investment in the ADSs will be diluted upon the completion of this offering.

If securities or industry analysts do not publish research or reports about our business, or if they adversely change their recommendations regarding the ADSs, the market price for the ADSs and trading volume could decline.

The trading market for the ADSs will be influenced by research or reports that industry or securities analysts publish about our business. If one or more analysts who cover us downgrade the ADSs, the market price for the ADSs would likely decline. If one or more of these analysts cease to cover us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for the ADSs to decline.

Our post-offering memorandum and articles of association contain anti-takeover provisions that could have a material adverse effect on the rights of holders of our ordinary shares and ADSs.

We will adopt an amended and restated memorandum and articles of association that will become effective immediately prior to completion of this offering. Our new memorandum and articles of association contain provisions that may discourage, delay or prevent a change of control of our company, including a provision that entitles each Class B ordinary share to 15 votes in respect of all matters subject to a shareholders’ vote and a provision that authorizes our board of directors to issue additional ordinary shares from time to time as our board of directors may determine, to the extent of available authorized but unissued shares. These provisions could have the effect of depriving our shareholders of an opportunity to sell their shares at a premium over prevailing market prices by discouraging third parties form seeking to obtain control of our company in a tender offer or similar transaction.

Techniques employed by short sellers may drive down the market price of the ADSs.

Short selling is the practice of selling securities that the seller does not own but rather has borrowed from a third party with the intention of buying identical securities back at a later date to return to the lender. The

short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's best interests for the price of the stock to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a stock short. These short attacks have, in the past, led to selling of shares in the market.

Public companies, including those having a substantial portion of their operations in China have been the subject of short selling. Much of the scrutiny and negative publicity has centered on allegations of a lack of effective internal control over financial reporting resulting in financial and accounting irregularities and mistakes, inadequate corporate governance policies or a lack of adherence thereto and, in many cases, allegations of fraud. As a result, many of these companies are now conducting internal and external investigations into the allegations and, in the interim, are subject to shareholder lawsuits and/or SEC enforcement actions.

It is not clear what effect such negative publicity could have on us. If we were to become the subject of any unfavorable allegations, whether such allegations are proven to be true or untrue, we could have to expend significant amount of resources to investigate such allegations and/or defend ourselves. While we would strongly defend against any such short seller attacks, we may be constrained in the manner in which it can proceed against the relevant short seller by principles of freedom of speech, applicable state law or issues of commercial confidentiality. Such a situation could be costly and time-consuming, and could distract our management from growing our business. Even if such allegations are ultimately proven to be groundless, allegations against us could severely impact our business operations and stockholders' equity, and any investment in the ADSs could be greatly reduced or rendered worthless.

The sale or availability for sale, or perceived sale or availability for sale, of substantial amounts of the ADSs could adversely affect their market price.

Sales of substantial amounts of the ADSs in the public market after the completion of this offering, or the perception that these sales could occur, could adversely affect the market price of the ADSs and could materially impair our ability to raise capital through equity offerings in the future. The ADSs sold in this offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, and shares held by our existing shareholders may also be sold in the public market in the future subject to the restrictions in Rule 144 and Rule 701 under the Securities Act and the applicable lock-up agreements. There will be ADSs (equivalent to Class A ordinary shares) outstanding immediately after this offering, we[, our officers, directors, existing shareholders and holders of share-based awards] have agreed not to sell any of our ordinary shares or the ADSs or are otherwise subject to similar lockup restrictions for 180 days after the date of this prospectus without the prior written consent of the representatives of the underwriters, subject to certain exceptions. However, the underwriters may release these securities from these restrictions at any time, subject to applicable regulations of the Financial Industry Regulatory Authority, or FINRA. We cannot predict what effect, if any, market sales of securities held by our significant shareholders or any other shareholder or the availability of these securities for future sale will have on the market price of the ADSs. See "Underwriting" and "Shares Eligible for Future Sale" for a more detailed description of the restrictions on selling our securities after this offering.

ADS holders do not have the same rights as our shareholders.

ADS holders do not have the same rights as our shareholders. For example, ADS holders may not attend shareholders' meetings or directly exercise the voting rights attaching to the Class A ordinary shares underlying their ADSs. ADS holders may vote only by instructing the depositary to vote on their behalf. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of the Cayman Islands and the provisions of our articles of association or similar documents, to vote or to have its agents vote the deposited common shares as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting

instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so. Except by instructing the depositary as described above, you will not be able to exercise voting rights unless you surrender the ADSs and withdraw the Class A ordinary shares. However, you may not know about the meeting enough in advance to withdraw the Class A ordinary shares. We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your Class A ordinary shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise voting rights and there may be nothing you can do if your Class A ordinary shares are not voted as you requested. In addition, ADS holders have no right to call a shareholders' meeting.

Owners or holders of the ADSs have limited recourse if we or the depositary fail to meet our respective obligations under the deposit agreement.

The deposit agreement expressly limits the obligations and liability of us and the depositary. For example, the depositary is not liable if any of us or our respective controlling persons or agents is prevented or forbidden from, or subjected to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement and any ADS, by reason of any provision of any present or future law or regulation of the United States or any state thereof, the Cayman Islands or any other country, or of any other governmental authority or regulatory authority or stock exchange, or on account of the possible criminal or civil penalties or restraint, or by reason of any provision, present or future, of our memorandum and articles of association or any provision of or governing any deposited securities, or by reason of any act of God or war or other circumstances beyond its control (including, without limitation, nationalization, expropriation, currency restrictions, work stoppage, strikes, civil unrest, revolutions, rebellions, explosions, and computer failure). See "Description of American Depositary Shares" for more information. In addition, the depositary and any of its agents also disclaim any liability for (i) any failure to carry out any instructions to vote, the manner in which any vote is cast or the effect of any vote or failure to determine that any distribution or action may be lawful or reasonably practicable or for allowing any rights to lapse in accordance with the provisions of the deposit agreement, (ii) the failure or timeliness of any notice from us, the content of any information submitted to it by us for distribution to you or for any inaccuracy of any translation thereof, (iii) any investment risk associated with the acquisition of an interest in the deposited securities, the validity or worth of the deposited securities or the credit-worthiness of any third party, (iv) any tax consequences that may result from ownership of ADSs, ordinary shares or deposited securities, or (v) any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the depositary or in connection with any matter arising wholly after the removal or resignation of the depositary, provided that in connection with the issue out of which such potential liability arises the depositary performed its obligations without gross negligence or willful misconduct while it acted as depositary. These provisions of the deposit agreement will limit the ability of owners or holders of the ADSs to obtain recourse if we or the depositary fail to meet our respective obligations under the deposit agreement.

You must rely on the judgment of our management as to the use of the net proceeds from this offering, and such use may not produce income or increase the price of our ordinary shares and/or ADSs.

Our management will have considerable discretion in the application of the net proceeds received by us. You will not have the opportunity, as part of your investment decision, to assess whether proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not improve our efforts to achieve or maintain profitability or increase the ADS price. The net proceeds from this offering may be placed in investments that do not produce income or that lose value.

You may experience dilution of your holdings due to the inability to participate in rights offerings.

We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to you in the United States unless we register both the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Under the deposit agreement, the depositary will not make rights available to you unless both the rights and the underlying securities to be distributed to ADS holders are either registered under the Securities Act or exempt from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to

be declared effective and we may not be able to establish a necessary exemption from registration under the Securities Act. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings.

As a holder of ADSs, you may not receive distributions on the Class A ordinary shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs.

Under the terms of the deposit agreement, the Depositary has agreed to pay to you the cash dividends or other distributions it or the custodian receives on the Class A ordinary shares or other deposited securities after deducting its fees and expenses and any taxes or other governmental charges. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution other than cash available to holders of ADSs. We have no obligation to take any other action to permit the distribution of the ADSs, Class A ordinary shares, rights or anything else to holders of the ADSs. This means that, as a holder of ADSs, you may not receive the distributions we make on the Class A ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have a material adverse effect on the value of your ADSs.

You may be subject to limitations on transfer of your ADSs.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems it expedient in connection with the performance of its duties. The depositary may also close its books in emergencies, and on weekends and public holidays. The depositary may refuse to deliver, transfer or register transfers of the ADSs generally when our share register or the books of the depositary are closed, or at any time if we or the depositary thinks it is advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason. In addition, ADS holders may not be able to cancel their ADSs and withdraw the underlying Class A ordinary shares when they owe money for fees, taxes and similar charges.

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

We are a company incorporated under the laws of the Cayman Islands and, to date, conduct the majority of our operations in China and a substantial portion of our assets are located in mainland China. In addition, many of our directors and executive officers reside within China for a significant portion of the time. As a result, it may be difficult for you to effect service of process upon us or those persons inside China. It may also be difficult for you to enforce in U.S. courts judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against us and our officers and directors residing in China. In addition, there is uncertainty as to whether the courts of the Cayman Islands or the PRC would recognize or enforce judgments of U.S. courts against us or such persons predicated upon the civil liability provisions of the securities laws of the United States.

The recognition and enforcement of foreign judgments are provided for under the PRC Civil Procedures Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedures Law based either on treaties between China and the country or region where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other forms of written arrangement with the United States that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, the PRC courts will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of PRC laws or national sovereignty, security, or the public interest. As a result, it is uncertain whether and on what basis a PRC court would enforce a judgment rendered by a court in the United States.

You may face difficulties in protecting your interests, and your ability to protect your rights through U.S. courts may be limited, because we are incorporated under Cayman Islands law.

We are an exempted company incorporated under the laws of the Cayman Islands. Our corporate affairs are governed by, among other things, our memorandum and articles of association, the Companies Act (As Revised) of the Cayman Islands, or the Companies Act, and the common law of the Cayman Islands. The

rights of shareholders to take action against our directors, actions by our minority shareholders and the fiduciary duties of our directors to us under the 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 the common law of England, the decisions of whose courts are of persuasive authority, but are not binding, on a court in the Cayman Islands. The rights of our shareholders and the fiduciary duties of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a less developed body of securities laws than the United States. Some U.S. states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands. In addition, the Cayman Islands companies may not have the standing to initiate a shareholder derivative action in a federal court of the United States.

Shareholders of Cayman Islands companies like us have no general rights under the Cayman Islands law to inspect corporate records, or to obtain copies of lists of shareholders of these companies. Our directors have discretion under our post-offering memorandum and articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

Certain corporate governance practices in the Cayman Islands, which is our home country, differ significantly from requirements for companies incorporated in other jurisdictions such as the United States. We may in the future rely on home country practice with respect to our corporate governance after we complete this offering. If we choose to follow home country practice in the future, our shareholders may be afforded less protection than they otherwise would under rules and regulations applicable to U.S. domestic issuers.

As a result of all of the above, public shareholders may have more difficulty in protecting their interests in the face of actions taken by our management, members of our board of directors or our controlling shareholders than they would as public shareholders of a company incorporated in the United States. For a discussion of significant differences between the provisions of the Companies Act and the laws applicable to companies incorporated in the United States and their shareholders, see “Description of Share Capital — Differences in corporate law.”

We are a foreign private issuer within the meaning of the rules under the Exchange Act, and as such we are exempt from certain provisions applicable to U.S. domestic public companies.

Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the securities rules and regulations in the United States that are applicable to U.S. domestic issuers, including:

- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q or current reports on Form 8-K;
- the sections of the Exchange Act regulating the solicitation of proxies, consents, or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time;
- the selective disclosure rules by issuers of material nonpublic information under Regulation FD; and
- certain audit committee independence requirements in Rule 10A-3 of the Exchange Act.

We will be required to file an annual report on Form 20-F within four months of the end of each fiscal year. In addition, we intend to publish our results on a quarterly basis as press releases, distributed pursuant to the rules and regulations of the Nasdaq Stock Market. Press releases relating to financial results and material events will also be furnished to the SEC on Form 6-K. However, the information we are required to file with or furnish to the SEC will be less extensive and less timely compared to that required to be filed with the SEC by U.S. domestic issuers. As a result, you may not be afforded the same protections or information that would be made available to you were you investing in a U.S. domestic issuer.

As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from the Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with the Nasdaq corporate governance listing standards.

The Nasdaq permits a foreign private issuer like us to follow the corporate governance practices of its home country. Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the Nasdaq corporate governance listing standards. For instance, we are not required to:

- have a majority of the board be independent (although all of the members of the audit committee must be independent under the Exchange Act);
- have a compensation committee or a nominations or corporate governance committee consisting entirely of independent directors; or
- have regularly scheduled executive sessions with only independent directors each year.

We may rely on home country practice with respect to our corporate governance after we complete this offering. If we choose to follow home country practice in the future, our shareholders may be afforded less protection than they otherwise would enjoy under the Nasdaq corporate governance listing standards applicable to U.S. domestic issuers.

We are an emerging growth company within the meaning of the Securities Act and may take advantage of certain reduced reporting requirements.

As a company with less than US$1.07 billion in revenues for our last fiscal year, we qualify as an "emerging growth company" pursuant to the JOBS Act. Therefore, we have elected to take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies and acknowledge such election is irrevocable pursuant to Section 107 of the JOBS Act. These provisions include exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, in the assessment of the emerging growth company's internal control over financial reporting and permission to delay adopting new or revised accounting standards until such time as those standards apply to private companies. As a result, if we elect not to comply with such reporting and other requirements, in particular the auditor attestation requirements, our investors may not have access to certain information they may deem important.

The JOBS Act also provides that an emerging growth company does not need to comply with any new or revised financial accounting standards until such date that a private company is otherwise required to comply with such new or revised accounting standards. We have elected to take advantage of the extended transition period for complying with new or revised accounting standards until those standards would otherwise apply to private companies. As a result, our results of operations and financial statements may not be comparable to the results of operations and financial statements of other companies that have adopted the new or revised accounting standards. If we cease to be an emerging growth company, we will no longer be able to take advantage of these exemptions or the extended transition period for complying with new or revised accounting standards.

Forum selection provisions in our post-offering memorandum and articles of association and our deposit agreement with the depositary bank could limit the ability of holders of our ordinary shares, ADSs, or other securities to obtain a favorable judicial forum for disputes with us, our directors and officers, the depositary bank, and potentially others.

Our post-offering memorandum and articles of association provide that the United States District Court for the Southern District of New York (or, if the United States District Court for the Southern District of New York lacks subject matter jurisdiction over a particular dispute, the state courts in New York County, New York) are the exclusive forum within the United States for the resolution of any complaint asserting a cause of action arising under the Securities Act and the Exchange Act. Our agreement with the depositary bank also provides that the United States District Court for the Southern District of New York (or, if the United States District Court for the Southern District of New York lacks subject matter jurisdiction over a

particular dispute, the state courts in New York County, New York) is the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act or the Exchange Act.

However, the enforceability of similar federal court choice of forum provisions has been challenged in legal proceedings in the United States, and it is possible that a court could find this type of provision to be inapplicable, unenforceable, or inconsistent with other documents that are relevant to the filing of such lawsuits. If a court were to find the federal choice of forum provision contained in our post-offering memorandum and articles of association or our deposit agreement with the depositary bank to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions. If upheld, the forum selection clause in our post-offering memorandum and articles of association, as well as the forum selection provisions in the deposit agreement, may limit a security-holder's ability to bring a claim against us, our directors and officers, the depositary bank, and potentially others in his or her preferred judicial forum, and this limitation may discourage such lawsuits.

In addition, the Securities Act provides that both federal and state courts have jurisdiction over suits brought to enforce any duty or liability under the Securities Act or the rules and regulations thereunder. Accepting or consent to this forum selection provision does not constitute a waiver by you of compliance with federal securities laws and the rules and regulations thereunder. You may not waive compliance with federal securities laws and the rules and regulations thereunder. The exclusive forum provision in our post-offering memorandum and articles of association will not operate so as to deprive the courts of the Cayman Islands from having jurisdiction over matters relating to our internal affairs.

ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our Class A ordinary shares provides that, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim that they may have against us or the depositary arising out of or relating to our Class A ordinary shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has nonexclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently, and voluntarily waives the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other owners or holders of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us or the depositary. If a lawsuit is brought against us or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action.

Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. The deposit agreement also provides that ADSs holders and the depositary have the right to elect to have any claim against us arising out of or relating to our Class A ordinary shares, ADSs, ADRs or the deposit agreement settled by arbitration in New York, New York rather than in a court of law, and to have any judgment rendered by the arbitrators entered in any court having jurisdiction. The arbitral tribunal in any such arbitration would not have the authority to award any

consequential, special, or punitive damages or other damages not measured by the prevailing party's actual damages and may not make any ruling, finding or award that does not conform to the provisions of the deposit agreement. The deposit agreement does not give us the right to require that any claim, whether brought by us or against us, be arbitrated. The optional arbitration provision does not apply to claims under federal securities laws or claims other than in connection with this offering.

No condition, stipulation, or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

The deposit agreement may be amended or terminated without your consent.

We and the depositary may amend or terminate the deposit agreement without your consent. Such amendment or termination may be done in favor of our company. Holders of the ADSs, subject to the terms of the deposit agreement, will receive notice in the event of an amendment that prejudices a substantial existing right or a termination. If you continue to hold your ADSs after an amendment to the deposit agreement, you agree to be bound by the deposit agreement as amended. The deposit agreement may be terminated at any time upon a prior written notice. Upon the termination of the deposit agreement, our company will be discharged from all obligations under the deposit agreement, except for our obligations to the depositary thereunder. See "Description of American Depositary Shares" for more information.

Our post-offering memorandum and articles of association contain anti-takeover provisions that could have a material adverse effect on the rights of holders of our ordinary shares and ADSs.

Our memorandum and articles of association contain certain provisions that could limit the ability of others to acquire control of our company and a provision that grants authority to our board of directors to establish from time to time one or more series of preferred shares without action by our shareholders and to determine, with respect to any series of preferred shares, the terms and rights of that series. These provisions could have the effect of depriving our shareholders of the opportunity to sell their shares at a premium over the prevailing market price by discouraging third parties from seeking to obtain control of our company in a tender offer or similar transactions.

We will be a "controlled company" within the meaning of the Nasdaq Stock Market listing rules and, as a result, may rely on exemptions from certain corporate governance requirements that provide protection to shareholders of other companies.

We will be a "controlled company" as defined under the Nasdaq Stock Market listing rules because Mr. Yang Lu, our founder, will continue to control more than 50% of our total voting power immediately after the completion of this offering. Pursuant to our post-offering memorandum and articles of association, an ordinary resolution to be passed at a shareholders' meeting requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast at a meeting, while a special resolution requires the affirmative vote of no less than two-thirds of the votes cast attaching to the outstanding and issued ordinary shares cast at a meeting. A special resolution will be required for important matters such as making changes to our post-offering memorandum and articles of association. As a result, Mr. Yang Lu will have the ability to control or significantly influence the outcome of matters requiring approval by shareholders. In addition, for so long as we remain a controlled company under that definition, we are permitted to elect to rely on, and may rely on, certain exemptions from corporate governance rules, including an exemption from the rule that a majority of our board of directors must be independent directors. We may also rely on the exemption available for foreign private issuers to follow our home country governance practices. See "— Risks Related to the ADSs — As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from the Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with the Nasdaq corporate governance listing standards" As a result, you will not have the same protection afforded to shareholders of companies that are subject to these corporate governance requirements.

We may be classified as a passive foreign investment company, which could result in adverse U.S. federal income tax consequences to U.S. investors of the ADSs or ordinary shares.

A non-U.S. corporation is a PFIC for U.S. federal income tax purposes for any taxable year in which (after taking into account the income and assets of subsidiaries in which it owns at least a 25% interest by

value), (i) at least 75% of its gross income is "passive" income, such as interest and income from financial investments (the "income test") or (ii) at least 50% of the average value of its assets (generally determined on a quarterly basis) consists of assets that produce or are held to produce passive income (the "asset test"). For purposes of the asset test, any cash, and cash equivalents (such as bank deposits) will count as passive assets, and goodwill should be treated as an active asset to the extent associated with activities that produce or intended to produce active income. In determining the average percentage value of our gross assets, the aggregate value of our assets will generally be deemed to be equal to our market capitalization (determined by the sum of the aggregate value of our outstanding equity) plus our liabilities. We could be a PFIC for any future taxable year if our market capitalization were to decrease significantly while we hold substantial cash and cash equivalents, or if the gross income that we and our subsidiaries earn from investing the portion of cash raised in this offering is substantial in comparison with the gross income from our business operation.

If we were treated as a PFIC for any taxable year, then U.S. investors could be subject to adverse U.S. federal income tax consequences (regardless of whether we continue to be a PFIC), including increased tax liability on disposition gains and certain "excess distributions" and additional reporting requirements. See "Taxation — United States federal income tax considerations — Passive foreign investment company" for further information. U.S. investors should consult their tax advisers regarding our PFIC status for any taxable year and the potential application of the PFIC rules to an investment in the ADSs or ordinary shares including the availability and the advisability of making certain elections under the PFIC rules.

We expect to incur increased costs as a result of being a public company, and will incur further increased costs after we cease to qualify as an "emerging growth company."

We will become a public company after this offering, and expect to incur significant legal, accounting, and other expenses that we would not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and the Nasdaq Stock Market, impose various requirements on the corporate governance practices of public companies. We expect these rules and regulations to increase our legal and financial compliance costs and to make some corporate activities more time-consuming and costly. Especially after we are no longer an emerging growth company, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and the other rules and regulations of the SEC. For example, as a result of becoming a public company, we need to increase the number of independent directors and adopt policies regarding internal controls and disclosure controls and procedures. We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. In addition, we will incur additional costs associated with our public company reporting requirements. It may also be more difficult for us to find qualified persons to serve on our board of directors or as executive officers. We are currently evaluating and monitoring developments with respect to these rules and regulations, and we cannot predict or estimate with any degree of certainty the amount of additional costs we may incur or the timing of such costs.

In the past, shareholders of a public company often brought securities class action suits against the company following periods of instability in the market price of that company's securities. If we were involved in a class action suit, it could divert a significant amount of our management's attention and other resources from our business and operations, which could harm our results of operations and require us to incur significant expenses to defend the suit. Any such class action suit, whether or not successful, could harm our reputation and restrict our ability to raise capital in the future. In addition, if a claim is successfully made against us, we may be required to pay significant damages.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that reflect our current expectations and views of future events. The forward-looking statements are contained principally in the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." Known and unknown risks, uncertainties, and other factors, including those listed under "Risk Factors," may cause our actual results, performance, or achievements to be materially different from those expressed or implied by the forward-looking statements.

You can identify some of these forward-looking statements by words or phrases, such as "may," "will," "expect," "anticipate," "aim," "estimate," "intend," "plan," "believe," "is/are likely to," "potential," "continue" or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events that we believe may affect our financial condition, results of operations, business strategy, and financial needs. These forward-looking statements include statements relating to:

- our business strategies and plans to achieve these strategies;
- the timing, progress, and results of preclinical studies, and clinical trials for drug candidates we may develop;
- the possibility to obtain the relevant requisite regulatory approvals of our drug candidates;
- the feasibility to successfully commercialize our drug candidates in a timely manner;
- changes in competitive conditions and the feasibility to compete under these conditions;
- the size of the market opportunity for our drug candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- the likelihood to maintain the collaboration with licensors, and establish or maintain future collaborations or strategic relationships;
- the feasibility to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our drug candidates;
- changes to the political and regulatory environment in the industry and markets in which we operate;
- effects of the global financial markets and economic crisis;
- change or volatility in interest rates, foreign exchange rates, equity prices, volumes, operations, margins, risk management, and overall market trends;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing resources and the proceeds from this offering.

These forward-looking statements involve various risks and uncertainties. Although we believe that our expectations expressed in these forward-looking statements are reasonable, our expectations may later be found to be incorrect. Our actual results could be materially different from our expectations. Important risks and factors that could cause our actual results to be materially different from our expectations are generally set forth in "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business," "Regulation," and other sections in this prospectus. You should read thoroughly this prospectus and the documents that we refer to with the understanding that our actual future results may be materially different from and worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This prospectus contains certain data and information that we obtained from various government and private publications. Statistical data in these publications also include projections based on a number of assumptions. Our industry may not grow at the rate projected by market data, or at all. Failure of this market to grow at the projected rate may have a material and adverse effect on our business and the market price of the ADSs. In addition, the rapidly evolving nature of this industry results in significant uncertainties for any

projections or estimates relating to the growth prospects or future condition of our market. Furthermore, if any one or more of the assumptions underlying the market data are later found to be incorrect, actual results may differ from the projections based on these assumptions. You should not place undue reliance on these forward-looking statements.

The forward-looking statements made in this prospectus relate only to events or information as of the date on which the statements are made in this prospectus. 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 prospectus and the documents that we refer to in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect.

USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately US$, or approximately US$ if the underwriters exercise their option to purchase additional ADSs, after deducting underwriting discounts and commissions and the estimated offering expenses payable by us. These estimates are based upon an assumed initial public offering price of US$ per ADS, which is the midpoint of the price range shown on the front page of this prospectus. A US$1.00 increase (decrease) in the assumed initial public offering price of US$ per ADS would increase (decrease) the net proceeds to us from this offering by US$, assuming the number of ADSs offered by us, as set forth on the front cover of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

The primary purposes of this offering are to create a public market for our Class A ordinary shares for the benefit of all shareholders, retain talented employees by providing them with equity incentives, and obtain additional capital. We plan to use the net proceeds of this offering as follows:

- approximately US$ million for expansion of the ongoing and future R&D activities, including planned preclinical studies, clinical trials, and future commercialization of our drug candidates;
  - to fund the ongoing registrational trial for AN2025 (buparlisib) and the milestone payments in connection with development of AN2025;
  - to fund the commercial launch, if approved, of AN2025;
  - to fund the ongoing Phase Ib trial for AN0025 (palupiprant) in the United States and France;
  - to fund the ongoing Phase I trial both in the United States and China for AN4005;
  - to fund the ongoing Phase I trial in the United States for the triple combination of AN2025, AN0025, and atezolizumab; and
  - to fund the discovery and IND enabling studies of pre-clinical drugs;
- approximately US$ million for expansion of our drug portfolio through a combination of internal R&D activities and external business development efforts; and
- approximately US$ million for our general working capital and general corporate purposes.

Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our planned operating expenses and capital expenditures through the next 12 months. The foregoing represents our current intentions based upon our present plans and business conditions to use and allocate the net proceeds of this offering. Our management, however, will have broad discretion in the application of our net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of these proceeds. See “Risk Factors — Risks relating to the ADSs — You must rely on the judgment of our management as to the use of the net proceeds from this offering, and such use may not produce income or increase the price of our ordinary shares and/or ADSs.”

We intend to invest the net proceeds in short- and intermediate-term interest-bearing obligations, investment-grade instruments, certificates of deposit or guaranteed obligations of the U.S. government, pending their use as described above.

In using the proceeds of this offering, we are permitted under PRC laws and regulations as an offshore holding company to provide funding to our PRC subsidiaries only through loans or capital contributions, subject to satisfaction of applicable government registration and approval requirements. We cannot assure you that we will be able to obtain these government registrations or approvals on a timely basis, or at all. See “Risk Factors — Risks relating to our operation in the People’s Republic of China — PRC regulation of loans to, and direct investments in, PRC entities by offshore holding companies may delay or prevent us from making loans or additional capital contributions to our PRC operating subsidiaries and thereby prevent us from funding our business.”

DIVIDEND POLICY

We have not set any regular dividend policy yet, and our board of directors has discretion as to whether and when to distribute dividends, subject to certain requirements of Cayman Islands law. In addition, our shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our directors. Under Cayman Islands law, a Cayman Islands exempted company may pay a dividend out of either profit, retained earnings or share premium, provided that in no circumstances may a dividend be paid if that would result in the company being unable to pay its debts as they fall due in the ordinary course of business. Even if our Board decides to pay dividends, the form, frequency, and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions, and other factors that the Board may deem relevant.

We are a holding company incorporated in the Cayman Islands. For our cash requirements, including any payment of dividends to our shareholders, we rely upon payments from our operating entities. PRC regulations may restrict the ability of our PRC subsidiaries to pay dividends to us. See "Regulation — PRC laws and regulations — Regulations relating to foreign exchange control" and "Regulation — PRC laws and regulations — Regulations relating to dividend distribution."

If we pay any dividends on our ordinary shares, we will pay those dividends which are payable in respect of the Class A ordinary shares underlying the ADSs to the depositary, as the registered holder of such Class A ordinary shares, and the depositary then will pay such amounts to the ADS holders in proportion to the Class A ordinary shares underlying the ADSs held by such ADS holders, subject to the terms of the deposit agreement, including the fees and expenses payable thereunder. See "Description of American Depositary Shares." Cash dividends on our ordinary shares, if any, will be paid in U.S. Dollars.

CAPITALIZATION

The following table sets forth our capitalization as of December 31, 2022:

- on an actual basis;
- on a pro forma basis to reflect (i) the automatic conversion and the re-designation of all of the issued and outstanding preferred shares on a one-for-one basis into ordinary shares immediately prior to the completion of this offering; (ii) the re-designation of 16,990,000 ordinary shares into Class B ordinary shares on a one-for one basis immediately prior to the completion of this offering;and (iii) the re-designation of all of the remaining ordinary shares into Class A ordinary shares on a one-for-one basis immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis to reflect (i) the automatic conversion and the re-designation of all of the issued and outstanding preferred shares on a one-for-one basis into ordinary shares immediately prior to the completion of this offering; (ii) the re-designation of 16,990,000 ordinary shares into Class B ordinary shares on a one-for-one basis immediately prior to the completion of this offering; and (iii) the re-designation of all of the remaining ordinary shares into Class A ordinary shares on a one-for-one basis immediately prior to the completion of this offering; and (iv) the issuance and sale of Class A ordinary shares in the form of ADSs by us in this offering at an assumed initial public offering price of US$ per ADS, the midpoint of the estimated range of the initial public offering price shown on the front cover of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with our consolidated financial statements and the related notes included elsewhere in this prospectus and the information under "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of December 31, 2022		
	Actual	Pro Forma	Pro forma As adjusted
	US$	US$	US$
	(in thousands, except for shares and par value data)		
Preferred shares liabilities			
Series B convertible redeemable preferred shares (par value of US$0.0001 per share; 13,607,896 shares authorized, issued and outstanding on an actual basis; and nil outstanding on a pro forma and pro forma as adjusted basis as of December 31, 2022)	90,384	—	
Series C convertible redeemable preferred shares (par value of US$0.0001 per share; 14,653,013 shares authorized, issued and outstanding on an actual basis; and nil outstanding on a pro forma and pro forma as adjusted basis as of December 31, 2022)	97,132	—	
Series D convertible redeemable preferred shares (par value of US$0.0001 per share; 14,722,505 shares authorized, issued and outstanding on an actual basis; and nil outstanding on a pro forma and pro forma as adjusted basis as of December 31, 2022)	102,852	—	
Total preferred shares liabilities	290,368	—	
Ordinary shares (par value of $0.0001 per share; 442,456,586 shares authorized; 40,440,000 shares issued and outstanding on an actual basis, and nil outstanding on a pro forma basis or pro forma as adjusted basis as of December 31, 2022)	4	—	
Class A Ordinary shares (par value of $0.0001 per share; nil outstanding at an actual basis, and 80,093,414 shares at pro forma basis as of December 31, 2022)	—	8	

	As of December 31, 2022		
	Actual	Pro Forma	Pro forma As adjusted
	US$	US$	US$
	(in thousands, except for shares and par value data)		
Class B Ordinary shares (par value of $0.0001 per share; nil outstanding at an actual basis, and 16,990,000 shares at pro forma basis as of December 31, 2022)	—	2	
Additional paid-in capital	6,415	307,757	
Series A convertible preferred shares	10,980	—	
Share option reserve	13,688	13,688	
Exchange fluctuation reserve	(4,159)	(4,159)	
Accumulated loss	(268,221)	(268,221)	
Total shareholders' (deficit) equity	(241,293)	49,075	
Total capitalization	49,075	49,075	

The information above is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed initial public offering price of $ per ADS, the midpoint of the estimated price range shown on the cover page of this prospectus, would increase (decrease) the amount of cash and cash equivalents, additional paid-in capital, total shareholders' deficits and total capitalization on a pro forma as adjusted basis by approximately $ million, assuming the number of ADSs offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of ADSs offered by us would increase (decrease) cash and cash equivalents, total shareholders' deficits and total capitalization on a pro forma as adjusted basis by approximately $ million, assuming the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

DILUTION

If you invest in the ADSs, your interest will be diluted to the extent of the difference between the initial public offering price per ADS and our net tangible book value per ADS after this offering. Dilution results from the fact that the initial public offering price per ordinary share is substantially in excess of the book value per ordinary share attributable to the existing shareholders for our presently outstanding ordinary shares.

Our net tangible book value as of December 31, 2022 was approximately US$ million, representing US$ per ordinary share on a pro forma basis and US$ per ADS. Net tangible book value represents the amount of our total consolidated tangible assets less total consolidated liabilities. Dilution is determined by subtracting net tangible book value per ordinary share after giving effect to the additional proceeds we will receive from this offering, from the assumed initial public offering price of US$ per ordinary share, which is the midpoint of the estimated initial public offering price range set forth on the front cover of this prospectus adjusted to reflect the ADS-to-ordinary share ratio, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Because the Class A ordinary shares and Class B ordinary shares have the same dividend and other rights, except for voting and conversion rights, the dilution is presented based on all issued and outstanding ordinary shares, including Class A ordinary shares and Class B ordinary shares.

Without taking into account any other changes in pro forma net tangible book value after December 31, 2022, other than to give effect to our sale of the ADSs offered in this offering at the assumed initial public offering price of US$ per ADS, which is the midpoint of the estimated initial public offering price range, after deduction of the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2022 would have been US$, or US$ per ordinary share and US$ per ADS. This represents an immediate increase in net tangible book value of US$ per ordinary share and US$ per ADS to the existing shareholders and an immediate dilution in net tangible book value of US$ per ordinary share and US$ per ADS to investors purchasing ADSs in this offering. The following table illustrates such dilution:

	Per Ordinary Share	Per ADS
Assumed initial public offering price	US$	US$
Net tangible book value as of December 31, 2022	US$	US$
Pro forma net tangible book value after giving effect to the conversion of our preferred shares	US$	US$
Pro forma as adjusted net tangible book value after giving effect to the conversion of our preferred shares and this offering	US$	US$
Amount of dilution in net tangible book value to new investors in this offering	US$	US$

A US$1.00 increase (decrease) in the assumed initial public offering price of US$ per ADS would increase (decrease) our pro forma as adjusted net tangible book value after giving effect to this offering by US$, the pro forma as adjusted net tangible book value per ordinary share and per ADS after giving effect to this offering by US$ per ordinary share and US$ per ADS, and the dilution in pro forma as adjusted net tangible book value per ordinary share and per ADS to new investors in this offering by US$ per ordinary share and US$ per ADS, assuming no change to the number of ADSs offered by us as set forth on the front cover of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, on a pro forma as adjusted basis as of December 31, 2022, the differences between existing shareholders and the new investors with respect to the number of ordinary shares (in the form of ADSs or shares) purchased from us, the total consideration paid and the average price per ordinary share and per ADS paid before deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The total number of ordinary shares does not include Class A ordinary shares underlying the ADSs issuable upon the exercise of the over-allot option granted to the underwriters.

	Ordinary shares purchased		Total consideration		Average price per ordinary share	Average price per ADS
	Number	Percent	Amount	Percent		
Existing shareholders			US$			
New investors			US$			
Total			US$			

The pro forma as adjusted information discussed above is illustrative only. Our net tangible book value following the completion of this offering is subject to adjustment based on the actual initial public offering price of the ADSs and other terms of this offering determined at pricing.

The discussion and table above assume no exercise of any share options outstanding as of the date of this prospectus. [As of the date of this prospectus, there are outstanding options with an average exercise price of US$ per share. To the extent that any of these options are exercised, there will be further dilution to new investors.]

CORPORATE HISTORY AND STRUCTURE

Our corporate history

We are a global clinical-stage biotechnology company focused on the discovery and development of innovative cancer therapies for patients across the spectrum of tumor types.

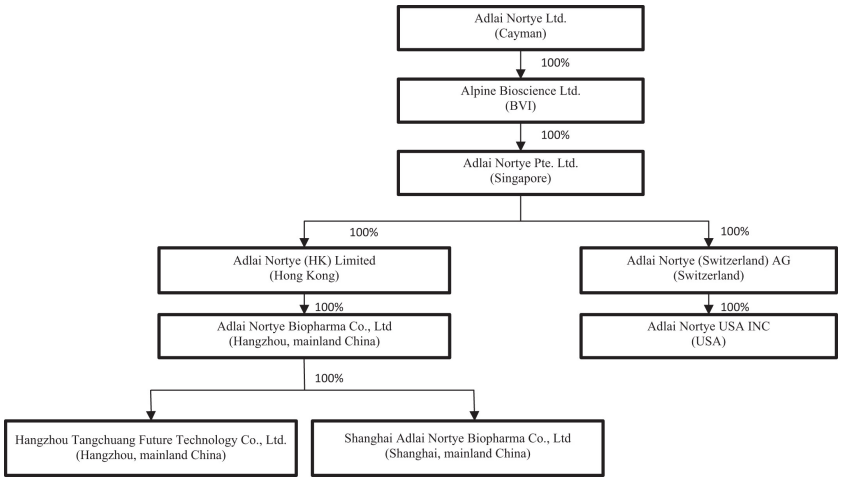
We commenced our business in mainland China in 2004 through Adlai Nortye Biopharma Co., Ltd., which we refer to as our operating subsidiary in the PRC. We initially focused primarily on generic pharmaceuticals and polypeptide intermediate, until 2016 when our founders, Mr. Yang Lu and Mr. Donghui Yang, led our strategic transition to become a R&D-driven pharmaceutical company, focusing on the discovery and development of innovative cancer therapies.

Our ultimate holding company was incorporated in the Cayman Islands in May 2018 to facilitate offshore financing activities, and our daily operations are conducted primarily through our operating subsidiaries in the United States and mainland China. Between January 2018 and June 2022, Alpine Bioscience Ltd., Adlai Nortye Pte. Ltd., Adlai Nortye (HK) Limited, and Adlai Nortye (Switzerland) AG were incorporated in the British Virgin Islands, Singapore, Hong Kong, and Switzerland as our intermediary holding entities. In March 2019, Adlai Nortye (HK) Limited acquired entire equity interests in the Adlai Nortye Biopharma Co., Ltd. from its then shareholders and Adlai Nortye Biopharma Co., Ltd. became a wholly owned subsidiary of our ultimate holding company.

In order to conduct clinical trials in the U.S., Adlai Nortye USA INC was incorporated under the laws of the State of Delaware in the U.S. in January 2018. In June 2022, as a part of a reorganization, Adlai Nortye (Switzerland) AG acquired all its shares and Adlai Nortye USA INC become a wholly owned subsidiary of our ultimate holding company.

Our corporate structure

The chart below sets forth our corporate structure and identifies our subsidiaries and their subsidiaries, as of the date of this prospectus:



MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with "Summary Consolidated Financial and Operating Data," and our financial statements and the related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk factors" and "Cautionary note regarding forward-looking statements" sections of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a global clinical-stage biotechnology company focused on the discovery and development of innovative cancer therapies for patients across the spectrum of tumor types. Our mission is to transform deadly cancer into a chronic and eventually curable disease. We are now developing multiple innovative antitumor drug candidates by leveraging our deep knowledge in cancer biology, as well as significant global R&D and clinical execution capabilities. These drug candidates are currently undergoing clinical trials, and in many cases, in collaboration with multinational pharmaceutical companies, to fully realize their commercialization potential on a global scale. Our combination therapy strategy is directed towards systematically activating the immune system through a combination of multiple drugs, aiming to enhance the clinical benefit by achieving superior efficacy and safety while overcoming drug resistance.

We have identified seven drug candidates and have developed a robust pipeline of drug candidates. Currently, our pipeline includes three clinical-stage drug candidates, buparlisib (AN2025), palupiprant (AN0025), and AN4005, as well as four preclinical candidates. Our most advanced program is AN2025, a pan-phosphoinositide 3-kinase ("PI3K") inhibitor that is designed to act against solid tumors. We believe that AN2025, if approved, has the potential to be first-to-market, and is currently the only drug candidate in active Phase III clinical trial targeting recurrent or metastatic HNSCC patients after progression on prior anti-PD-1/PD-L1 therapy, potentially addressing a global unmet medical need. We are also collaborating with MSD International GmbH, or MSD, to evaluate AN0025, a small molecule prostaglandin E receptor 4 ("EP4") antagonist, in combination with Keytruda or pembrolizumab, in a Phase Ib clinical trial for five different types of advanced solid tumors after progression with anti-PD-1/PD-L1 therapy or standard of care treatment. In addition, a Phase I clinical trial has been initiated for a combination therapy consisting of AN2025, AN0025, and Tecentriq or atezolizumab targeting a variety of PIK3CA mutant solid tumors. AN4005, which is currently being studied in a Phase I clinical trial, is an internally discovered, oral small molecule PD-L1 inhibitor in development to induce and stabilize PD-L1 dimerization and thereby disrupt the interaction between PD-1 and PD-L1.

We have assembled a management team and a scientific advisory board with industry leaders and influential scientists, who provide international and strategic guidance to our R&D, business development, and operational teams. In addition to building our own R&D capabilities, we continue to seek and secure partnerships with leading multi-national pharmaceutical companies such as Eisai and Novartis to fully realize the potential of our pipeline programs. We believe our partnerships validate our clinical expertise and reflect belief in our ability to deliver on our development and commercialization capabilities across a versatile pipeline.

Since our inception, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials. We do not have any drug candidates approved for sale and have not generated any revenue from product sales. We have financed operations through a combination of equity financings and payments from our collaborators. We use the capital we have raised to fund operations and investing activities across research for technology creation, drug discovery and clinical development programs, infrastructure, creation of our portfolio of intellectual property, and administrative support.

Since our founding, we have incurred significant operating losses. Our net losses were US$64.7 million, US$56.7 million, and US$58.8 million for the years ended December 31, 2020, 2021, and 2022, respectively.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. In addition, we anticipate that our expenses will increase significantly in connection with our ongoing activities as we:

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our clinical trials for our drug candidates;
- initiate additional preclinical studies or clinical or other trials for our drug candidates, including under our collaboration agreements;
- continue to invest in our R&D platforms to conduct research to identify novel technologies;
- add additional infrastructure to our quality control, quality assurance, legal, compliance and other groups to support our operations as we progress our drug candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts, including expansion of sites in the United States and Europe;
- seek marketing approvals and reimbursement for our drug candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional drug candidates;
- acquire or in-license other drug candidates and technologies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We do not expect to generate revenue from the sale of our drug candidates unless and until we successfully complete clinical development and obtain regulatory approval for such drug candidates. If we seek to obtain regulatory approval for any of our drug candidates, we expect to incur significant commercialization expenses.

As a result, we will need substantial additional funding to support our continued operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings, government funding arrangements, collaborations and marketing, or distribution and licensing arrangements. We may be unable to raise additional funds or enter into such other arrangements on favorable terms, or at all. If we fail to raise capital or enter into such arrangements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our programs.

Because of the numerous risks and uncertainties associated with pharmaceutical development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our products, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Key components of our results of operations

Revenue

To date, we have not generated any revenue from product sales. In 2021, our revenue of US$45.7 million consisted of the revenue from the sale of intellectual property pursuant to the collaboration agreement with Biotime. Revenue was recognized when we sold the rights to the intellectual property and after there was no future performance obligation to be performed. For more details, see “Business — License and collaboration agreements — Collaboration with Biotime.” Our ability to generate product revenue and to become profitable will depend upon our ability to successfully develop, obtain regulatory approval and commercialize our drug

candidates. Because of the numerous risks and uncertainties associated with product development and regulatory approval, we are unable to predict the amount, timing or ability to obtain product revenue.

Administrative expenses

Administrative expenses primarily include payroll, share-based compensation expenses, and other related expenses for employees involved in general corporate functions including finance, legal and human resources, rental and depreciation expenses related to facilities and equipment used by these functions, professional service expenses and other general corporate related expenses.

We expect our administrative expenses to increase in the future to support our continued research and development activities and, if any of our drug candidates receive marketing approval, commercialization activities. We also anticipate increased expenses related to professional fees, including audit, legal, regulatory and tax-related services, associated with maintaining compliance with Nasdaq listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

Research and development expenses

Research and development expenses consist primarily of costs incurred in connection with our research activities and include: (i) cost of personnel engaged in research and development activities, including salaries, benefits and share-based compensation expenses, if any; (ii) costs of funding research performed by third parties including laboratory, CRO, and other investigator and vendor expenses related to the execution of preclinical and clinical trials; (iii) costs related to production of preclinical and clinical materials; (iv) licensing fees for maintaining licenses under our third-party licensing agreements; (v) facility costs including rent, depreciation and maintenance expense; and (vi) expenses related to regulatory activities, including filing fees paid to regulatory agencies.

Research and development costs are expensed as incurred. Costs for certain activities, such as manufacturing and preclinical studies and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and investigators.

Research and development activities are central to our business model. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase over the next several years as our existing clinical programs progress and as we seek to initiate clinical trials of additional drug candidates. We also expect to incur increased research and development expenses as we selectively identify and develop additional drug candidates. However, it is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our drug candidates.

The duration, costs and timing of clinical trials and development of our drug candidates will depend on a variety of factors that include, but are not limited to, the following:

- successful enrollment in and completion of clinical trials;
- establishing an appropriate safety profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of marketing approvals from applicable regulatory authorities;
- commercializing the drug candidates, if approved, whether alone or in collaboration with others;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our drug candidates;
- continued acceptable safety profiles of products following approval; and
- retention of key research and development personnel.

A change in the outcome of any of these variables with respect to the development of any of our drug candidates would significantly change the costs, timing and viability associated with the development of that drug candidate.

Other income and gains

Other income and gains primarily consist of government subsidies that we receive from local government in the PRC.

Fair value changes on financial liabilities at FVTPL

Fair value changes on financial liabilities at FVTPL consists primarily of the non-cash items incurred in connection with changes in the fair value of our preferred share liabilities that we issued to certain investors.

Taxation

Cayman Islands and British Virgin Islands

Under the current laws of the Cayman Islands and the British Virgin Islands, the Company and its subsidiaries are not subject to tax on income or capital gains.

The United States

Under the current laws of the United States of America, the subsidiary which operates in the United States America is subject to federal tax at a rate of 21% and state tax at a rate of 9% in New Jersey.

Hong Kong

The subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the rate of 16.5% on any estimated assessable profits arising in Hong Kong during the period presented. The first HKD2,000 thousands of assessable profits of this subsidiary are taxed at 8.25% and the remaining assessable profits are taxed at 16.5%.

Mainland China

The provision for corporate income tax in Mainland China is based on a statutory rate of 25% of the assessable profits as determined in accordance with the PRC Corporate Income Tax Law which was approved and became effective on January 1, 2008. Certain other subsidiaries qualified as “High and New Technology Enterprise” and “Small and Medium-sized Technological Enterprises”, for details of their preferential tax treatments, see Note 6 to our consolidated financial statements for a detailed discussion.

Singapore

The subsidiary incorporated in Singapore is subject to Singapore corporate income tax effectively at the rate of 4.25%-17.00% on any estimated assessable profits arising in Singapore during the period presented. In the first three years since the establishment of the Singapore subsidiary, the first SGD100 of assessable profits of this subsidiary are taxed at an effective tax rate of 4.25% and the next SGD100 of assessable profits are taxed at an effective tax rate of 8.5%, and the remaining assessable profits are taxed at 17%.

Switzerland

The subsidiary incorporated in Switzerland is subject to a total corporate income tax rate of 11.9%, including 8.5% federal, and Zug cantonal and communal tax, during the Relevant Periods on the estimated assessable profits of the Swiss subsidiary. If the main business is operated in other cantons, the total corporate income tax, including federal, cantonal, and communal tax, could be up to 21.6%.

Results of operations

The following table summarizes key components of our results of operations for the years indicated:

	For the Year Ended December 31,		
	2020	2021	2022
	US$	US$	US$
		(in thousands)	
Revenue	—	45,726	—
Other operating income, net	50	183	259
Administrative expenses	(6,524)	(12,450)	(13,039)
Research and development expenses	(21,146)	(42,105)	(54,490)
Total operating loss	**(27,620)**	**(8,646)**	**(67,270)**
Other income and gains	559	213	2,079
Other expenses	(69)	(70)	(1,395)
Investment income	18	32	550
Fair value gain on financial assets at FVTPL	—	40	484
Fair value (loss)/gain on financial liabilities at FVTPL	(35,839)	(46,910)	7,195
Finance costs	(1,797)	(1,337)	(433)
Loss before tax	**(64,748)**	**(56,678)**	**(58,790)**
Income tax expense	—	—	—
Loss for the year	**(64,748)**	**(56,678)**	**(58,790)**
Attributable to:			
Ordinary equity holders of the parent	(64,748)	(56,678)	(58,790)

Comparison of twelve months ended December 31, 2022 and 2021

Revenue

We did not generate any revenue in 2022.

Administrative expenses

Our administrative expenses increased by 4.7%, from US$12.5 million in 2021 to US$13.0 million in 2022, primarily attributable to (i) an increase in employee compensation due to an increase in the number of employees and (ii) an increase in share-based compensation expenses from additional options granted to new employees in 2022.

Research and development expenses

Our research and development expenses increased by 29.4%, from US$42.1 million in 2021 to US$54.5 million in 2022. This increase was primarily due to (i) an increase in payroll and other related costs of personnel, primarily due to increased share-based compensation and expansion of the R&D staff; (ii) an increase in the CRO service fees as we advanced some of our existing drug candidates into more advanced clinical development stages; and (iii) an increase in the cost of materials and consumables used for our discovery projects and preclinical studies.

Other income and gains

Our other income and gains increased significantly, from US$0.2 million in 2021 to US$2.1 million in 2022, primarily due to additional government grants received in 2022.

Fair value changes on financial liabilities at FVTPL

We had fair value loss on financial liabilities at FVTPL of US$46.9 million in 2021 and fair value gain on financial liabilities at FVTPL of US$7.2 million in 2022. This change was primarily due to the increased likelihood of the shares being listed publicly, which reduced the liquidation value.

Finance costs

Our finance costs decreased by 67.6% from US$1.3 million in 2021 to US$0.4 million in 2022, primarily due to a decrease of private financing related expenses.

Loss for the year

For the reasons described above, our loss for the year increased by 3.7%, from US$56.7 million in 2021 to US$58.8 million in 2022.

Comparison of twelve months ended December 31, 2021 and 2020

Revenue

We generated revenue of US$45.7 million in 2021 due to the sale of intellectual property pursuant to the collaboration agreement with Biotime. For more details, see "Business — License and collaboration agreements — Collaboration with Biotime." No revenue was generated in 2020.

Administrative expenses

Our administrative expenses increased by 90.8%, from US$6.5 million in 2020 to US$12.5 million in 2021, primarily attributable to (i) an increase in employee compensation due to an increase in average payroll and an increase in the number of employees; (ii) an increase in the share-based compensation expenses from additional options granted to certain employees in 2021; and (iii) an increase in professional service fees in relation to accounting and legal services.

Research and development expenses

Our research and development expenses increased significantly from US$21.1 million in 2020 to US$42.1 million in 2021. This increase was primarily due to (i) an increase in licensing fees as our drug candidates further advance into later clinical trial phases; (ii) an increase in payroll and other related costs of personnel primarily due to increased share-based compensation and expansion of R&D staff; (iii) an increase in the CRO service fees as we initiated a few more research and development programs and advanced some of our existing investigational drugs into more advanced clinical development stages; and (iv) an increase in cost of materials and consumables used for our preclinical studies and clinical trials.

Other income and gains

Our other income and gains decreased by 61.9%, from US$0.6 million in 2020 to US$0.2 million in 2021, primarily due to the cessation of COVID-19 related government grants in 2021.

Fair value changes on financial liabilities at FVTPL

Our fair value loss on financial liabilities at FVTPL increased by 30.9%, from US$35.8 million in 2020 to US$46.9 million in 2021. This increase was primarily attributable to the change in fair value of preferred shares due to the increase in the valuation of our company.

Finance costs

Our finance costs decreased by 25.6% from US$1.8 million in 2020 to US$1.3 million in 2021, primarily due to a decrease in transaction costs for issuance of convertible redeemable preferred shares.

Loss for the year

For the reasons described above, our loss for the year decreased by 12.5%, from US$64.7 million in 2020 to US$56.7 million in 2021.

Liquidity and capital resources

Since inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development activities and administrative costs associated with our operations. We incurred net loss of US$64.7 million, US$56.7 million, and US$58.8 million in 2020, 2021, and 2022, respectively. We used US$32.9 million, US$3.0 million, and US$43.2 million in cash for our operating activities in 2020, 2021, and 2022, respectively. Historically, we have financed our operations primarily through proceeds from the issuance and sale of preferred shares, warrants in private placement translation, and bank borrowings. For more information of our equity financing, see "Description of Share Capital — History of share capital."

Currently, our primary source of liquidity are cash and cash equivalents and financial assets at FVTPL. As of December 31, 2022, we had US$42.8 million in cash and cash equivalents and US$21.3 million in financial assets at FVTPL. Our cash and cash equivalents consist primarily of bank deposits. Our financial assets at FVTPL represent the wealth management products purchased from commercial banks in the PRC and Hong Kong, and they are with low investment risk or value fluctuation and can be redeemed within 3 months when liquidity needs arise.

Based on our current operating plan, we believe that our current cash and cash equivalents and proceeds from this offering will be sufficient to meet our current and anticipated working capital requirements and capital expenditures for at least the next 12 months. In that time, we expect that our expenses will increase substantially as we fund new and ongoing research and development activities and working capital needs. The assumptions on which our estimates are based may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our drug candidates.

The following table sets forth a summary of our cash flows for the years presented:

	For the Year Ended December 31,		
	2020	2021	2022
	US$	US$	US$
	(in thousands)		
Net cash used in operating activities	(32,851)	(3,034)	(43,223)
Net cash (used in)/generated from investing activities	(2,032)	(54,857)	28,376
Net cash from/(used in) financing activities	53,071	97,200	(6,780)
Net increase/(decrease) in cash and cash equivalents	**18,188**	**39,309**	**(21,627)**
Cash and cash equivalents at the beginning of the year	6,006	24,261	64,131
Effect of foreign exchange rate changes, net	67	561	254
Cash and cash equivalents at the end of the year	**24,261**	**64,131**	**42,758**

Operating activities

In 2022, we had US$43.2 million net cash used in operating activities. The difference with US$58.8 million of loss before tax on accrual basis was mainly the result of adding back non-cash items such as US$6.1 million of equity-settled share-based payment expenses and US$1.1 million of depreciation of right-of-use assets. In 2022, US$15.2 million of cash was released from working capital mainly due to (i) our trade payables increasing by US$10.1 million as a result of certain drug candidates entered into more advanced clinical development stage and (ii) our prepayments, other receivables and other assets decreasing by US$4.3 million.

In 2021, we had US$3.0 million net cash used in operating activities. The difference with US$56.7 million of loss before tax on accrual basis was mainly the result of adding back non-cash items such as US$46.9 million of fair value loss on financial liabilities at FVTPL and US$3.4 million of equity-settled share-based payment expenses. In 2021, US$0.3 million of cash was released from working capital.

In 2020, we had US$32.9 million net cash used in operating activities. The difference with US$64.7 million of loss before tax on accrual basis was mainly the result of adding back non-cash items such as US$35.8 million of fair value loss on financial liabilities at FVTPL and US$2.3 million of equity-settled share-based payment expenses. In addition, a total of US$9.5 million of cash was used in working capital mainly as (i) our prepayments, other receivables and other assets decreased by US$3.8 million due to the reduced prepayments for CRO service fees; (ii) our trade payables increased by US$3.3 million due to trade payables of licensing fee; and (iii) other payables and accruals increased by US$2.2 million.

Investing activities

In 2022, our net cash generated from investing activities was US$28.3 million, primarily as a result of disposal of financial assets at FVTPL.

In 2021, our net cash used in investing activities was US$54.9 million, primarily as a result of purchase of financial assets at FVTPL of US$81.2 million, partially offset by disposal of financial assets at FVTPL of US$27.5 million.

In 2020, our net cash used in investing activities was US$2.0 million, primarily as a result of purchase of property, plant and equipment of US$1.8 million.

Financing activities

In 2022, our net cash used in financing activities was US$6.8 million, primarily due to repayment of bank and other borrowings of US$13.3 million, partially offset by the addition of bank and other borrowings of US$7.9 million.

In 2021, our net cash generated from financing activities was US$97.2 million, primarily due to (i) US$97.4 million of proceeds from issuance of financial instruments and (ii) US$12.4 million of addition of bank and other borrowings, partially offset by US$10.4 million repayment of bank and other borrowings.

In 2020, our net cash generated from financing activities was US$53.1 million, primarily due to (i) US$58.7 million of proceeds from issuance of financial instruments and (ii) US$12.9 million of addition of bank and other borrowings, partially offset by US$15.5 million repayment of bank and other borrowings.

Operating capital requirements

We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our drug candidates, which we expect will take a number of years. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements.

However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing shareholders, including investors in this offering, will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our shareholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or to grant licenses on terms that may not be favorable to us. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the timing, receipt and amount of sales of any future approved or cleared products, if any;
- the scope, progress, results and costs of researching and developing our existing drug candidates or any future drug candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals or clearances for our existing drug candidates or any future drug candidates;
- the time and costs involved in obtaining regulatory approval for our drug candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these drug candidates;
- the number and characteristics of any additional drug candidates we develop or acquire;
- the cost of manufacturing our drug candidates and any products we successfully commercialize, including costs associated with developing our manufacturing capabilities;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other drug candidates or technologies;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the expenses needed to attract and retain skilled personnel and senior management; and
- the costs associated with being a public company.

Furthermore, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Capital expenditures

We made capital expenditures of US$1.8 million, US$1.1 million, and US$1.2 million in 2020, 2021, and 2022, respectively. Our capital expenditures were primarily for the purchase of property, plant and equipment and the purchase of intangible assets.

Contractual obligations and commitments

The following table sets forth material cash requirements from our contractual obligations as of December 31, 2022:

	Less than 1 year	1 to 3 years	3 to 5 years	Total
	(in thousands)			
Lease liabilities	$1,001	$1,236	$ —	$2,237

Off-balance sheet commitments and arrangements

We have not entered into any financial guarantees or other commitments to guarantee the payment obligations of any unconsolidated third parties. In addition, we have not entered into any derivative contracts that are indexed to our shares and classified as shareholders' equity or that are not reflected in our consolidated financial statements. Furthermore, we do not have any retained or contingent interest in assets transferred to an unconsolidated entity that serves as credit, liquidity, or market risk support to such entity. Moreover, we do

not have any variable interest in any unconsolidated entity that provides financing, liquidity, market risk or credit support to us or engages in leasing, hedging or product development services with us.

Quantitative and qualitative disclosures about market risk

Market risk is the risk that the fair value of, or future cash flows from, a financial instrument will vary due to changes in market prices. The type of market risk that primarily impacts us is foreign currency risk.

Foreign currency risk

We are subject to currency risk as our income and expenditures are denominated in U.S. dollar and Renminbi. As such, we are exposed to exchange rate fluctuations between these currencies. We currently plan to utilize our financial resources denominated in Renminbi to fund our expenditure in China, and we do not hedge this exposure. If we increase our operation in China, especially if we roll out additional clinical trials in China, we expect to have significant increases in expenses denominated in Renminbi, while we would expect our near-term revenue, after the commercialization of our product candidates, and the proceeds from our financial activities to remain denominated in U.S dollars.

We prepare and publish our consolidated financial statements in U.S dollars. Revenue and expenses incurred in Renminbi will be translated into U.S. dollars when they are reported in our consolidated financial statements. As a result, any substantial future appreciation or decline of the Renminbi against U.S. dollar could have a material effect on our financial performance. For example, CNY/USD has fluctuated from 6.3561 at the beginning of 2022 to 6.8675 as of the date of this prospectus. Assuming Renminbi weakens by 10% against U.S. dollar, our cash and cash equivalents as of December 31, 2022 would decrease by US$2.6 million, or 6.1%.

Liquidity risk

We monitor and maintain a level of cash and cash equivalents deemed adequate by the management to finance the operations and mitigate the effects of fluctuations in cash flows.

Internal control over financial reporting

Prior to this offering, we have been a private company with limited reporting and accounting personnel and other resources with which to address our internal control over financial reporting. In connection with the audits of our consolidated financial statements included in this prospectus, we and our independent registered public accounting firm identified material weaknesses. As defined in the standards established by the PCAOB, a “material weakness” is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Our internal control over financial reporting was not effective due to (i) inadequate segregation of duties and effective risk assessment; (ii) lack of personnel adequately trained in IFRS including income taxes; and (iii) insufficient written policies and procedures for accounting and financial reporting with respect to the requirements and application of both IFRS and SEC guidelines for reporting and compliance. Further, our internal controls over information technology general controls were not effective due to (i) lack of program change management controls, (ii) inadequate segregation of duties and effective risk assessment, (iii) and lack of computer operations controls to ensure that critical batch jobs are monitored and data backups are authorized and monitored. In addition, we identified numerous cutoff issues related to accrual accounting, resulting in us completing cutoff assessments across multiple accounts and over multiple years. We revised our accounting records after initial accounting records were received and provided multiple versions of trial balances and financial statements. These inefficiencies created rework and required incremental and unplanned audit time.

We are in the process of implementing a number of measures to address the material weaknesses and deficiencies that have been identified including: (i) hiring additional accounting and financial reporting personnel with IFRS and SEC reporting experience, (ii) expanding the capabilities of existing accounting and financial reporting personnel through continuous training and education in the accounting and reporting

requirements under IFRS, and SEC rules and regulations, (iii) developing, communicating and implementing an accounting policy manual for our accounting and financial reporting personnel for recurring transactions and period-end closing processes, (iv) establishing effective monitoring and oversight controls for non-recurring and complex transactions to ensure the accuracy and completeness of our company's consolidated financial statements and related disclosures, and (v) implementing additional IT control procedures including those to ensure proper system access.

The process of designing and implementing an effective financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to devote significant resources to maintain a financial reporting system that is adequate to satisfy our reporting obligation. However, we cannot assure you that all these measures will be sufficient to remediate our material weakness in a timely manner, or at all. See "Risk Factors — Risks related to our business — If we fail to implement and maintain an effective system of internal controls to remediate our material weaknesses over financial reporting, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud, and investor confidence in our company and the market price of the ADSs may be materially and adversely affected."

Change in auditor

We engaged Ernst & Young, or E&Y, in December 2018 to audit our consolidated financial statements for the two years ended December 31, 2019 and 2020 and the five months ended May 31, 2020 and 2021, to facilitate our previous attempt to access the Hong Kong capital market. We dismissed E&Y in June 2022.

As part of our new plan to seek an initial public offering in the United States, in August 2022, we engaged Mazars USA LLP, or Mazars, which is located in the United States and can be subject to inspection by the PCAOB, as our independent auditor to audit our consolidated financial statements for the three years ended December 31, 2020, 2021, and 2022. The change of independent auditor was approved by our board of directors.

We and E&Y agreed on a draft report relating to the financial statements for the two years ended December 31, 2019 and 2020 and the five months ended May 31, 2020 and 2021, which does not contain an adverse opinion or a disclaimer of opinion, and is not qualified or modified as to uncertainty, audit scope, or accounting principles. This report however was not ultimately signed or delivered as we suspended our plan for the Hong Kong IPO. During E&Y's engagement and up to the interim period before E&Y's dismissal, there had been no disagreements between E&Y and us on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, and there had been no "reportable events" as defined under Item 16F(a)(1)(v) of Form 20-F that would require disclosure.

We provided a copy of this disclosure to E&Y, and requested it to furnish us with a letter addressed to the SEC stating whether it agrees with the above statements, and if not, stating the respects in which it does not agree. Although we sent the draft disclosure to E&Y, and requested E&Y to submit a letter addressed to the SEC confirming the above statement, as of the date of this submission, E&Y has neither prepared nor submitted a letter confirming or denying the above statement, and has not otherwise confirmed or denied the above statement.

During 2020, 2021, and 2022, and any subsequent interim period prior to the engagement of Mazars in August 2022, neither we nor any person on our behalf consulted with Mazars regarding either (i) the application of accounting principles to a specific completed or contemplated transaction, or the type of audit opinion that might be rendered on our financial statements and no written or oral advice provided by Mazars was an important factor considered by us in reaching a decision as to any accounting, auditing or financial reporting issue, or (ii) any matter that was the subject of a disagreement or reportable event as defined in the Form 20-F.

Critical accounting policies, judgments and estimates

Our consolidated financial statements are prepared in accordance with IFRS as issued by the IASB. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates and

assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates. Our most critical accounting policies are summarized below. See note 2.4 to our consolidated financial statements beginning on page F-1 of this prospectus for a description of our other significant accounting policies.

Research and development costs

All research costs are charged to expense as incurred. Expenditure incurred on projects to develop new products is capitalized and deferred only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and our ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Share-based payments

We operate a share option scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of our operations. Employees (including directors) receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments, or equity settled transactions.

The cost of equity-settled transactions with employees for grants is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using a binomial model, further details of which are given in note 19 of our consolidated financial statements included elsewhere in this prospectus.

The cost of equity-settled transactions is recognized in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognized for equity-settled transactions at the end of each of the relevant periods until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the statement of profit or loss and other comprehensive income for a period represents the movement in the cumulative expense recognized as at the beginning and end of that period. Service and non-market performance conditions are not considered when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of our best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

Fair value of financial liabilities measured at FVTPL

The fair value of the financial liabilities, including convertible redeemable preferred shares, convertible loans, forwards and warrants, are measured at FVTPL and determined using the valuation techniques, including the discounted cash flow method and the back-solve method. Such valuation requires us to make estimates of the key assumptions including the risk-free interest rate, discount for lack of marketability and volatility, which are subject to uncertainty and might materially differ from the actual results. Further details are included in note 15 of our consolidated financial statements included elsewhere in this prospectus.

Fair value of share-based payment

The fair value of the awarded shares is determined at the grant dates by the binomial option-pricing model. Significant estimates on assumptions, including the underlying equity value, discount rate, expected volatility, and dividend yield, are made by management. Further details are included in note 19 of our consolidated financial statements included elsewhere in this prospectus.

The preparation of the consolidated financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the reporting amounts of assets and liabilities, and disclosure

of contingent assets and liabilities, as of the date of the consolidated financial statements, and the reported amount of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the valuation and accounting for financial liabilities at FVTPL and equity awards.

Impairment of non-financial assets (other than goodwill)

We assess whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each of the relevant periods. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm's length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

Deferred tax assets

Deferred tax assets are recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgement is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and level of future taxable profits together with future tax planning strategies. Further details are contained in note 6 of our consolidated financial statements included elsewhere in this prospectus.

Leases — estimating the incremental borrowing rate

The Group cannot readily determine the interest rate implicit in a lease; therefore, it uses an incremental borrowing rate, or IBR, to measure lease liabilities. The IBR is the rate of interest that we would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what the Group "would have to pay", which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when it needs to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary's functional currency). The Group estimates the IBR using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates (such as the subsidiary's stand-alone credit rating).

Recent accounting pronouncements

A list of recently issued accounting pronouncements that are relevant to us is included in note 2.2 of our consolidated financial statements included elsewhere in this prospectus.

BUSINESS

Overview

We are a global clinical-stage biotechnology company focused on the discovery and development of innovative cancer therapies for patients across the spectrum of tumor types. Our mission is to transform deadly cancer into a chronic and eventually curable disease. We are now developing multiple innovative antitumor drug candidates by leveraging our deep knowledge in cancer biology, as well as significant global R&D and clinical execution capabilities. These drug candidates are currently undergoing clinical trials, and in many cases, in collaboration with multinational pharmaceutical companies to fully realize their commercialization potential on a global scale. Our combination therapy strategy is directed towards systematically activating the immune system through a combination of multiple drugs, aiming to enhance the clinical benefit by achieving superior efficacy and safety while overcoming drug resistance.

We have identified seven drug candidates and have developed a robust pipeline of drug candidates. Currently, our pipeline includes three clinical-stage drug candidates, buparlisib (AN2025), palupiprant (AN0025), and AN4005, as well as four preclinical candidates. Our most advanced program is our lead product AN2025, a pan-phosphoinositide 3-kinase ("PI3K") inhibitor that is designed to act against solid tumors. AN2025 is currently undergoing a Phase III, multi-regional, randomized, open-label clinical trial for the treatment of recurrent or metastatic HNSCC after anti-programmed death-1 ("PD-1") or its ligand ("PD-L1") treatment in more than 180 sites in 18 jurisdictions covering North America, Europe, Asia, and South America. We believe that AN2025, if approved, has the potential to be first-to-market, and is currently the only drug candidate in active Phase III clinical trial targeting recurrent or metastatic HNSCC patients after progression on prior anti-PD-1/PD-L1 therapy, potentially addressing a global unmet medical need.

We are collaborating with MSD International GmbH, or MSD, to evaluate AN0025, a small molecule prostaglandin E receptor 4 ("EP4") antagonist. It is currently being developed to modulate the tumor microenvironment in combination with Keytruda or pembrolizumab, in a Phase Ib clinical trial for the treatment of recurrent non-small cell lung cancer ("NSCLC") and urothelial cancer after anti-PD-1/PD-L1 treatments, recurrent triple-negative breast cancer ("TNBC"), microsatellite stable colorectal cancer ("MSS CRC") and cervical cancer after standard of care treatments in the U.S. and France. In addition, a Phase I clinical trial has been initiated for a combination therapy consisting of AN2025, AN0025, and Tecentriq or atezolizumab targeting a variety of PIK3CA mutant solid tumors. This triple combination is expected to target the PI3K mediated tumorigenesis while inhibiting the immunosuppressive tumor microenvironment through multiple non-overlapping mechanisms, leading to synergistic action for tumor regression. AN4005, which is currently being studied in a Phase I clinical trial in the U.S. and China, is an internally discovered oral small molecule PD-L1 inhibitor in development to induce and stabilize PD-L1 dimerization and thereby disrupt the interaction between PD-1 and PD-L1.

Additionally, we continue to advance four in-house preclinical programs which we believe have high global commercial viability. We are performing investigational new drug ("IND") enabling studies for AN3025, an immune-stimulatory anti-tumor necrosis factor receptor 2 ("TNFR2") antibody, with a goal to submit an IND application in the second half of 2023. Our earlier preclinical candidates are: AN8025, a multifunctional antibody as T cell and antigen-presenting cell ("APC") modulator; AN1025, an oral small molecule degrader of β-catenin; and AN6025, an oral small molecule hematopoietic progenitor kinase 1 ("HPK1") inhibitor. We anticipate submitting the IND for AN8025 in the first half of 2024.

We believe the next frontier in cancer immunotherapy lies in the category of combination therapies. Our drug candidates combine an immune checkpoint inhibitor with two or more additional cancer therapies in effort to elicit synergistic anti-cancer effects and improved tolerability relative to monotherapies. As we endeavor to engender complementary and synergistic results across our portfolio, our primary consideration is the potential interaction with our other pipeline candidates and/or currently available treatments. We strive to develop innovative antitumor candidates focusing on druggability as well as combinational strength to be leveraged in the next wave of immuno-oncology treatments, ultimately helping to shape the next-generation of cancer therapy.

Through our multi-national R&D centers established in New Jersey and Hangzhou, we execute on our global vision for drug development innovation. The geographic span of our R&D footprint empowers us to

more effectively identify and develop novel early-stage programs, as well as recruit top R&D talent from the U.S. and China. We have assembled a management team and a scientific advisory board with industry leaders and influential scientists, who provide international and strategic guidance to our R&D, business development and operational teams. In addition to building our own R&D capabilities, we continue to seek and secure partnerships with leading multi-national pharmaceutical companies such as Eisai Co., Ltd. or Eisai and Novartis Pharma AG or Novartis, to fully realize the potential of our pipeline programs. We believe our partnerships validate our clinical expertise and reflect belief in our ability to deliver on our development and commercialization capabilities across a versatile pipeline.

Our pipeline

We are advancing a robust pipeline of innovative drug candidates in various stages of development. The following chart provides an overview of the status of our drug candidates:

Abbreviations: MOA = Mechanism of Action; NDA = New Drug Application; TNBC = Triple Negative Breast Cancer; NSCLC = Non-Small Cell Lung Cancer; MSS CRC = Microsatellite Stable Colorectal Cancer; RP2D = Recommended Phase 2 Dose; IND: Investigational New Drug; PCC: Preclinical Candidate; POC: Proof of Concept.

AN2025: a pan-PI3K inhibitor aimed at becoming the vanguard for recurrent or metastatic HNSCC after anti-PD-1/PD-L1 therapy

Our lead product AN2025, the most clinically advanced drug candidate in our pipeline, is a pan-PI3K inhibitor currently undergoing a global Phase III trial. In-licensed from Novartis, we have the exclusive global rights to develop and commercialize AN2025. It is currently the only drug candidate we are aware of in active registrational clinical trial for the treatment of recurrent or metastatic HNSCC after disease progression with anti-PD-1/PD-L1 therapy. Although anti-PD-1/PD-L1 therapy is becoming first line treatment in patients with recurrent or metastatic HNSCC since its U.S. Food and Drug Administration ("FDA") approval in 2019, the current treatments are unable to meet the needs of HNSCC patients progressed on prior anti-PD-1/PD-L1 treatment. We believe that AN2025, if approved, has potential to be the first product globally with such label to address this unmet medical need and capture the sizable addressable market.

AN2025 is a widely studied molecule with Novartis alone having sponsored 40 clinical trials on over 4,200 patients across a variety of cancers. These studies include a Phase II trial that demonstrated that the combination of AN2025 with paclitaxel achieved a superior median overall survival ("mOS"), and significant improvements in median progression-free survival ("mPFS") and overall response rate ("ORR") compared to the control group in recurrent or metastatic HNSCC after disease progression with platinum based chemotherapy. In July 2016, AN2025 was granted Fast Track designation by the FDA for the treatment of recurrent or metastatic HNSCC with disease progression on or after platinum-based therapy. For the Phase III trial, we expect to enroll 483 patients in more than 180 sites around the world, spanning over 18 markets in North America, Europe, Asia, and South America. Leveraging the benefit of using ORR data from the planned Phase III interim analysis, we expect to submit the NDA to the FDA seeking a potential accelerated approval in the first half of 2024, followed by further marketing approval applications to National Medical

Products Administration ("NMPA"), European Medicines Agency ("EMA"), Pharmaceuticals and Medical Devices Agency ("PMDA") and other authorities.

AN0025: a tumor microenvironment modulator

AN0025, in-licensed from Eisai, is a small molecule EP4 antagonist designed to modulate the tumor microenvironment. It is designed to block the prostaglandin E2 ("PGE2")-EP4 signaling pathway to inhibit PGE2-mediated immunosuppression in cancer patients. In the CT26 murine colon cancer model, for those which are not responsive to anti-PD-1/PD-L1 therapy, AN0025 combined with an anti-PD-1 antibody treatment demonstrated stronger antitumor activity compared to each standalone compound. In June 2020, we initiated a Phase Ib clinical trial to evaluate the combination of AN0025 and pembrolizumab for the treatment of recurrent NSCLC and urothelial cancer after anti-PD-1/PD-L1 treatments, as well as recurrent TNBC, MSS CRC and cervical cancer after standard of care treatments. As of December 31, 2022, we were in the dose expansion stage having enrolled 54 patients in the U.S. and France, and expect to obtain top-line results in the second half of 2023. We aim to identify specific cancer types sensitive to this combination based on the results and will proactively communicate with the regulatory authorities for the design of Phase II/III registrational trials.

Triple combination of AN2025, AN0025 and atezolizumab: an example of our combination therapy strategy

To fully explore the potential of AN2025 and AN0025, we initiated a study of the triple combination of AN2025, AN0025 and atezolizumab, an anti-PD-L1 antibody. This study exemplifies our combination therapy strategy to achieve synergistic effects from both targeted therapy and immunotherapy perspectives. AN2025 targets not only PI3K mediated tumorigenesis (e.g., via inhibition of PI3Kα / PIK3CA mutants) but also the immunosuppression of the tumor microenvironment (e.g., via inhibition of PI3Kδ and PI3Kγ). Leveraging the complementary and synergistic antitumor effects of our drug candidates in combination therapies, AN2025 is designed to mechanistically complement and synergize with the combination of anti-PD-1/PD-L1 antibody and AN0025 to form an improved treatment regimen for patients with multiple advanced solid tumors. In different tumor-bearing mouse models, we have consistently observed significantly stronger antitumor activity in the triple combination of AN2025, AN0025 and atezolizumab compared with the doublet combinations. In July 2021, we initiated a Phase I clinical trial to evaluate the triple combination of AN2025, AN0025, and atezolizumab, for a variety of PIK3CA mutant solid tumors. In September 2022, subsequent to the doublet arm dose-ranging studies, we initiated a dose-ranging study for the triple combination, and we expect to identify the recommended Phase II dose ("RP2D") in the second quarter of 2023.

AN4005: a backbone of our future oral combination therapies

AN4005, a drug candidate discovered in-house, is an oral small-molecule PD-L1 inhibitor designed to induce and stabilize PD-L1 dimerization and thereby disrupt the interaction between PD-1 and PD-L1. Compared to the crowded development of anti-PD-1/PD-L1 antibodies, with multiple brands already available to patients and many potential candidates in clinical trials, small-molecule PD-L1 inhibitors are underdeveloped and do not have a drug approved in any jurisdiction globally, despite advantages such as shorter half-life that may allow for dose titration and schedule modifications to minimize immune-related AEs and lower production costs. In our preclinical studies, AN4005 was well tolerated and exhibited excellent tumor growth inhibition ("TGI") to an extent comparable to an approved anti-PD-L1 antibody, and promoted an adaptive immune response for antitumor activities. We received allowance to proceed under INDs from the FDA and NMPA for the treatment of advanced tumors in June 2021 and December 2021, respectively, dosed the first patient in January 2022, and expect to identify the RP2D from the Phase I clinical trial in the second half of 2023.

Our preclinical programs

We continue actively advancing four in-house preclinical programs which we believe have high global commercial viability. We are performing IND enabling studies for AN3025, an immune-stimulatory anti-TNFR2 antibody and aim to submit the IND in the second half of 2023. Our earlier preclinical candidates are: AN8025, a multifunctional antibody as T cell and APC modulator; AN1025, an oral small molecule

degrader of β-catenin; and AN6025, an oral small molecule HPK1 inhibitor. We anticipate submitting the IND for AN8025 in the first half of 2024.

Our company history and team

We rebranded in 2016 as Adlai Nortye Biopharma and began development activities focusing on the discovery and development of innovative cancer therapies, after originally incorporating in 2004. We have assembled an experienced management team consisting of successful entrepreneurs and industry veterans. Largely, our success stems from management's leadership and industry expertise, covering the full spectrum of the cancer therapy development process, from design and execution of preclinical and clinical studies through the regulatory process and commercialization.

Our management team has more than 100 cumulative years of industry experience and a proven track record of innovative drug R&D, clinical development and commercialization. Our founder, chief executive officer, and chairman of our board of directors, Mr. Yang Lu is a successful entrepreneur who brings expertise across the domains of business development, operations, and management. Our president, chief medical officer and chief executive officer of our U.S. subsidiary, Dr. Lars Erik Birgerson, has extensive experience as a senior leader with numerous well-known companies in the biopharmaceutical industry, including Roche Pharmaceuticals, Genentech, and Bristol-Myers Squibb ("BMS"). Our senior vice president and global head of clinical operations, Dr. Kaiyang Tang, has deep experience in global clinical operations and regulatory affairs in the pharmaceutical industry, and has served as a clinical leader in a number of companies, including Generon (Shanghai) Corporation Ltd. and Hutchison MediPharma Ltd, a company triple listed on the Nasdaq, Hong Kong Stock Exchange, and Alternative Investment Market. Our senior vice president and global head of regulatory affairs, Dr. Victoria Elizabeth Demby has over 20 years of industry experience and has served in various senior positions for several multinational pharmaceutical companies such as GSK, MSD, and BMS.

Since our inception, we have received strong support from our shareholders, including financial investors as well as several industry-leading strategic investors. This investor base is, and we expect will continue to be, aligned with our vision and strategy going forward.

Our strengths

We believe our competitive advantage is underpinned by the following competitive strengths:

- ***Multi-modality pipeline with several innovative drug candidates targeting a range of tumor indications.*** We plan to continue to leverage our expertise in drug discovery and our proficiency in executing promising collaborations and partnerships to bring innovative drugs to patients across the cancer type spectrum. Our candidates utilize a multitude of different mechanisms of action, enabling us to employ our assets on a standalone basis or in combination across tumor types and treatment combinations.
- ***Robust Phase II data laying a concrete foundation for potential registration.*** In a Phase II clinical trial of our lead asset, AN2025, for the treatment of recurrent or metastatic HNSCC on or after disease progression with platinum-based chemotherapy, the clinical data showed that the combination of AN2025 with paclitaxel achieved an mOS of over 10 months (vs. 6.5 months in the placebo plus paclitaxel group), an mPFS of 4.6 months (vs. 3.5 months in the placebo plus paclitaxel group), and a 39.2% ORR (vs. 13.9% in the placebo plus paclitaxel group). These data also showed that when AN2025 was combined with paclitaxel, grade 3-4 adverse events ("AEs") (82% in the AN2025 plus paclitaxel group vs. 72% in the placebo group), serious adverse events ("SAEs") (57% in the AN2025 plus paclitaxel group vs. 47% in the placebo group) or on-treatment deaths (20% in the AN2025 plus paclitaxel group vs. 22% in the placebo group) is comparable to paclitaxel alone. The most frequent SAEs for AN2025 plus paclitaxel combination were pneumonia (7.89% vs. 7.69% in the placebo group), and diarrhea (5.26% vs. 0.00% in the placebo group). The most frequent SAEs for AN2025 plus paclitaxel combination that occurred less in the placebo group were diarrhea (5.26% vs. 0.00%), hyperglycaemia (3.95% vs. 0.00%), and general physical health deterioration (3.95% vs. 0.00%). In addition, the Phase II clinical trial was designed to be a thoroughly placebo-controlled double-arm study, which provides us with further confidence in the success of the ongoing Phase III clinical trial.

- ***Targeting unmet medical need with large total addressable markets.*** AN2025 is designed to address globally urgent unmet medical demands for effective treatments of HNSCC after anti-PD-1/PD-L1 treatment. In seven major markets (the U.S., the U.K., Germany, France, Italy, Spain, and Japan), it is estimated that by 2028 there can be more than 50,000 recurrent or metastatic HNSCC patients experiencing progression after anti-PD-1/PD-L1 therapy. As the only drug candidate currently in Phase III clinical trial for the treatment of recurrent or metastatic HNSCC after anti-PD-1/PD-L1 therapy of which we are aware, we believe that AN2025, if approved, has potential to be the first product globally to address this unmet need and capture the sizable addressable market.
- ***Strong R&D capabilities.*** Spanning the full spectrum from target identification to clinical development, our in-house drug discovery platforms deploy a suite of powerful and specialized techniques. They consist of two platforms, PAINT-2D™ and ANEAT-Id™. PAINT-2D™ provides us with a "one-stop" function for early-stage development of immuno-oncology therapies. ANEAT-Id™ is a highly efficient and robust yeast display system dedicated to therapeutic antibody discovery and development.
- ***Sustainable patent portfolio in our key jurisdictions.*** As of December 31, 2022, we owned or had the exclusive rights to (i) 162 granted patents and 92 pending patent applications in jurisdictions such as the U.S., European Patent Office ("EPO"), mainland China, Japan, South Korea, Canada, Australia, Taiwan, Mexico and Brazil, and (ii) 11 patent applications under the Patent Cooperation Treaty, or PCT, that have not been nationalized. Granted patents and pending patent applications cover the key inventions for our pipeline candidates in clinical trials under IND, as well as our key technologies. Protection over potential approved use of core matters of AN2025 and AN0025 can expire in 2032 and 2036, respectively, both taking into account of the possible 5-year patent term extensions in jurisdictions where patent term extension is available, including but not limited to the U.S., Europe, China and Japan.
- ***Seasoned industry veterans and strong shareholder support.*** We believe our team, with a proven track record of innovative drug R&D, clinical development, and commercialization knowledge, as well as rich expertise in business development and operational execution, can successfully drive our drug candidates to approval and clinical use on a global scale. Additionally, we are supported by the strategic guidance of a visionary scientific advisory board with members from both academia and the pharmaceutical industry. We have also received continued support from our shareholders including financial investors and several industry-leading strategic investors.

Our vision & strategy

We strive to become a global leader in the next wave of immuno-oncology therapies employing a combination therapy strategy. Our mission is to transform deadly cancer into a chronic and eventually curable disease. We intend to execute the following strategies to achieve this goal:

- ***Advance the development of and pursue regulatory approval for our lead drug candidate AN2025.*** We have advanced AN2025, in combination with paclitaxel for the treatment of recurrent or metastatic HNSCC after anti-PD-1/PD-L1 therapy into a Phase III clinical trial. We expect to enroll 483 patients across 180 sites in North America, Europe, Asia, and South America, and to submit an NDA to the FDA for a potential accelerated approval as early as the first half of 2024 leveraging the ORR data from the Phase III interim analysis, followed by further marketing approval applications to the NMPA, EMA, PMDA and other authorities.
- ***Continue advancing pipeline products through in-house development and strategic partnerships to maximize value.*** As we evaluate assets, we place a strong emphasis on first-in-class potential, combinational synergies with our current pipeline or other available therapies, as well as global development and commercialization rights. We intend to continue to develop our novel drug candidates by leveraging our proprietary R&D platforms, our strong early and clinical stage drug discovery expertise, as well as through the support of our various global collaborators. We intend to continue building upon our existing partnership success, exploring new opportunities through strategic collaborations and potentially co-development arrangements, ultimately maximizing the clinical and commercial value of our drug candidates.

- ***Utilize manufacturing partnerships to maximize economies of scale.*** We currently work with qualified contract manufacturing organizations, or CMOs, to manufacture drug candidates for preclinical and clinical supply. In the near future, we plan to continue outsourcing the manufacturing of our drug candidates, including commercial-scale manufacturing of our approved drugs, to industry-leading, highly reputable, and qualified CMOs/contract development and manufacturing organizations, or CDMOs globally. We have historically adopted and planned to continue to implement robust procedures to ensure that production qualifications, facilities, and processes of our CMOs/CDMOs comply with applicable regulatory requirements as well as our own internal guidelines and quality standards. We may also engage additional qualified CMOs/CDMOs in the future to ensure sufficient supply of drug candidates for our clinical trials as well as for commercial sale of our approved drugs.
- ***Assemble a world-class marketing team to accelerate the adoption of emerging next-wave immuno-oncology treatments.*** We aim to capture market share in the U.S. and gradually enter other significant markets including Europe, China, and Japan. To ensure maximum commercial value of our late-stage drug candidates globally, we intend to form our core in-house commercial leadership team by recruiting senior-level sales and marketing personnel to support commercialization of our drug candidates in the U.S. We may also consider strategic collaboration opportunities for the commercialization of our drug candidates in other countries in Europe and Asia. In particular, we may selectively out-license, establish joint ventures, or consider other forms of commercialization partnerships with leading biopharmaceutical companies.
- ***Seek and nurture top talent to fuel our innovation and ingenuity.*** We place a high priority on selecting and retaining top talent. Our R&D centers in New Jersey and Hangzhou provide access to a global talent pool of highly skilled scientists and physicians. To support our continued growth, we plan to continue investing in recruiting and retaining top talent for our various operations around the world, including drug discovery, chemistry, manufacturing and controls ("CMC"), clinical development, regulatory affairs, and sales and marketing.

Scientific background — cancer therapies: immunotherapy, combination therapy, and others.

Cancer is a disease in which some of the body's cells grow uncontrollable and potentially spread to other parts of the body. As the understanding of the human body's functioning has evolved, it has become clear that cancer is caused by genetic abnormalities that lead to changes in cells' function, primarily how they grow and divide. Three types of genetic changes principally contribute to cancer: the upregulation of genes that promote cancer; the downregulation of genes that suppress cancer; and the dysfunction of genes that repair DNA damage. Conventional cancer treatments commonly used include radiation therapy, chemotherapy, and surgery.

Although still a first-line treatment for some types of cancer, often chemotherapy cannot effectively control progression of advanced cancer and causes side effects significantly affecting the quality of patients' lives, which necessitates research and development of new therapies for cancer treatments. After a long process of historical development, the field of cancer treatment has advanced rapidly in recent decades, leading to more advanced treatment options represented by targeted therapies, and more recently, immunotherapies. These therapies aim to improve patient outcomes while mitigating systemic adverse effects. Targeted therapy and immunotherapy, through targeting specific oncogenic pathways and leveraging patients' immune systems respectively, can benefit patients in terms of improved efficacy, reduced symptoms, or better quality of life.

Targeted therapy is a form of cancer treatment that encompasses chemical drugs and biological products, and targets proteins that regulate cancer cells' growth, division, and spread. As small molecules, chemical drugs can enter cells easily and are usually designed to target tumor-specific proteins inside cancer cells. Biological products, especially antibodies, identify targets on the surface of cancer cells and consequently are designed to directly identify and fight cancer cells, carry anti-tumor chemical toxins to the cancer cells, or mark cancer cells to facilitate easy targeting and destruction by the immune system.

Immunotherapy is a type of cancer treatment that helps the immune system fight cancer. The human immune system can recognize and attack foreign substances and protect its own cells from those attacks. However, cancer cells escape attack in various ways. For example, cancer cell may "pretend" to be healthy cells by completing a "handshake" with immune cells called T cells. Another way is through building a tumor

microenvironment that silences the immune system. Immune checkpoint inhibitors, mostly biological products such as anti-PD-1/PD-L1 antibodies, can block the "handshake" between cancer cells and T cells, thereby enabling T cells to recognize and attack cancer cells as foreign objects. Drugs that target tumor microenvironments are designed to reverse the tumor-associated immunosuppressive state. The tumor microenvironment is a complex ecosystem, which includes immune cells, the extracellular matrix, blood vessels, and other cells such as fibroblasts. Therefore, drugs targeting tumor microenvironments are designed to function in different ways, such as reducing immunosuppressive cells surrounding a tumor or suppressing generation of blood vessels.

Cancer development and progression is a complex process that can involve multiple levels of cell functional disorders. Combination therapy that addresses disorders through different mechanisms is considered a promising next generation cancer treatment. Many studies have shown that immunotherapeutic combinations can significantly boost response rates in cancer patients as compared to monotherapies. An increasing number of studies are testing combinations with previously failed monotherapy drug candidates or shelved drugs. Moreover, scientists believe that targeted therapy can be potentiated by combination with immunotherapy, because the combination will make cancer cells more susceptible to the immune system and thus potentially yield both higher response rates and longer treatment benefit.

Despite the promising future of combination therapy, there are challenges to overcome, especially escalated safety issues observed in many previously failed combinations. Therefore, deep understanding of cancer biology and strong R&D and preclinical and clinical design and execution capabilities are needed to develop the right paring, sequencing, timing, and dosage of therapies.

Our differentiated oncology portfolio

Buparlisib (AN2025): a pan-PI3K inhibitor aimed at becoming the vanguard for recurrent or metastatic HNSCC after anti-PD-1/PD-L1 therapy

Overview

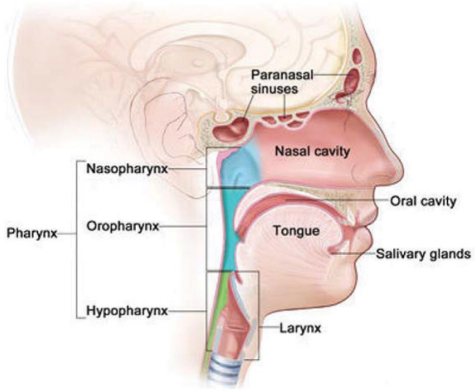
Our lead drug candidate, buparlisib, or AN2025, is a global registrational trial-stage pan-PI3K inhibitor, which specifically targets the PI3K signaling pathway and reverses the immunosuppressive tumor microenvironment through inhibition of class I PI3Ks. We have the exclusive global rights to develop and commercialize AN2025 through in-licensing agreement with Novartis. For more details, see "— License and collaboration agreements — Collaboration with Novartis". Novartis has conducted 40 clinical trials on over 4,200 patients across a variety of tumor types and a multi-center Phase II clinical trial of AN2025 demonstrated strong antitumor activity and a manageable safety profile in combination with paclitaxel in the treatment of recurrent or metastatic HNSCC on or after disease progression with platinum based chemotherapy. In July 2016, AN2025 was granted Fast Track designation by the FDA for the treatment of recurrent or metastatic HNSCC with disease progression on or after platinum-based therapy. We are now advancing AN2025 in combination with paclitaxel for the treatment of recurrent or metastatic HNSCC after anti-PD1/PD-L1 therapy in a Phase III clinical trial, in which we expect to enroll a total of 483 patients in more than 180 sites around the world, spanning over 18 significant markets in North America, Europe, Asia, and South America. We expect to complete the patient enrollment in the third quarter of 2023, and submit an NDA to the FDA for the potential accelerated approval using the ORR readout in the first half of 2024, followed by further marketing approval applications to the NMPA, EMA, PMDA, and other authorities. To the best of our knowledge, AN2025 is currently the only drug candidate in Phase III clinical development for the treatment of recurrent or metastatic HNSCC after disease progression with anti-PD-1/PD-L1 therapy. We believe that AN2025, if approved, has the potential to be the first drug product with such label globally to address this unmet medical need and capture the sizable addressable market.

Background on HNSCC

Head and neck cancers are defined as any cancer that begins in cells of the oral cavity, pharynx, nose, sinuses, or salivary glands. The overwhelming majority (>90%) of head and neck cancers are squamous cell carcinomas ("HNSCC"). HNSCC is one of the most morbid, mortal, and genetically diverse malignancies. Studies show that HNSCC can be caused by various risk factors including tobacco consumption, alcohol

abuse, viral infections (e.g., HPV or Epstein-Barr virus), and other carcinogens such as radiation exposures and occupational exposures to wood dust, nickel dust, or formaldehyde. Most patients present with locally advanced disease with a high risk of recurrence, and approximately 10% of HNSCC patients present with metastatic disease. Platinum-based chemotherapy was the standard regimen that dominated the treatment of first-line recurrent or metastatic HNSCC for 30 years with a mOS of less than 9 months. Despite initial responses to chemotherapy, many patients experience recurrence, which can later progress into advanced stages of these diseases with debilitating symptoms impacting their quality of life.

An illustration of head and neck cancer regions



Source: National Institutes of Health

Targeted therapy was the first major alternative treatment for first-line recurrent or metastatic HNSCC. In 2011, cetuximab, a chimeric monoclonal antibody that targets EGFR, in combination with platinum-based therapy plus fluorouracil was approved as a first-line treatment for HNSCC by the FDA. Compared to chemotherapy alone, this treatment regimen has an improved efficacy with a higher response rate of about 36% and extends mOS to 10.1 months. In the next few years, immunotherapy became the most popular area of cancer research and was accepted by medical authorities for its durable response and long-term survival, which largely changed the therapeutic landscape of cancer. Currently, there are two anti-PD-1 antibodies, i.e., pembrolizumab (Keytruda) and nivolumab (Opdivo) approved by the FDA for the treatment of recurrent or metastatic HNSCC. Pembrolizumab was the first immune checkpoint inhibitor approved for the treatment of HNSCC. It was first approved in the U.S. and Europe for second-line treatment of recurrent or metastatic HNSCC in 2016, and later approved for first-line treatment in 2019. Pembrolizumab alone or in combination with chemotherapy significantly prolonged mOS to around 14 months, tripled the five-year survival rate compared to cetuximab in combination with chemotherapy, and also exhibited a favorable safety profile. As a result, it became the mainstream drug for first-line treatment of HNSCC in major developed countries in the U.S., Europe, and Japan.

However, it is observed that most recurrent or metastatic HNSCC patients do not respond to immunotherapy (manifested by a response rate of ~23%) and about 85% patients experience disease progression after immunotherapy. At present, these patients can only use chemotherapies, cetuximab, or combined chemotherapy drugs that were marketed in this therapeutic field before the advent of immunotherapy, notwithstanding that these treatment options have never been verified by registrational clinical trials on efficacy in progressed HNSCC patients. Presently, there is an unmet medical need for more effective therapies for recurrent or metastatic HNSCC patients after anti-PD-1/PD-L1 treatment approved by medical authorities.

Mechanism of action

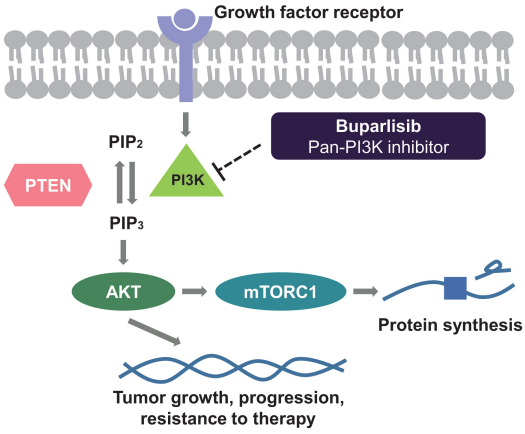
PI3K regulates many physiologic cellular functions, including protein synthesis and glucose metabolism, cell survival growth, proliferation, cell migration, and angiogenesis. It is a family of phospholipid kinase,

which is categorized into three classes based on structure, function, and substrate specificity. Class I PI3Ks are widely implicated in cancer. They function as heterodimers consisting of one catalytic subunit selecting from p110α, p110ß, p110δ, and p110γ, and one regulatory subunit selecting from p85α (or its splice variants p55α and p50α), p85ß, p55γ, p101, and p84. Between the two subunits, the catalytic subunit plays the central role of performing the action of PI3K, which is to convert PIP2 to PIP3, and the regulatory subunit regulates the catalytic subunit's activation in response to the absence or presence of upstream stimulation by growth factors. Depending on the catalytic subunit, class I PI3K is categorized into four isoforms PI3Kα, PI3Kß, PI3Kδ, and PI3Kγ.

Upon activation (e.g., by growth factor stimulation) of the PI3K signaling pathway, PI3K converts PIP2 to PIP3, a lipid second messenger that binds to the pleckstrin homology domain of target proteins and recruits them to the inner surface of the plasma membrane. The best understood PI3K target is AKT/PKB, a serine/threonine kinase, which functions as a "molecular hub" to regulate diverse cellular functions such as cell proliferation, growth, metabolism, survival, and angiogenesis. PI3K signaling can be negatively regulated by action of dual specificity protein phosphatases, also known as 3-PI phosphatases. The prototype member of this family of phosphatases is the tumor suppressor phosphatase and tensin homologue ("PTEN"), which has the potential to attenuate the downstream signaling of multiple PI3K complexes.

Evidence suggests that constitutive PI3K activation is a critical step in mediating the transforming potential and growth stimulating activity of various oncogenes and tumor suppressors, which contribute to the onset and growth of many solid tumors as well as tumors of the hematopoietic system. Activation of the PI3K signaling pathway will lead to the subsequent activation of downstream pathways, including the PI3K/AKT/mTOR signaling pathway. The PI3K/AKT/mTOR pathway is an important intracellular signaling network that regulates cellular metabolism, proliferation, and survival. Abnormal activation of the PI3K/AKT/mTOR pathway has been identified as an important step in the initiation and maintenance of tumors and a key regulator of angiogenesis and upregulated metabolic activities in tumor cells. Activation of the PI3K pathway frequently occurs in HNSCC, through a number of mechanisms including PIK3CA or PTEN molecular alterations, overexpression of EGFR, or in association with HPV infection.

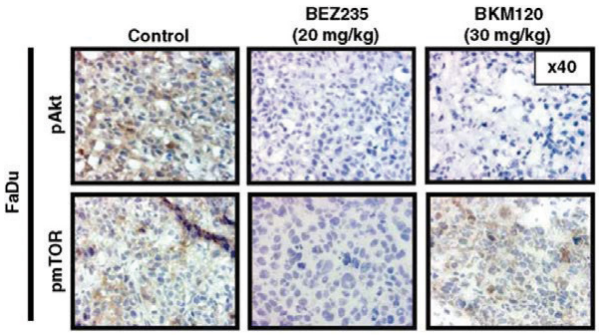
Our lead product AN2025 is designed to specifically inhibit PI3Kα isoform (and PI3Kß to a lesser extent) in the PI3K/AKT signaling pathway in an adenosine triphosphate (ATP)-competitive manner, inhibiting the production of the PIP3 and the subsequent activation of the PI3K signaling pathway, including the PI3K/AKT/mTOR signaling pathway. As a pan-PI3K inhibitor, it also targets PI3Kδ and PI3Kγ, which play important roles in the immune system, empowering it to be a partner for combination therapies. For details, see "— Triple combination of AN2025, AN0025, and Tecentriq, or atezolizumab".



Summary of preclinical results

In a study conducted on mice transfected with FaDu cells, an HNSCC cell line, AN2025 (previously known as BKM120) showed down regulation of AKT in tumor in the animals treated with doses equivalent to

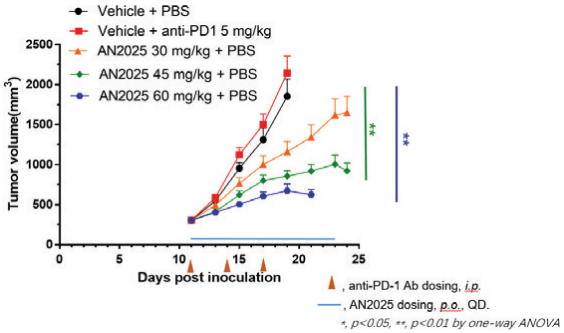
patient's maximum tolerated dose ("MTD"), to an extent more significant than BEZ235 (also known as dactolisib, another PI3K inhibitor developed by Novartis).



Source: https://doi.org/10.1158/0008-5472.CAN-11-2263

In an animal study we conducted before the initiation of our Phase III clinical trial, AN2025 showed an encouraging outcome for the treatment of anti-PD-1 antibody refractory tumors. In anti-PD-1 antibody refractory tumor bearing mice, single agent treatment with AN2025 significantly inhibited tumor growth in a dose range consistent with doses equivalent to patient's MTD. This animal model result suggests AN2025 could potentially address anti-PD-1 antibody refractory tumors.

Activity of AN2025 in anti-PD-1 antibody refractory CT26 mice model



Summary of clinical trial results

Phase Ia trial in patients with advanced solid tumors by Novartis

Trial design. This trial was a Phase Ia, multi-center, open-label dose escalation study of AN2025 in patients with advanced solid tumors. A total of 83 patients enrolled in five clinical sites in the U.S., Canada, Spain, and Netherlands. The study was designed to consist of two stages. One was the dose escalation phase, during which patients were assigned to cohorts over six dose levels: 12.5 mg/day, 25 mg/day, 50 mg/day, 80 mg/day, 100 mg/day, and 150 mg/day. At the end of the dose escalation phase where the MTD was declared, the next stage, an MTD expansion phase, was initiated enrolling additional patients with advanced solid tumors. The primary objective of this study was to determine the MTD of AN2025 as a monotherapy. The secondary objectives included assess the safety, tolerability, pharmacokinetic ("PK") portfolio, pharmacodynamics ("PD"), and preliminary evidence of efficacy of AN2025.

Trial status. This trial was completed in August 2012.

Safety data. All patients reported at least one AE, with the most commonly reported (≥ 30%) AEs being nausea (45.8%), decreased appetite (42.2%), asthenia (37.3%), diarrhea (36.1%), hyperglycemia (33.7%), rash (31.3%), and constipation (30.1%). The AE profile of patients treated at the determined MTD (100 mg/day) was similar to the overall AE profile, with the most commonly reported AEs being nausea (27 patients, 49.1%), asthenia (26 patients, 47.3%), diarrhea (25 patients, 45.5%), decreased appetite (22 patients, 40.0%), hyperglycemia (19 patients, 34.5%), rash (18 patients, 32.7%), and constipation (18 patients, 32.7%). Overall, 68.7% of patients experienced at least one grade 3–4 AE. In patients treated at MTD of 100mg/day, the incidence of grade 3–4 AE was 65.5%.

Of all patients treated with AN2025, 36 (43.4%) experienced SAE, including four patients in the 50 mg/day dose group (80%), four patients in the 80 mg/day group (36.4%) and 23 patients in the 100 mg/day group (41.8%), four patients in the 150 mg/day group (100%) and 1 patient in the TEC 100mg/day group (20%). Eleven patients experienced SAEs suspected to be drug-related including one patient in the 80 mg/day dose group (9.1%), and seven patients in the 100 mg/day group (12.7%), and three patients in the 150 mg/day group (75.0%). The most frequent SAEs suspected to be treatment-related were hyperglycemia, diarrhea and fatigue. 29 (34.9%) patients died during the study, with 13 (15.7%) deaths occurring on treatment or up to 28 days after end of treatment. None of the deaths were considered by the investigator to be related to the study treatment.

Summary of deaths and AEs of patients being treated with AN2025

Category	12.5 mg N=1 n (%)	25 mg N=2 n (%)	50 mg N=5 n (%)	80 mg N=11 n (%)	100 mg N=55 n (%)	150 mg N=4 n (%)	TEC 100 mg N=5 n (%)	All patients N=83 n (%)
All deaths	0	0	3 (60.0)	3 (27.3)	21 (38.2)	1 (25.0)	1 (20.0)	29 (34.9)
AEs	1 (100)	2 (100)	5 (100)	11 (100)	55 (100)	4 (100)	5 (100)	83 (100)
AEs suspected to be drug- related	1 (100)	2 (100)	4 (80.0)	9 (81.8)	54 (98.2)	4 (100)	3 (60.0)	77 (92.8)
Grade 3-4 AEs	0	1 (50.0)	4 (80.0)	8 (72.7)	36 (65.5)	4 (100)	4 (80.0)	57 (68.7)
Suspected to be drug- related G3-4								
AEs	0	1 (50.0)	0	3 (27.3)	25 (45.5)	3 (75.0)	1 (20.0)	33 (39.8)
SAEs	0	0	4 (80.0)	4 (36.4)	23 (41.8)	4 (100)	1 (20.0)	36 (43.4)
Suspected to be drug- related SAEs	0	0	0	1 (9.1)	7 (12.7)	3 (75.0)	0	11 (13.3)
AEs leading to discontinuation	0	0	1 (20.0)	2 (18.2)	13 (23.6)	1 (25.0)	3 (60.0)	20 (24.1)
AEs, suspected to be drug-related, leading to discontinuation	0	0	0	1 (9.1)	11 (20.0)	1 (25.0)	1 (20.0)	14 (16.9)
AEs requiring dose interruption and/or reduction	1 (100)	1 (50.0)	3 (60.0)	7 (63.6)	42 (76.4)	2 (50.0)	1 (20.0)	57 (68.7)

Abbreviation: TEC=terminal elimination half-life assessment cohort.
Source: Novartis Clinical Trial Results Website

Efficacy data. Among 83 patients treated with AN2025, there was one confirmed partial response (“PR”), and 33 patients (39.8%) had a best overall response of stable disease (“SD”). The disease control rate (“DCR”) for patients in the MTD/RP2D cohort was 41.8%.

Conclusion. AN2025, at the MTD of 100 mg/day, was well tolerated with preliminary antitumor activity.

Phase II trial in patients with recurrent or metastatic HNSCC by Novartis

Trial design. The trial was a multi-center, randomized, double-blind, placebo-controlled Phase II study assessing patients with histologically or cytologically-confirmed recurrent or metastatic HNSCC after disease progression on or after one previous platinum-based chemotherapy regimen in the metastatic setting. A total of 158 eligible patients were enrolled from 58 centers across 18 jurisdictions and randomly assigned (1:1) to receive second-line oral AN2025 (n=79, 76 treated with 100 mg once daily) or placebo (n=79, 78 treated with 80 mg/m^2 on days 1, 8, 15 and 22) plus intravenous paclitaxel in 28-day treatment cycles. The primary endpoint

of this study was PFS for the patients. Secondary endpoints included safety and PK profile and other efficacy measurements such as OS, ORR, time to response ("TTR"), DCR, duration of response ("DoR"), and health related quality of life ("HRQoL").

Trial status. This trial was completed in March 2017.

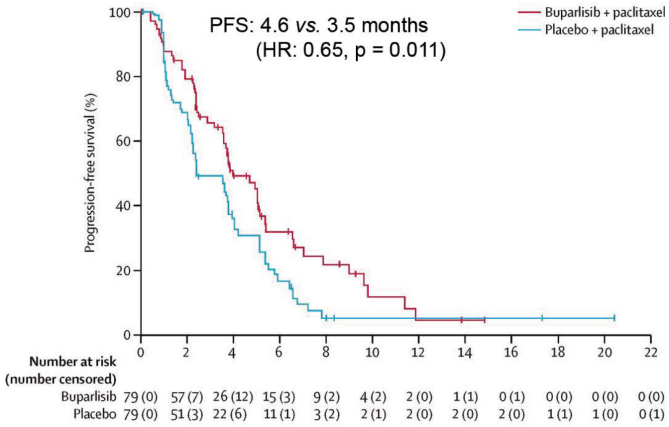
Demographic and baseline characteristics. The following table sets forth the age, demographic, and ECOG for the 158 randomized patients.

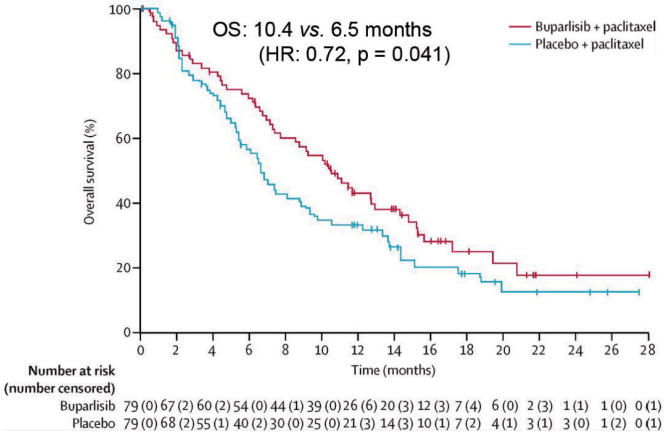
	AN2025 arm N=79	Placebo arm N=79
Median age in years (25^{th} – 75^{th} percentile)	59.0 (53-65)	58.0 (53-65)
Distribution male/female	65/14	68/11
Distribution ECOG at baseline 0/1/2/missing	31/48/0/0	25/53/0/1

Abbreviation: ECOG=Eastern Cooperative Oncology Group
Source: http://doi.org/10.1016/S1470-2045(17)30064-5

Efficacy data. This trial met the primary endpoint of PFS based on the protocol pre-specified criteria. Median PFS in this trial was 4.6 months in the AN2025 in combination with paclitaxel treatment arm and 3.5 months in the placebo in combination with paclitaxel treatment arm. The study also met the key secondary endpoint of OS based on the protocol pre-specified criteria. The median OS showed a 3.9-month difference in favor of the AN2025 arm. The clinical result suggested that adding AN2025 to paclitaxel for the treatment of recurrent or metastatic HNSCC improved the median OS to over 10 months (i.e., 10.4 months compared to 6.5 months in the placebo plus paclitaxel group), a superior outcome in the treatment of recurrent or metastatic HNSCC on or after disease progression with platinum-based chemotherapy. The study also demonstrated a clinically meaningful improvement of an approximately three-fold increase in ORR by local investigator assessment (39.2% vs 13.9%) favoring AN2025 arm. In addition, TTR (~1.0 month) and DCR (~56%) were similar in both study arms; median time to deterioration was 5.6 months in AN2025 arm and 4.2 months in the placebo arm while DoR was 3.06 (2.1–9.6) months in AN2025 arm compared with 4.17 (2.7–5.6) months in the placebo arm.

Progression free and overall survival data





Source: http://doi.org/10.1016/S1470-2045(17)30064-5

Safety data. Grade 3-4 AEs were reported in 62 (82%) of 76 patients in the AN2025 in combination with paclitaxel treatment arm and 56 (72%) of 78 patients in the placebo in combination with paclitaxel treatment arm. The most common grade 3-4 AEs with AN2025 treatment in combination with paclitaxel were hyperglycemia (22%), anemia (18%), neutropenia (17%), and fatigue (8%). SAEs (regardless of relation to study treatment) were reported in 43 (57%) of 76 patients in the AN2025 in combination with paclitaxel treatment arm and in 37 (47%) of 78 patients in the placebo in combination with paclitaxel treatment arm. The most frequent SAEs for AN2025 plus paclitaxel combination were pneumonia (7.89% vs. 7.69% in the placebo group), and diarrhea (5.26% vs. 0.00% in the placebo group). The most frequent SAEs for AN2025 plus paclitaxel combination that occurred less in the placebo group were diarrhea (5.26% vs. 0.00%), hyperglycaemia (3.95% vs. 0.00%), and general physical health deterioration (3.95% vs. 0.00%).The frequency of hyperglycemia was higher with AN2025 versus placebo, suggesting effective PI3K on-target inhibition. Known AEs associated with AN2025, including hyperglycemia and gastrointestinal AEs (e.g., stomatitis, diarrhea, nausea, and vomiting) were managed with established strategies of dose reduction and treatment of symptoms with appropriate concomitant medications. The proportions of patients discontinuing treatment because of AEs were similar in AN2025 and placebo groups, suggesting that AN2025 did not substantially increase paclitaxel toxicity. There were a total of 110 deaths reported among patients in the safety set with 32 being on-treatment deaths. Among the 32 on-treatment deaths, 15 (20%) patients were in the AN2025 plus paclitaxel group, and 17 patients (22%) were in the placebo plus paclitaxel group. In the AN2025 plus paclitaxel group, nine deaths were due to study indication and six deaths were due to AEs. No on-treatment deaths were suspected by the investigator to be study treatment related.

Conclusion. The results of this trial warranted further development of AN2025 in combination with paclitaxel in patients with platinum-pretreated recurrent or metastatic HNSCC. In July 2016, the FDA concluded that AN2025 met the criteria for the “Fast Track” designation and designated the investigation of AN2025 for recurrent or metastatic HNSCC with disease progression on or after platinum-based therapy as a Fast Track development program.

Phase III multi-center clinical trial of AN2025 in combination with paclitaxel for the treatment of patients with recurrent or metastatic HNSCC after anti-PD-1/PD-L1 treatment

The evolving therapeutic landscape of first-line HNSCC led us to pivot treatment background from platinum pre-treated to anti-PD-1/PD-L1 based therapy pre-treated patients for the clinical design of Phase III trial to capture the sizable addressable market. Based on the strong preclinical evidence and encouraging Phase II clinical results, we are currently conducting a global Phase III multi-center clinical trial of AN2025 in combination with paclitaxel for the treatment of patients with recurrent or metastatic HNSCC after anti-PD-1/PD-L1 treatment.

Trial design. The study is a randomized, open-label Phase III study to assess the treatment effect of AN2025 in combination with paclitaxel in patients with recurrent and metastatic HNSCC that have progressed after anti-PD-1/PD-L1 treatment.

A total of 483 patients are expected to be enrolled in approximately 180 clinical trial sites in the U.S., Canada, the U.K., Spain, Italy, Germany, France, Poland, Hungary, Belgium, Russia, mainland China, Hong Kong, Taiwan, Japan, South Korea, Australia, and Argentina. Enrolled patients will be randomized in a 2:1 ratio to receive either daily AN2025 (100 mg) in combination with weekly paclitaxel (80 mg/m^2) or weekly paclitaxel alone in a 21-day treatment cycle. The primary endpoint of this study is OS for the entire (intent-to-treat) population of patients. The interim endpoint of the study is ORR on a subset of patients with at least six-month follow-up at the time the last patient is enrolled. Secondary endpoints include safety profile and other efficacy measurements such as PFS, ORR, DoR, and HRQoL.

Trial status and future plan. In 2020, we communicated with the FDA regarding the updated Phase III clinical protocol. Based on the FDA's feedback, we are currently focusing on recruiting patients with recurrent or metastatic HNSCC after anti-PD-1/PD-L1 treatment instead of patients progressing after platinum-based chemotherapy. The first patient was dosed in April 2021 in this Phase III trial. We expect to complete the patient enrollment in the third quarter of 2023, and submit an NDA to the FDA for the potential accelerated approval using the ORR readout in the first half of 2024, followed by further marketing approval applications to the NMPA, EMA, PMDA and other authorities.

Market opportunities

According to Datamonitor Healthcare, the annual incidence of HNSCC is expected to reach 71,267 and 183,193 new cases in the U.S. and in seven major markets (including the U.S., the U.K., Germany, France, Italy, Spain, and Japan) in 2028, respectively. Most patients present with locally advanced disease are of a high risk of recurrence. Around 50–60% of HNSCC patients develop recurrence or metastasis, with a projected incidence of approximately 32,000 in the U.S. and 89,000 in seven major markets, among which approximately 22,000 patients in the U.S. and around 68,000 patients in these seven major markets are expected to be treated by anti-PD-1/PD-L1 therapy in 2028. Although anti-PD-1/PD-L1 based therapy has become a mainstream drug for first-line treatment of HNSCC in these seven major markets, about 85% of patients would progress after anti-PD-1/PD-L1 treatment. As such, in 2028, recurrent or metastatic HNSCC patients progressing after anti-PD-1/PD-L1 treatment can be more than 50,000 in the seven major markets. Considering the lack of effective therapies validated by registrational clinical studies and the popularization of anti-PD-1/PD-L1 treatment around the world, the market opportunity for HNSCC patient population after anti-PD-1/PD-L1 based treatment should be significant.

Competitive landscape

Among the investigational drugs targeting the recurrent or metastatic HNSCC patients progressing after anti-PD-1/PD-L1 based therapy, we believe AN2025 is currently the most advanced candidate globally, being the only drug under active development in the Phase III clinical trial. Monalizumab, an anti-NKG2A antibody developed by Innate Pharma S.A./AstraZeneca PLC, in combination with cetuximab, failed to meet the pre-defined efficacy threshold in a predefined futility interim analysis as compared with cetuximab, and thus was terminated in August 2022. Based on our knowledge, current potential competitive candidates in Phase I/II trial include: (1) Duvelisib, a selective PI3Kδ/γ inhibitor, developed by Secura Bio, Inc., entered an investigator-initiated Phase II study in combination with docetaxel in September 2021; (2) Ficlatuzumab, an anti-HGF antibody developed by Aveo Pharmaceuticals Inc. ("Aveo"), in combination with cetuximab demonstrated ORR of 38% and mPFS of 4.1 months in an interim analysis based on HPV 16- patients. Aveo may initiate the registrational study in the first half of 2023; (3) Tisotumab vedotin, an antibody-drug conjugate developed by Genmab A/S, entered into a Phase II study on locally advanced or metastatic disease in solid tumors including HNSCC with prior platinum and/or anti-PD-1/PD-L1 treatment, and demonstrated ORR of 16% and mOS of 9.4 months in an interim analysis based on 31 patients; (4) Tipifarnib, a farnesyltransferase inhibitor developed by Kura Oncology Inc., is designed for patients with HRAS mutations, which account for only about 4% of HNSCC patients; (5) Lenvatinib, a multi-tyrosine kinase inhibitor developed by MSD and Eisai, is currently being evaluated in a phase II study in combination with pembrolizumab against standard chemotherapy; the study will also assess the efficacy of lenvatinib monotherapy, (6) Cabozantinib, another

multi-tyrosine kinase inhibitor developed by Exelixis, Inc., has just entered a Phase II study in combination with nivolumab in August 2022, and (7) Cue-101, a targeted interleukin 2-based immunotherapy developed by Cue Biopharma Inc., demonstrated one PR and six with SD for ≥ 12 weeks based on 14 HPV16+ patients in a Phase I dose escalating trial.

Palupiprant (AN0025): a tumor microenvironment modulator

Overview

Palupiprant, or AN0025, is an oral EP4 antagonist with high potency and selectivity. It is designed to block the PGE2-EP4 signaling pathway by preventing the binding of prostaglandin E2 to its EP4 receptor, thereby inhibiting PGE2-mediated immunosuppression in the tumor microenvironment. In-licensed from Eisai in January 2018, we have exclusive rights and license to develop and commercialize AN0025 globally, excluding Japan, Korea, Singapore, Taiwan, India, Thailand, Philippines, Indonesia, Malaysia, Vietnam, Myanmar, Laos, and Cambodia. For more details, see "— License and collaboration agreements — Collaboration with Eisai". The mechanism of action and preliminary safety profile of AN0025 have been demonstrated in early clinical trials. Based on its mechanism of action, we believe that AN0025 has the potential to be used in combination with multiple therapies including immune checkpoint inhibitors to treat solid tumors. Currently, we are in collaboration with MSD to evaluate the combination of AN0025 and MSD's pembrolizumab for the treatment of solid tumors as a second or third-line therapy in a Phase Ib study. For more details, see "— License and Collaboration Agreements — Supply agreement with MSD". As of December 31, 2022, we have enrolled 54 patients in this trial in the U.S. and France and expect to obtain proof of concept clinical results in the second half of 2023.

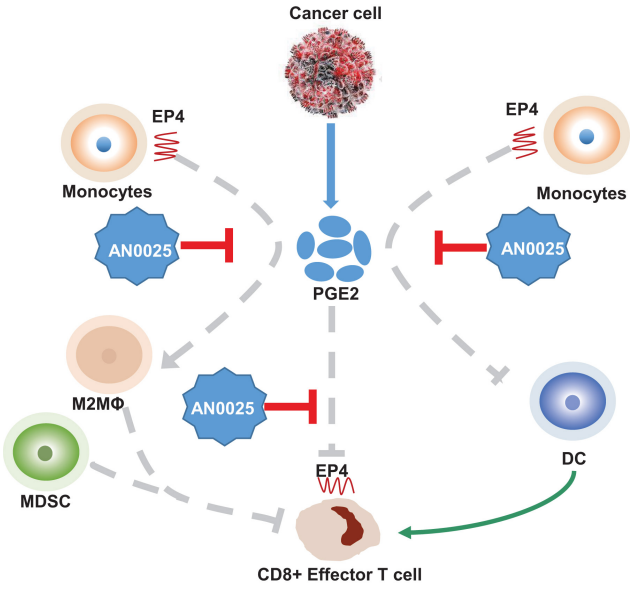
Mechanism of action

A permissive tumor microenvironment is critical for tumor progression and metastasis. The development of a tumor-favoring microenvironment is a hallmark of cancer progression. As recent studies begin to reveal the mechanisms of how a tumor can successfully embed itself within a network supporting normal cells and reprogram it into an immunosuppressive tumor microenvironment, targeting alternatively activated tumor associated M2 macrophage, myeloid-derived suppressor cells ("MDSC") and regulatory T cells ("Tregs") represents a promising strategy for developing novel cancer immunotherapy. Tackling immunosuppression in tumor microenvironments, EP4 is considered a promising target for developing novel immune-targeting anti-cancer therapies.

Prostaglandins play a key role in mediating inflammatory responses, and their effects on the differentiation of monocytic cells and suppression of T-cell activation are exploited by tumors to maintain an immunosuppressive tumor microenvironment. A key signaling pathway related to the re-shaping of tumor-promoting immunosuppressive microenvironments is the PGE2-mediated pathway.

Upon binding of PGE2 to its receptors, e.g., EP4, PGE2/EP4 signaling pathway produces cAMP and subsequently activates the cAMP/PKA signaling cascade, which has long been regarded as a pathway that negatively regulates T cell and NK cell functions. In addition, this pathway has been well recognized as an essential mediator that not only enhances the differentiation of immunosuppressive cells, such as M2 macrophage ("M2M") and MDSC, which inhibit the antitumor activity of T cells like $CD8^+$, but also compromises the maturation of dendritic cells, a type of APC, in the tumor microenvironment. Early studies have shown that the presence or accumulation of M2M and MDSC in tumors is associated with a poorer prognosis in many types of solid tumors.

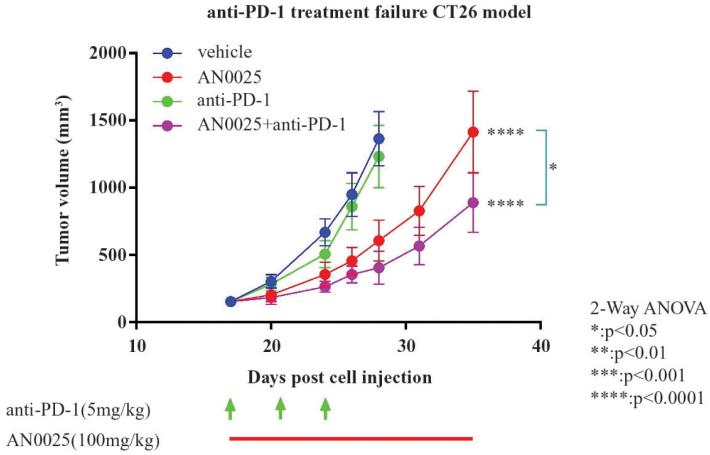
Our AN0025, a small molecule EP4 antagonist, is designed to prevent the binding of PGE2 to its EP4 receptor to change the immunosuppressive character of the tumor microenvironment. By blocking the downstream signaling of PGE2/EP4 pathway, AN0025 is designed to inhibit the differentiation and accumulation of MDSC and M2M, promote the maturation of dendritic cells ("DC") and antitumor M1 type macrophage, thereby increasing the activity of $CD8^+$ cells and the T-cell immune responses against tumors.



Summary of preclinical results

Animal studies supported the combination of AN0025 with PD-1 inhibitor for treating tumors that are not responsive to anti-PD-1 therapy. In the CT26 murine colon cancer model, a portion of non-responders after anti-PD-1 treatment were selected, re-grouped and re-treated by combining AN0025 with an anti-PD-1 antibody. As shown in the figure below, AN0025 combined with anti-PD-1 antibody treatment demonstrated stronger antitumor activity, compared with each compound alone.

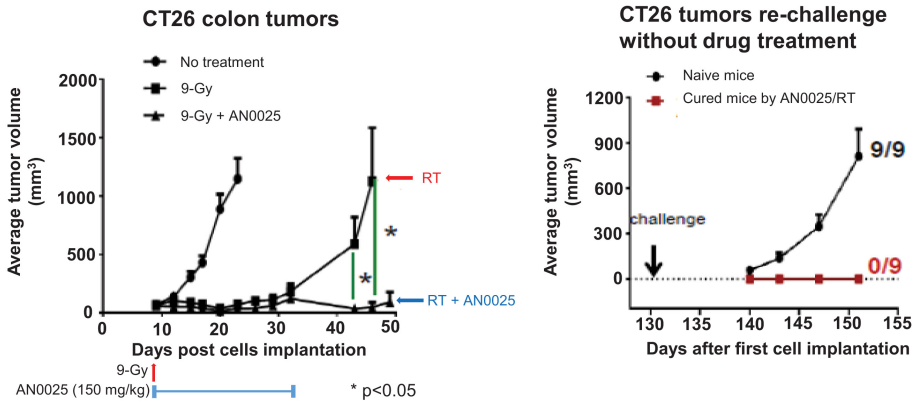
Antitumor Activity of AN0025 in combination with anti-PD-1 treatment in CT26 Murine Colon Cancer Syngeneic Model



In another preclinical study, the combination of AN0025 and radiotherapy ("RT") demonstrated improved antitumor activity, and antitumor memory T-cell response in mice compared with RT treatment

alone. As shown in the figure below, in a CT26 murine colon cancer model, treatment of AN0025 plus a single 9 Gy of RT rendered nine of the 12 animals tumor free, which was significantly better than RT alone. None of the tumor free animals regrew tumors over a subsequent 2-month period that followed the cessation of treatment, and all the nine mice completely rejected tumor rechallenge. These results suggested an antitumor memory response in those nine animals cured by the combination of AN0025 and RT.

Antitumor activity of AN0025 in combination with RT in CT26 murine colon cancer isograft model



Summary of clinical trial results

Phase I study for AN0025 monotherapy in solid tumors by Eisai

Trial design. This trial was a multi-center, open-label, dose escalation study in patients with selected advanced malignancies with high myeloid infiltrate. This trial was conducted in the U.S. and France. A total of 30 patients were enrolled and received study treatment, of which 80% had received at least three lines of prior treatment. Most common tumor types were colorectal cancer (43%), pancreatic cancer (20%), and HNSCC (13%). The patients were randomized into four cohorts and administered 125 mg to 750 mg AN0025 orally, once daily ("QD").

Primary objectives of this trial were to assess the safety and tolerability of AN0025 and determine the MTD and/or the RP2D of AN0025. Secondary objectives included studying of PK, ORR, and DCR. Exploratory objectives included PD assessments on immune cells infiltrated into tumors and in peripheral blood and metabolic response.

Trial status. This trial was completed on February 27, 2018.

Efficacy data. Seven out of 30 patients (23%) achieved SD, including four patients who achieved SD of more than 18 weeks, and three patients had metabolic responses.

Safety data. No dose limiting toxicities ("DLTs") were observed and the MTD was not reached. The most common treatment-related adverse events ("TRAEs") (≥10%) were fatigue (36.7%), diarrhea (33.3%), nausea (30.0%), anemia (23.3%), decreased appetite (23.3%), vomiting (20.0%), abdominal pain (16.7%), and dyspnea (16.7%). Grade 3 or above TRAE occurred in three patients. Two patients discontinued treatment due to TRAEs. There were no treatment-related deaths.

PK/PD profile. AN0025 exposure was dose proportional up to 500 mg, QD with no incremental increase in exposure at 750 mg, QD. AN0025 was extensively metabolized. Elimination half-life was approximately 12 hours and accumulation on multiple dosing was around 2 to 3-fold.

Conclusion. In this trial, single-agent AN0025 was well tolerated up to 750 mg, QD with no MTD reached in heavily pretreated patients with myeloid-rich tumors.

Phase Ib study for AN0025 in combination with Keytruda, or pembrolizumab, in solid tumors

Trial design. This trial is an open-label, multicenter, Phase Ib study to evaluate the safety and preliminary efficacy of AN0025 in combination with pembrolizumab in patients with locally advanced/ advanced solid tumors in the U.S. and France. The study will include a DLT observation phase followed by an expansion phase. The pembrolizumab dose will remain constant at 200 mg every 3 weeks for each dose level of AN0025 and in each cohort.

The DLT observation period will employ a dosing de-escalation scheme. If the results of DLT observation phase yield an acceptable number of DLTs, then the expansion Phase Ib will start. Approximately 10-12 patients will be enrolled in each of the expansion cohorts, including urothelial cancer, NSCLC, TNBC, cervical cancer, and MSS CRC cohorts. For urothelial cancer and NSCLC, patients who received previous treatment of anti-PD-1/PD-L1 therapy will be enrolled. For the other three cancer types, patients who did not receive anti-PD-1/PD-L1 treatment but progressed on standard of care will be enrolled. The trial is primarily designed to evaluate the safety and tolerability and determine the DLT of this combination therapy. Secondary objectives include ORR, PFS, DoR, and OS.

Trial status and future plan. As of December 31, 2022, we were in the dose expansion stage with 54 patients enrolled in the U.S. and France. We expect to obtain results of this trial in the second half of 2023, in which we aim to identify specific cancer types sensitive to this combination based on the results. We will then proactively communicate with the regulatory authorities for the design of Phase II/III registrational trials.

Market opportunities

Although anti-PD-1/PD-L1 therapy has been primarily used to treat patients with NSCLC and urothelial cancer, current treatments are still unable to meet the needs of patients who have progressed on anti-PD-1/PD-L1 therapy. According to Datamonitor Healthcare, incidences of NSCLC treated with anti-PD-1/PD-L1 therapy in 2021 reached approximately 84,000 in the U.S., and approximately 201,590 in seven major markets of the U.S., the U.K., Germany, France, Italy, Spain, and Japan. Around 70 – 80% of NSCLC patients would progress after anti-PD-1/PD-L1 treatment, with approximately 59,000 patients in the U.S. and 141,000 patients in seven major markets. Incidences of urothelial cancer treated with anti-PD-1/PD-L1 therapy in 2021 reached approximately 18,000 in the U.S., and approximately 27,517 in seven major markets. Around 80 – 90% of urothelial cancer patients would progress after anti-PD-1/PD-L1 treatment, with approximately 14,000 patients in the U.S. and 22,000 patients in seven major markets. Furthermore, current treatments are limited for MSS CRC, TNBC, and cervical cancer after standard of care treatment. According to Datamonitor Healthcare, in 2021, the incidences of MSS CRC, TNBC and cervical cancer after standard of care treatment reached approximately 30,000, 4,074, and 5,800, respectively, in the U.S., and 113,000, 15,747, and 15,600, respectively, in the aforementioned seven major markets. Effective treatments are therefore urgently needed to address these unmet medical demands.

Competitive landscape

Our Phase Ib study for AN0025 in combination with pembrolizumab is in dose expansion stage to evaluate preliminary efficacy in patients with the progression after standard of care treatment. Based on our knowledge, there are several programs also in early clinical development targeting EP4, including those run by Ono Pharmaceutical Co., Ltd./BMS (ONO-4578/BMS-986310), Ikena Oncology Inc. (Grapiprant (IK-007)), Rottapharm Biotech S.r.l. (CR6086), Tempest Therapeutics Inc. (TPST-1495), Shenzhen Ionova Life Science Co., Ltd. (INV-1120), Shanghai Yuyao Biotech Ltd. (YY001), and Keythera (Suzhou) Pharmaceutical Co., Ltd. (KF-0210).

Triple combination of AN2025, AN0025, and Tecentriq, or atezolizumab: an example of our combination therapy strategy

Overview

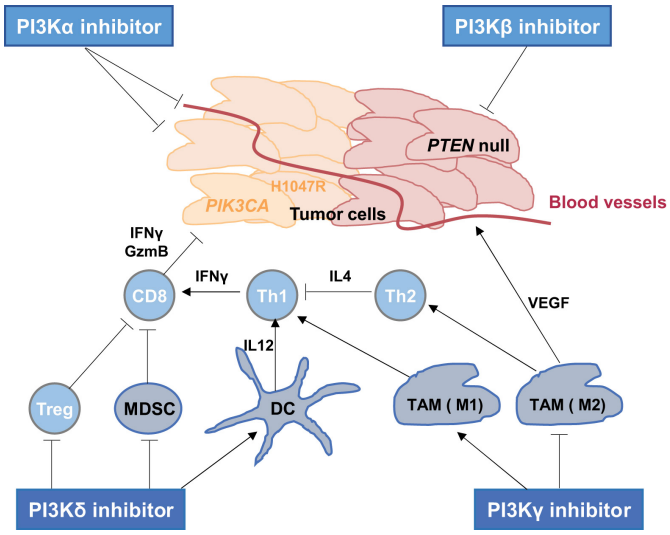
To fully explore the potential of AN2025 and AN0025, we initiated a study of the triple combination of AN2025, AN0025, and an anti-PD-1/PD-L1 antibody for the treatment of solid tumors. This study exemplifies

our combination therapy strategy to achieve synergistic effects of targeted therapy and immunotherapy. In different tumor-hearing mouse models, we have consistently observed significantly stronger antitumor activity in the triple combination of AN2025, AN0025, and an anti-PD-1 antibody compared with the doublet combinations. We initiated a Phase I clinical trial to evaluate the triple combination of AN2025, AN0025, and atezolizumab, for a variety of PIK3CA mutant solid tumors. For more details, see "— License and collaboration agreements — Supply agreement with Roche". In September 2022, subsequent to the doublet arm dose-ranging studies, we initiated a dose-ranging study for the triple combination, and we expect to identify RP2D from this Phase I clinical trial in the second quarter of 2023.

Rationale of triple combination design

Immune checkpoint inhibitors, such as anti-CTLA-4 and anti-PD-1/PD-L1 antibodies, have revolutionized cancer treatment. However, there are still a significant number of cancer patients who do not respond to immune checkpoint inhibitors. One hypothesis explaining this phenomenon is that the tumor immunosuppressive microenvironment can cause resistance to immune checkpoint blockade. It is now increasingly accepted that the tumor microenvironment contributes to cancer cells' escape from immunosurveillance. Although immune checkpoint inhibitors can block the interaction between cancer cell and T cells to enable T cells recognize and kill cancer cells, T cells may not be able to reach the targets through the microenvironment that harbors the tumor (for example extravasate from tumor blood vessels and infiltrate barriers such as stromal tissue) to reach the cancer cells, which necessitates an improved combination therapy regimen that could further exploit the immune system for cancer treatment.

As a pan-PI3K inhibitor, AN2025 targets not only PI3K mediated tumorigenesis (e.g., via inhibition of PI3Kα/PIK3CA mutants) but also the immunosuppression of the tumor microenvironment (e.g., via inhibition of PI3Kδ and PI3Kγ). PI3Kδ is well established to control the function and integrity of Tregs, whereas both PI3Kδ and PI3Kγ help recruit suppressive myeloid cells (including tumor-associated macrophages (TAMs) and MDSCs) into the tumor microenvironment and also strengthen their inhibitory effects on antitumor T cell immune responses. As Tregs and suppressive myeloid cells are key contributors to immunosuppression within the tumor microenvironment, targeting PI3Kδ and PI3Kγ provides an excellent opportunity to improve the antitumor immune response. As targeting the tumor-promoting microenvironment, especially those suppressive immune cells inside become an attractive way to promote antitumor immune response, agents like PI3Kδ and PI3Kγ inhibitors (such as AN2025) could serve as great combination partners for the checkpoint inhibitors in the field of cancer immunotherapy.



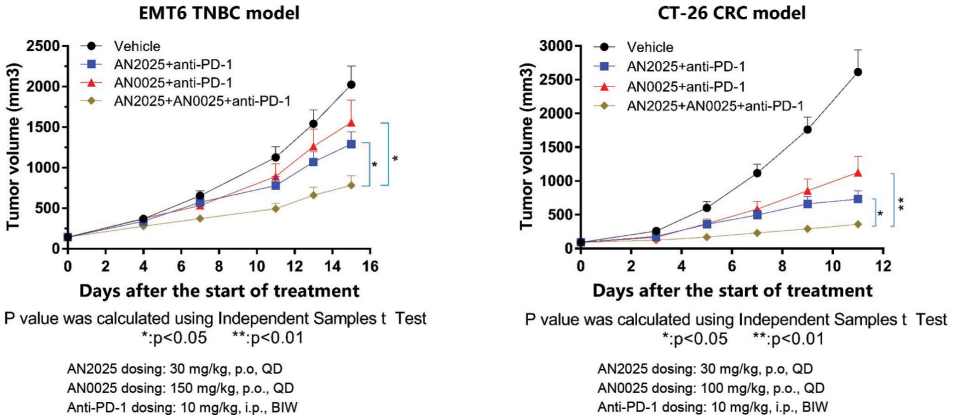
Leveraging the complementary and synergistic antitumor effects of our drug candidates in combination therapies, AN2025 is expected to mechanistically complement and synergize with the combination of anti-PD-1/PD-L1 antibody and AN0025 to form an improved treatment regimen for patients with multiple advanced solid tumors.

Summary of preclinical results

By targeting Tregs as well as tumor-promoting myeloid cells in the tumor microenvironment, AN2025 is designed to mechanistically synergize with the combination of anti-PD-1/PD-L1 antibody and AN0025 to improve the treatment of advanced solid tumors.

We conducted preclinical studies of the triple combination of AN2025, AN0025, and an anti-PD-1 antibody, and observed encouraging antitumor activity in the following studies. As illustrated by the figures below, the triple combination showed significantly stronger TGI compared with doublet combinations in syngeneic mice models:

Triple combination of AN2025, AN0025, and anti-PD-1 antibody in syngeneic mice models



P value was calculated using Independent Samples t Test
*:p<0.05 **:p<0.01

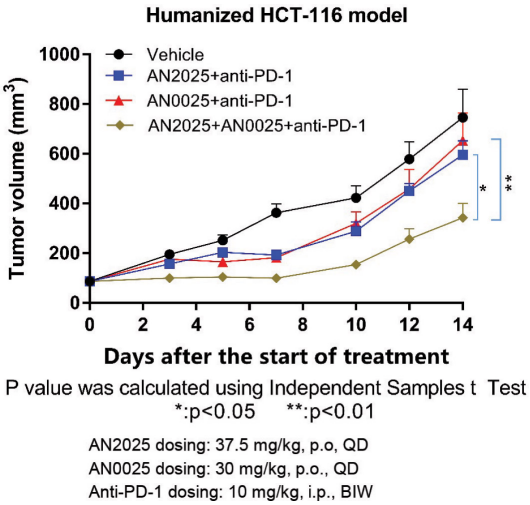
AN2025 dosing: 30 mg/kg, p.o, QD
AN0025 dosing: 150 mg/kg, p.o., QD
Anti-PD-1 dosing: 10 mg/kg, i.p., BIW

P value was calculated using Independent Samples t Test
*:p<0.05 **:p<0.01

AN2025 dosing: 30 mg/kg, p.o, QD
AN0025 dosing: 100 mg/kg, p.o., QD
Anti-PD-1 dosing: 10 mg/kg, i.p., BIW

In another humanized mice model, the triple combination also demonstrated superior anti-tumor activities to the doublet combinations.

Triple combination of AN2025, AN0025, and an anti-PD-1 antibody in humanized mouse models



Summary of clinical trial results

Phase Ia clinical trial of AN2025, AN0025, and atezolizumab, in patients with advanced solid tumors

Trial design. The trial is a Phase Ia, multi-center, open-label clinical trial study in patients with locally advanced or metastatic cancer that were previously treated with one to four lines of therapy. This trial is conducted in the U.S. It consists of three DLT observations I, II, and III. Observations I (AN2025 + atezolizumab) and II (AN0025 + atezolizumab) are double combination treatments, which will be conducted in parallel, whereas observation III (AN2025 + AN0025 + atezolizumab) will be initiated only after a thorough review of the safety data from observations I and II.

Primary objectives of this trial are to evaluate the safety and tolerability of the double combinations (observations I and II) and triple combination (observation III) in patients with advanced solid tumors. Secondary objectives include studying of ORR, PFS, DoR, OS, and efficacy by PI3KCA mutation in observations I and III.

Trial status and future plan. In September 2022, subsequent to the doublet arm dose-ranging studies, we initiated a dose-ranging study for the triple combination, and we expect to identify RP2D from this Phase I clinical trial in the second quarter of 2023.

Market opportunities

Mutations in PIK3CA are associated with high rates of mutations in important cancer-associated pathways such as the tyrosine kinase receptors/K-Ras/BRAF/MAPK and the Wnt/β-catenin pathway. PIK3CA mutations are found in approximately 13% of all solid tumors globally, including 25% to 40% of cervical cancer, 30% to 40% of breast cancer, 30% to 35% of endometrial cancer, 30% of ovarian cancer, 24% of urothelial cancer, 20% of colorectal cancer, and 10% to 20% of HNSCC globally, indicating a large addressable market and significant commercial potential. To date, only Novartis' Piqray® has been approved for the treatment of breast cancer with a PIK3CA mutation (in combination with hormonal therapy fulvestrant), and thus treatment options for patients with PIK3CA mutant solid tumors around the world are limited.

Competitive landscape

To our knowledge, we believe that we are the first to explore the combination of PI3K inhibitor, EP4 antagonist and checkpoint inhibitor for the treatment of advanced solid tumors in a clinical trial.

AN4005: a backbone for our future oral combination therapies

Overview

AN4005 is an in-house developed, oral small-molecule PD-L1 inhibitor. In our preclinical studies, AN4005 was well tolerated and exhibited excellent TGI when compared to an approved anti-PD-L1 antibody and promoted an adaptive immune response for antitumor activity. In view of the encouraging preclinical data, we entered into a collaboration agreement assigning the related patent rights to develop, manufacture, and commercialize AN4005 in China to Xiamen Biotime Biotechnology Co., Ltd., reserving the exclusive rights to explore AN4005 in the rest of the world. For more details, see "— License and collaboration agreements — Collaboration with Biotime". We received IND clearance from the FDA and NMPA for AN4005 for the treatment of advanced tumors in June 2021 and December 2021, respectively, and dosed the first patient in January 2022. We expect to identify the RP2D in the second half of 2023.

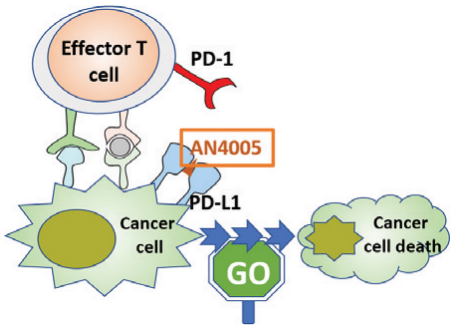
Mechanism of action

The immune system defends the human body against foreign objects. To function properly, it needs to be able to differentiate between normal cells in the body and those considered "abnormal" or "foreign" (such as cancer cells). Part of how the immune system does this is through "checkpoint" proteins on the surface of immune cells. Checkpoints act like switches that need to be turned on or off to start an immune response. However, cancer cells sometimes manage to escape attacks by the immune system through certain interactions with these checkpoints.

T cells play a key role in the human immune system and fight cancer. The ultimate function of T cells relies on the balance between the activating and suppressing pathways. PD-1 is a checkpoint protein found on the surface of T cells. It interacts with its ligand, PD-L1, a protein usually found on the surface of normal cells. The interaction between PD-1 and PD-L1 will activate the downstream signals of PD-1 and suppress T cell activation. Therefore, PD-1 usually acts as an "off switch" that prevents T cells from attacking normal cells of human body.

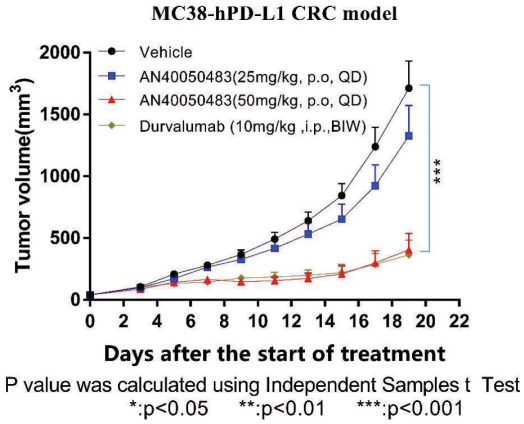
However, like normal cells, a wide range of cancer cells also express PD-L1 protein on the cell surface and sometimes in a vast amount. As a result, cancer cells can pretend to be normal cells by interacting with PD-1 on the T cells through their cell surface PD-L1 and thus avoid being attacked by the T cells.

AN4005 is a small-molecule PD-L1 inhibitor, which is designed to induce and stabilize PD-L1 dimerization to disrupt the protein-protein interactions between PD-1 and PD-L1.

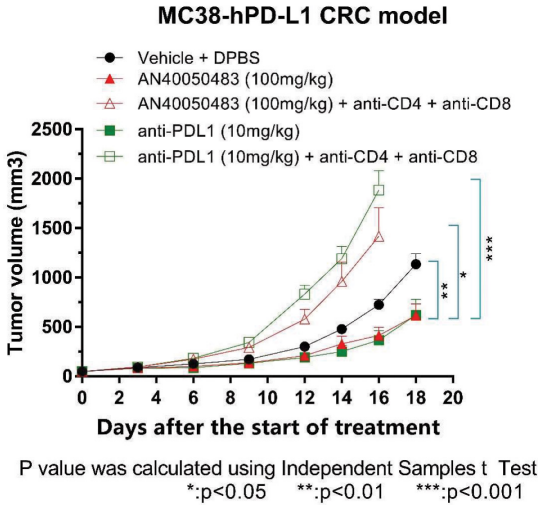


Summary of preclinical results

In our preclinical studies, AN4005 demonstrated excellent antitumor activity in the MC38-hPD-L1 syngeneic mouse model. AN4005 (50 mg/kg, QD) showed significant TGI compared with the vehicle control. Furthermore, AN4005 (50 mg/kg, QD) showed a comparable effect in antitumor activity as durvalumab, an FDA-approved anti-PD-L1 antibody developed by Medimmune/AstraZeneca, as both agents inhibited the tumor growth to a similar extent.



The anti-tumor activities of AN4005 were convincingly demonstrated to be stringently dependent on the immune system, as depletion of the T cells (both $CD4^+$ and $CD8^+$ T cells) in mice abolished AN4005's antitumor activity, a phenomenon that was similarly observed in anti-PD-L1 antibody treated subjects as well.



Summary of clinical trial results

Phase I study for AN4005 monotherapy in advanced tumors

Trial design. The trial is a Phase I, multi-center, open-label clinical trial study in patients with advanced solid tumors. This study is designed to determine a RP2D/MTD. The study is conducted in the U.S. and China in approximately 31–36 patients, and the actual enrollment number will depend upon the identified safe dose. Once RP2D/MTD dose level has been determined, we will recruit additional patients in China to confirm the RP2D/MTD in the Chinese population as required by local regulatory authorities. Dosing will begin with dose level 0 (50 mg BID) and proceed to escalated dose levels of 100 mg BID, 200 mg BID, 400 mg BID, and 600 mg BID, successively. Dose escalation is conditioned upon the finding that the current dose is well tolerated at the completion of the cohort.

Primary objectives of this trial are to evaluate the safety and tolerability of AN4005. Secondary objectives include studying of PK/PD, ORR, PFS, DoR, complete remission rate ("CRR"), and OS.

Trial status and future plan. The first U.S. patient was dosed in January 2022 and the first Chinese patient was dosed in July 2022. We expect to identify RP2D from the Phase I clinical trial in the second half of 2023.

Market opportunities

Immunotherapies blocking the immune checkpoint PD-1/PD-L1 have achieved a significant success in treating various types of cancers. In the past few years, several monoclonal antibodies ("mAbs") targeting PD-1 or PD-L1 have been approved for clinical use by the FDA, which exhibit significant benefits with durable clinical responses and acceptable treatment-related toxicities in several types of solid tumors. Although these mAbs have transformed cancer immunotherapy, they still have several disadvantages such as low permeability to tumors, immunogenicity, complex production process, high manufacturing and treatment costs and immune-related AEs due to very long half-life. Therefore, developing small-molecule inhibitors as an alternative to antibodies to interrupt the PD-1/PD-L1 pathway has emerged as an important area of research in cancer immunotherapy. The small molecule PD-L1 inhibitors are expected to bring a number of benefits over antibodies, such as amenability for oral administration, lower production costs, improved tumor penetration, and lack of immunogenicity.

Competitive landscape

Our Phase I study for AN4005 monotherapy in advanced tumors is in the dose escalation stage. Based on our knowledge, there are several oral small-molecule PD-L1 candidates also in early development stage, including those developed by Incyte, Corp., Chemocentryx Inc. (acquired by Amgen Inc. in August 2022), Maxinovel Pharmaceuticals Co., Ltd., Abbisko Cayman Ltd., Ascletis Pharma Inc., Betta Pharmaceuticals Co., Ltd., and Chase Sun Pharmaceutical Co., Ltd. INCB086550, developed by Incyte, is the globally first small-molecule PD-L1 inhibitor to enter the clinical trial. Although the clinical development of this molecule has been terminated due to likely compound-specific peripheral neuropathy, preliminary efficacy of this molecule in tumor types known to be responsible to anti-PD-1/PD-L1 antibody is encouraging and warrants further investigation to develop small-molecule PD-1/PD-L1 inhibitors.

Our preclinical programs

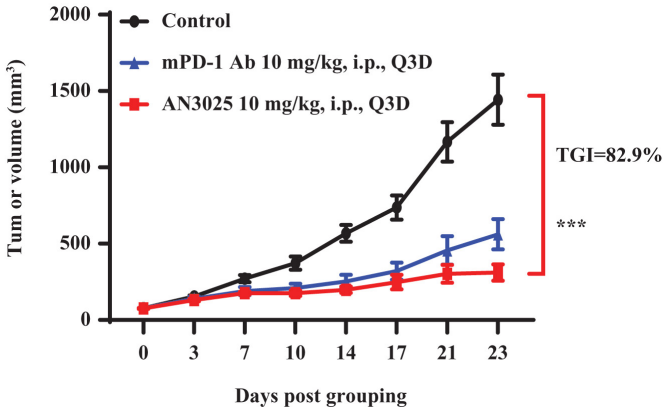
AN3025:an anti-TNFR2 mAb

AN3025 is an in-house developed anti-TNFR2 mAb. Its discovery was published in Frontiers in Immunology, a leading journal publishing rigorously peer-reviewed research across basic, translational, and clinical immunology. We are conducting IND enabling work for AN3025 and expect to submit an IND application in the second half of 2023.

Tumor necrosis factor ("TNF") is a key regulator of the immune system that initiates and orchestrates inflammation. Elevation of TNF expression and signaling has been associated with different autoimmune diseases. TNF is also a cytokine produced by T helper cells, natural killer cells and neutrophil, which can induce tumor cell apoptosis to inhibit tumor growth and viral replication, especially when accumulated at high concentration in a local tumor environment or viral infection site. This property can be employed as an anti-cancer therapy. TNF exerts its effect through two receptors, TNFR1 and TNFR2. TNFR2 is found typically in cells of the immune system and responds to the membrane-bound form of the TNF homotrimer. Upon binding to TNF ligand, TNFR2 results in recruitment of the TNF receptor-associated factor 2 ("TRAF2") and stimulates the pro-survival nuclear factor kappa B ("NF-κB") pathway, contributing to immune regulation and tissue regeneration.

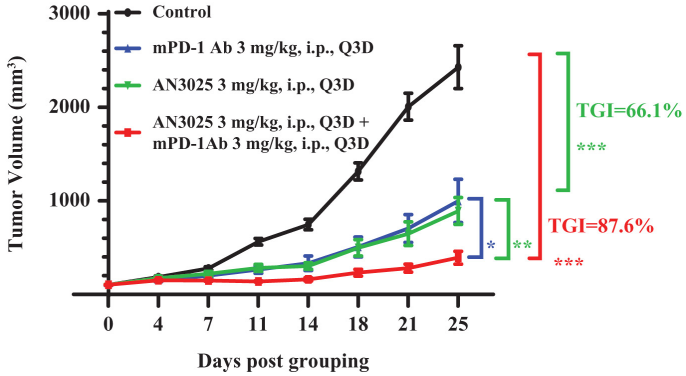
AN3025 demonstrated promising antitumor activity in MC38-hTNFR2 syngeneic mouse model. AN3025, as another mechanism of immune checkpoint inhibitor besides PD-1/PD-L1 pathway, showed comparable TGI compared to the mouse anti-PD-1 antibody.

Antitumor effects of single agent AN3025 in MC38 tumor bearing hTNFR2 mouse model



In addition, AN3025 in combination with anti-mouse PD-1 antibody demonstrated stronger *in vivo* antitumor activity than either monotherapy.

Antitumor effects of single agent AN3025 in combination with anti-mouse-PD-1 antibody in MC38 tumor bearing hTNFR2 mouse model



The unique biology and expression pattern of TNFR2 make it an attractive drug target for cancer therapy. Firstly, TNFR2 expresses on a subset of Tregs and MDSCs that can activate the proliferation of these cells through the NF-KB pathway. TNFR2 positive Treg has been shown to be most suppressive among all Treg population in tumor. Secondly, TNFR2 is also abundantly expressed on the surface of many human tumors. TNFR2 blocking antibody is expected to relieve TNFR2 positive tumor-infiltrating Tregs mediated immunosuppression and directly kill TNFR2-expressing tumors. Lastly, mice lacking the TNFR2 gene failed to progress to systemic autoimmunity but have shown improved immune responses to tumors due to the lack of TNFR2- expressing Tregs.

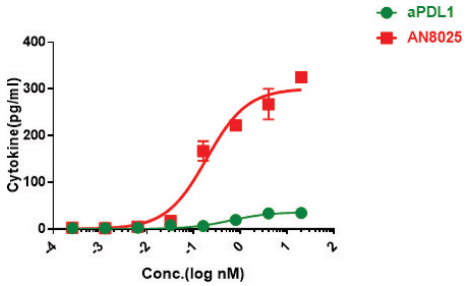
In view of the promising preclinical data, we have entered into a collaboration agreement assigning the related patent rights to develop, manufacture, and commercialize AN3025 in China to Xiamen Biotime Biotechnology Co., Ltd. For more details, see "— License and collaboration agreements — Collaboration with Biotime".

AN8025: a T cell and APC modulator

AN8025 is an in-house developed multifunctional antibody, which serves as a T cell and APC modulator. We are currently in the lead optimization stage and expect to submit the IND in the first half of 2024.

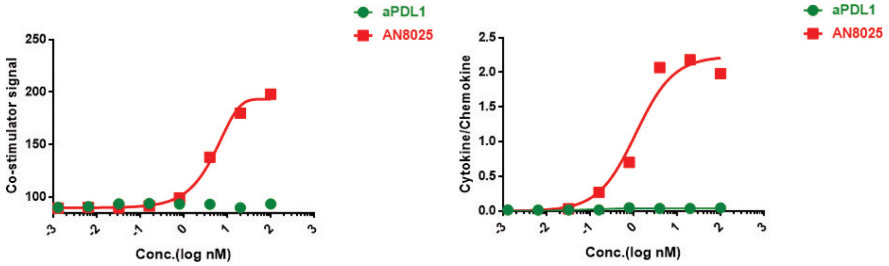
To confirm the ability of AN8025 to stimulate T cell activation, we conducted an enzyme-linked immunosorbent assay ("ELISA") to measure cytokine concentrations *in vitro*. The results demonstrated that AN8025 provides almost eight times cytokine concentration induced by an anti-PD-L1 mAb.

Comparison of T-cell activation by AN8025 and anti-PD-L1 mAb



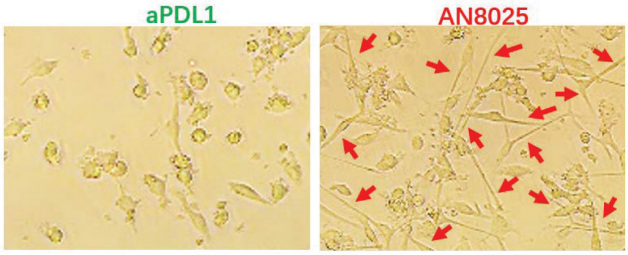
We also tested the T cell co-stimulation and relevant cytokines/chemokines to determine and compare AN8025's ability to fully induce immune response *in vitro*. Compared to an anti-PD-L1 mAb, where almost no co-simulation signals were detected, AN8025 showed significantly stronger co-stimulation signals, which represented enhanced interactions between T cells and APC.

Comparison of immune response induction by AN8025 and anti-PD-L1 mAb



Furthermore, the micrograph result revealed that AN8025 induced the maturation of more primary DC than an anti-PD-L1 mAb. The results showed that AN8025 improved the quantity and quality of antigen presenting cells.

Comparison of dendritic cell maturation by AN8025 and anti-PD-L1 mAb

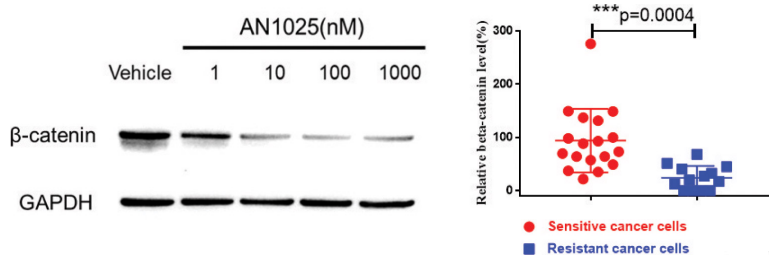


AN1025: a β-catenin degrader

AN1025 is an in-house developed, oral small molecule degrader of β-catenin, which is currently in the lead optimization phase. Wnt/β-catenin pathway is one of the key tumor-promoting signaling cascades that regulate cell cycle progression, epithelial-mesenchymal transition, angiogenesis, stemness, and tumor immune microenvironment. Aberrant activation of Wnt signaling as a result of genetic mutation has been linked to different cancers. Therefore, this pathway represents a promising target for therapeutic intervention.

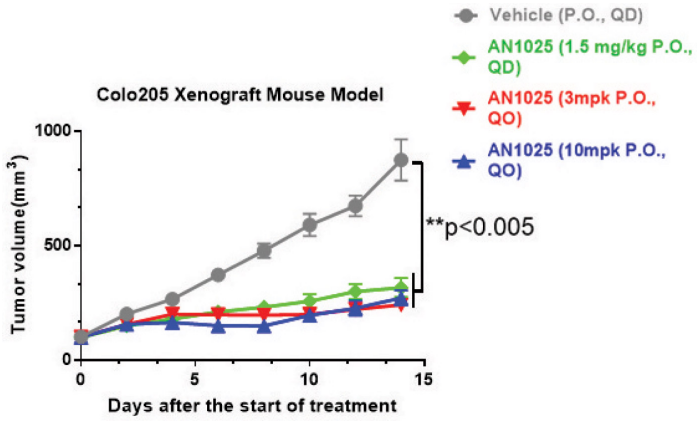
In our preclinical studies, we demonstrated that AN1025 efficiently inhibited Wnt signaling with a low nanomolar IC_{50}. AN1025 treatment led to the reduction of β-catenin (a key component in Wnt signaling pathway) level in tumor cells. In addition, human cancer cell lines with high β-catenin expression were more sensitive to AN1025, when compared with those having low β-catenin expression, suggesting that β-catenin could serve as a biomarker of sensitivity to AN1025.

β-catenin expression is sensitive to AN1025's anti-tumor effects



In addition, we also demonstrated that AN1025 showed dose-dependent anti-tumor activities in colo205 xenograft mice models. As shown below, after a 14-day treatment, the tumor volume in subjects administered with AN1025 (1.5 mg/kg, QO) was around 62% less than the tumor volume in the control group.

Antitumor effects of AN1025 in colo205 xenograft mice model



AN6025: an HPK1 inhibitor

AN6025 is an in-house developed, oral small-molecule HPK1 inhibitor, which is currently in the lead optimization phase. Inhibiting kinase activity of HPK1 results in activation of antigen presenting properties of DC and stimulates maturation and proliferation of T cells. Therefore, small-molecule inhibitors could serve

as a novel agent to transform cold and resistant tumors into hot sensitive tumors and provide additional benefit in combination with existing immunotherapies.

Other programs

AN1004

Pelareorep, or AN1004, is an intravenously delivered oncolytic virus. We own the exclusive rights to AN1004 in China, Singapore, and South Korea through an in-licensing agreement with Oncolytics Biotech, Inc. Ongoing phase Ib clinical trial of AN1004 in combination with atezolizumab and gemcitabine/nab-paclitaxel demonstrated encouraging results as first-line treatment in advanced or metastatic pancreatic ductal adenocarcinoma cancer ("PDAC''), demonstrating ORR of 69% that is substantially higher than historical response rate (ORR~25%) reported for PDAC patients treated with gemcitabine/nab-paclitaxel. In addition, a Phase II clinical trial of AN1004 in combination with paclitaxel in patients with HR+/HER2- metastatic breast cancer ("mBC") showed that adding AN1004 to paclitaxel has significantly increased the median OS from 10.8 months in the paclitaxel group to 21 months in the combination group. AN1004 has been administered to ≥1100 patients, and was well tolerated with most AEs of grade 1 or 2. We are conducting a bridging trial in China to assess the safety and tolerability of AN1004 in combination with paclitaxel for the Chinese patient population with HR+/HER2- mBC and obtained the safety and efficacy data of this bridging trial in December 2022.

AN0025 in combination with RT/CRT for the treatment of rectal cancer

In addition to evaluating the combination of AN0025 and pembrolizumab for the treatment of advanced solid tumors, we also completed a Phase Ib study to evaluate AN0025 in combination with RT/CRT for the treatment of preoperative rectal cancer where primary resection without chemoradiotherapy is unlikely to achieve clear margins. We presented encouraging interim results of this trial cut off on August 8, 2019 at the European Society for Medical Oncology ("ESMO") in October 2019. In particular, the combination therapy with AN0025 and RT/CRT reported an exceptionally high clinical complete response ("cCR") of 20%, indicating surgery is no longer required for these patients, as well as a high pathologic complete response ("pCR") of 16%, indicating no residual tumors were found in these patients after the surgery. The promising results from the Phase Ib study warrants further development.

Research and development

We believe that R&D is key to driving our therapeutic strategy and maintaining our competitiveness in the biopharmaceutical industry. Our in-house research and development function had 90 members with extensive drug discovery and development experience as of December 31, 2022. Around 82% of our research and development team members have master or doctorate degrees in biology or chemistry related majors. Leveraging our strong research and development capabilities, we have developed a pipeline with significant potential.

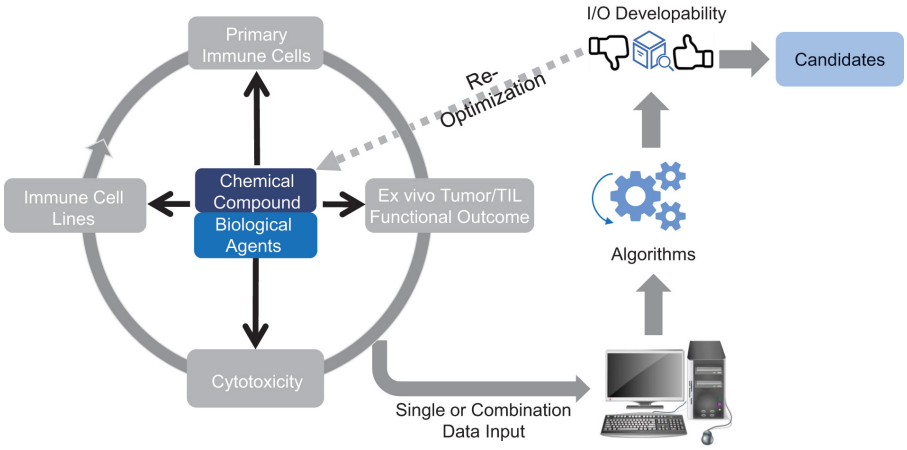
In addition to our R&D team, we have established our scientific advisory board with both industrial and academic leadership experience. It currently comprises five distinguished scientists and key opinion leaders. Chaired by Dr. Ronald M. Evans, the inaugural members are leading experts in the areas of oncology, clinical science, and life science investment. All members of our scientific advisory board serve to provide scientific portfolio and project strategy advice to us, including the evaluation of research and development strategies and plans.

Drug discovery platforms

Spanning the full spectrum from target identification to clinical development, our in-house drug discovery platforms deploy a suite of powerful and specialized techniques and know-how. They consist of the following two platforms: PAINT-2D™ platform (i.e., the Platform for AN's Immune Therapeutics Discovery and Development) and ANEAT-Id™ platform (i.e., AN's high-Efficiency Antibody Technology for Identification/Development).

PAINT-2D™ platform (the platform for AN's immune therapeutics discovery and development)

PAINT-2D™ platform is our proprietary platform equipped with "one-stop" functionalities for the early-stage development of immuno-oncology therapies, and enables us to study the functions of immuno-oncology therapies and their effects on immune cells in an efficient manner, as well as to evaluate the combination potential of different immuno-oncology therapies and the toxicity and AEs for different combination regimens. The following flowchart illustrates the functions of the PAINT-2D™ platform:

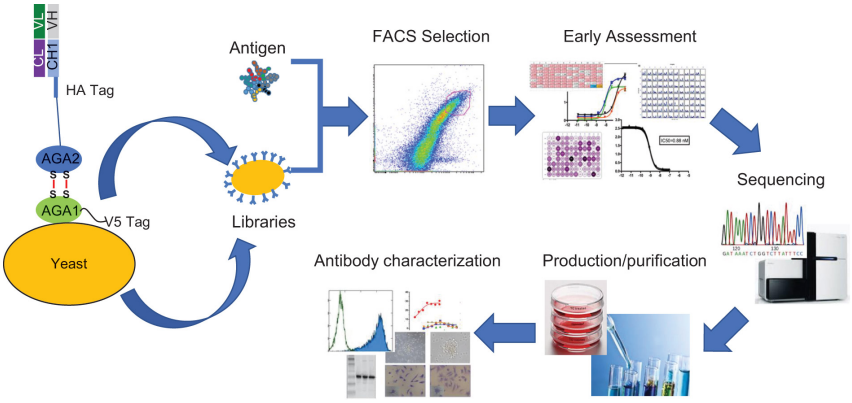


The platform begins with chemical compounds or biological agents first being tested *in vitro* in immune cell lines and/or primary immune cells to assess the preliminary activity as well as cytotoxicity. The effects of activity and cytotoxicity of potential candidate molecules are further tested in more physiologically relevant immune cells, which are tumor infiltrating lymphocytes ("TIL") collected from tumors *ex vivo*. Data from those tests are evaluated using established algorithms, which are generated through comprehensive data analyses of clinical immune related drugs (either approved or unapproved) after being tested in similar assays. If compounds show favorable efficacy/cytotoxicity profiles (or benefit/risk ratios) similar to those of approved drugs, they might be considered to move on for extensive preclinical evaluation before going into clinical trials. Otherwise, they will be sent back and further optimized until they pass the evaluation.

By utilizing immune cell lines, primary immune cells, and *ex vivo* tumor/tumor-infiltrating lymphocyte (TIL), our PAINT-2D™ platform can perform a series of assays to comprehensively assess (i) the effects of immuno-oncology drugs on the functioning of immune cells, including T-cells, B-cells, dendritic cells, monocytes, and macrophages, and (ii) the combination potential and off-target effects for different immuno-oncology drugs. This allows us to (i) thoroughly optimize the efficacy and undesired AEs of drug candidates to maximize their efficacy in immuno-oncology, (ii) fully assess the combinational synergies between different drugs in preclinical stages, and (iii) potentially correlate preclinical output with clinical performance using data generated internally. This platform is expected to lead to optimal candidate molecules and combination regimens to potentially reduce the risks associated with subsequent clinical trials.

ANEAT-Id™ platform (AN's high-efficiency antibody technology for identification / development)

ANEAT-Id™ platform is a highly efficient and robust yeast display system that is dedicated to therapeutic antibody discovery and development. The following flowchart illustrates the functions of our ANEAT-Id technology:



The platform operation begins with the antigen of interest first being incubated with an antibody library displayed on the surface of yeasts. Preliminary binders are selected and enriched via flow cytometry-based sorting. After several rounds of selection and enrichment, strong binders are subjected to early assessment to identify functional candidates, which are further sequenced to obtain detailed information of the preliminarily selected antibodies. The candidates are then expressed and purified for extensive characterization *in vitro* and *in vivo*, where those with good *in vitro* and *in vivo* activities are moved to further preclinical evaluation.

This yeast display technique-based antibody platform in combination with flow cytometry allows for high-throughput, and high-speed detection and selection of appropriate antibody candidates. It features by (i) a super-sized library of over 50 billion human antibodies, (ii) high display efficiency to successfully express antibodies on yeast surface, (iii) a display/secretion switchable design to allow flexibility in small-scale antibody purification and subsequent functional test, and (iv) various developability assessment tools to minimize risks in late-stage development. We are utilizing our ANEAT-Id technology to facilitate and speed therapeutic antibody R&D.

Research and development for in-licensed drug candidates

We promptly commence research and development activities after in-licensing drug candidates from our licensing 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 approval, and (ii) the preparation of clinical trials. We also engage third-party service providers, such as CROs to manage the day-to-day execution of clinical trials under the close supervision and management of our research and development team and clinical development team. We set up standards of project management and clinical operations, and give detailed instructions and guidance to such third parties. Additionally, we invite leading experts in relevant areas to share their expertise in R&D of drug candidates, and arrange training sessions for potential investigators in preparation for the clinical trials.

Competition

The pharmaceutical and biopharmaceutical industries are highly competitive and subject to rapid and significant change. While we believe that our pipeline of innovative drug candidates in clinical and preclinical trials, strong R&D capability, integrated platform and cohesive leadership team provide us with competitive advantages, we face potential competition from many different sources working to develop therapies targeting the same indications against which we develop our drug candidates, in particular in the immuno-oncology field. These include major pharmaceutical companies as well as specialty pharmaceutical and biotechnology companies, academic institutions, government agencies, and research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing drugs and with any new drugs that may become available in the future.

License and collaboration agreements

Collaboration with Novartis

On December 22, 2017, we entered into a license agreement (as amended, the "Novartis Agreement") with Novartis, a global pharmaceutical company regarding the worldwide development and commercialization of products containing AN2025 as an active ingredient (the "Novartis Licensed Product(s)").

Pursuant to the Novartis Agreement, Novartis granted us (a) an exclusive, royalty-bearing, sublicensable, assignable worldwide license under Novartis' certain know-how and patent rights related to AN2025 (the "Product-Specific Patents"), and (b) a non-exclusive, royalty-bearing, sublicensable, assignable license under Novartis' certain platform patents (the "Platform Patents"), in each case of (a) and (b), to develop and commercialize the Novartis Licensed Products for therapeutic, prophylactic and/or diagnostic uses in humans (the "Novartis Licensed Field") worldwide and to manufacture and have manufactured AN2025 for use in Novartis Licensed Products in the Novartis Licensed Field worldwide. Novartis and its affiliates retain or share full and unencumbered rights under all relevant patents and know-how for AN2025 worldwide outside the Novartis Licensed Field.

We are solely responsible for and have final decision-making authority with respect to the development, commercialization, and manufacturing of the Novartis Licensed Products in the Novartis Licensed Field worldwide. We are obligated to develop a clinical development plan for the Novartis Licensed Products that is consistent with certain clinical trials to which we have agreed with Novartis. We have shared the clinical development plan with Novartis. We are obligated to use commercially reasonable efforts to develop, manufacture, and commercialize the Novartis Licensed Products and to use commercially reasonable efforts to obtain regulatory approval for as many indications as possible, as included in the development plan. We are required to bear 100% of all costs and expenses associated with the development, commercialization, and manufacturing of the Novartis Licensed Products.

In accordance with the terms of the Novartis Agreement, Novartis is eligible to receive a series of payments from us, comprising an upfront payment, milestone payments, royalty payments, and, if any, sublicense payments. The upfront payment amounted to US$9.5 million and was paid in full in 2018. In addition we are obliged to pay to Novartis (i) regulatory milestone payments with an aggregate amount up to US$74 million upon the achievement of regulatory milestones, including dosing of the first patients in the first registrational study for Novartis Licensed Products, submission of certain applications to regulatory authorities and receipt of certain approvals from regulatory authorities for different indications; and (ii) sales-based payments ranging from US$10 million to US$100 million upon achievement of certain annual net sales targets for Novartis Licensed Products. As of June 30, 2022, we had made regulatory milestone payments of US$4 million for achievement of dosing of the first patient in the first registrational study for a Novartis Licensed Product.

In addition, under the Novartis Agreement, unless otherwise provided, during the applicable royalty term, we shall also pay royalties based on annual net sales of Novartis Licensed Products worldwide at progressive rates ranging from the mid-teens to the mid-twenties. Currently, we do not owe royalty payments to Novartis under the Novartis Agreement. The royalty term continues on a country-by-country and product-by-product basis with each such royalty term commencing on the first commercial sale in such country until the latest of (i) the expiration of the last-to-expire valid claim of any licensed patent covering such Novartis Licensed Product in such country; (ii) the expiration of regulatory-based exclusivity for such licensed product in such country; or (iii) the tenth anniversary of the date of first commercial sale of such Novartis Licensed Product in such country.

In addition, under the Novartis Agreement, in further consideration for the sublicensing rights granted to us, we shall pay to Novartis up to 50% of net profit from any payments or other consideration received by us or our affiliates in connection with the grant of any sublicense depending on the development stage of the Novartis Licensed Products at the time of occurrence of sublicense event. Currently, we do not owe any sublicense fees payable to Novartis under the Novartis Agreement.

The Novartis Agreement may be terminated (i) by either us or Novartis for the other party's uncured material breach, (ii) by us at our sole discretion with at least 90 days' prior written notice to Novartis for any

reason, or (iii) by Novartis in case of our insolvency. In the event of a termination for any reason, all rights and licenses granted to us under the Novartis Agreement shall terminate, we are obligated to cease any and all development, manufacture, and commercialization activities with respect to all Novartis Licensed Products, and all rights and licenses granted by Novartis to us shall revert to Novartis. Unless terminated earlier, the Novartis Agreement will expire, on a product-by-product and country-by-country basis, on the date of the expiration of all applicable royalty terms with respect to such Novartis Licensed Product in such country, and, in its entirety, expire upon the expiration of all applicable royalty terms with respect to all Novartis Licensed Products in all countries globally. Following expiration of the royalty term for a Novartis Licensed Product in a given country, the license granted to us with respect to the Novartis Licensed Product in such country will automatically become fully paid-up, perpetual, irrevocable, and royalty-free.

Collaboration with Eisai

In January 2018, we entered into a license agreement (the "Eisai Agreement") with Eisai Co, Ltd. ("Eisai"), concerning the products containing the compound formerly referred to as E7046 (renamed as AN0025), an EP4 antagonist, including its therapeutically-active metabolites and prodrugs (the "Eisai Licensed Products"). Pursuant to the Eisai Agreement, we obtained exclusive, sub-licensable rights and license to research, develop, manufacture, and commercialize the Eisai Licensed Products in any and all preventative, therapeutic, and/or diagnostic uses in human (the "Eisai Licensed Field"), worldwide excluding Japan, Korea, Taiwan, Thailand, India, Philippines, Indonesia, Singapore, Malaysia, Vietnam, Myanmar, Laos, and Cambodia (the "Eisai Licensed Territory"). In addition, Eisai obtained exclusive, sub-licensable rights and license under our technology invented or created under this agreement to research, develop, manufacture, and commercialize the Eisai Licensed Products outside the Eisai Licensed Territory.

Pursuant to the Eisai Agreement, we will be solely responsible for the development of Eisai Licensed Products in the Eisai Licensed Field in the Eisai Licensed Territory, and shall use commercially reasonable efforts to complete the Development Plan (as defined below) and submit for regulatory approval in specified major countries. We have formulated a high-level development plan for AN0025 towards regulatory approval (the "Development Plan") which was included as part of the Eisai Agreement. According to the Development Plan, (i) after analysis of available clinical data from the Phase I study (monotherapy and combination with chemo-radiotherapy), we can move to multiple, small scale Phase I/II studies in the U.S. to evaluate new combination therapies in ICI sensitive tumor types; (ii) we can also conduct novel study design to combine the molecule with anti-PD-1 in both PD-1 naïve and PD-1 failed patient populations; (iii) we can have early interaction with health authorities to help future registration study design and work closely with experienced KOLs to identify potential registration opportunities. Our recent development plan of AN0025 was in line with the Development Plan under the Eisai Agreement. We will bear all the costs and expenses associated with the development of the Eisai Licensed Products. In addition, we are solely responsible for sourcing the manufacturing and supplying of, and all commercialization activities for the Eisai Licensed Products in the Eisai Licensed Territory. Eisai is obliged to provide reasonable assistance to facilitate the transfer of development, manufacturing, and commercialization responsibilities to us as we request.

Under the Eisai Agreement, Eisai and we have established a joint development committee (the "JDC") to implement and oversee the development activities in the Eisai Licensed Field in the Eisai Licensed Territory and to serve as a forum for exchanging data, information and strategy regarding the Eisai Licensed Products. The JDC has equal representation from each party with a chairperson designated by us, and it shall take actions by simple majority vote with each representative having one vote. If the JDC cannot reach agreement on a matter within a specified period, such matter should be elevated to C-level executive officers of both parties; if such matter is still unresolved within a specified period after the elevation, the chairperson designated by us shall have the controlling vote unless such matter involves an amendment of the Development Plan. In accordance with the Eisai Agreement, neither us nor Eisai is allowed to directly or indirectly make, market, promote, sell, offer for sale, import, export, or commercialize any competitive product in the Eisai Licensed Field, or in-license or otherwise acquire any competitive product in the Eisai Licensed Field in the Eisai Licensed Territory.

For the period of time commencing with enrollment of the first five patients in a Phase III clinical trial for the Eisai Licensed Products pursuant to the Development Plan and ending 90 days following the completing of such Phase III clinical trial, Eisai has the option, by written notice, to notify us that it is

interested in re-acquiring the rights to develop, manufacture, and commercialize the Eisai Licensed Products in the Eisai Licensed Territory. Upon receipt of the notice, we will negotiate with Eisai on an exclusive basis for up to 90 days in good faith with regard to the terms of Eisai's exercising of its option at a fair market value.

In accordance with the terms of the Eisai Agreement, Eisai would be eligible to receive a series of payments from us, comprising an upfront payment, milestone payments, royalty payments, and, if any, sublicense remuneration payments. In terms of the upfront payment, we shall pay to Eisai an amount up to US$6.0 million, and such amount has been paid by us in May and June 2018. Moreover, under the Eisai Agreement, we are obliged to pay to Eisai milestone payments up to an aggregate amount of approximately US$367 million upon (i) the first achievement of the net sales target of Eisai Licensed Products in a rolling 12-month period; and (ii) the achievement of development milestones, including dosing of the first patient in various clinical trial stages for Eisai Licensed Products, submission of NDA or marketing authorization applications and receipt of regulatory approval for various indications. As of August 31, 2022, we had made milestone payments of US$4.0 million.

Under the Eisai Agreement, during the applicable royalty term, we will also pay royalties based on annual net sales of Eisai Licensed Products in the Eisai Licensed Territory at progressive rates ranging from low-teens to high-teens. Currently, we do not owe any royalty payments to Eisai. The royalty term continues on a country-by-country and product-by-product basis with each such royalty term commencing on the first commercial sale in such country until the latest of (i) expiration of the last-to-expire licensed patent that contains a valid claim in such country, (ii) the tenth anniversary of the date of first commercial sale of such Eisai Licensed Product in such country, or (iii) expiration of regulatory exclusivity for such Eisai Licensed Product in such country, provided that with respect to an Eisai Licensed Product being commercialized in certain major countries, the royalty term shall continue in all these countries until expiration of the last-to-expire licensed patent that contains a valid claim in these countries.

In addition, under the Eisai Agreement, if we sublicense our rights and license to a third party, we shall pay to Eisai sublicense remuneration payments at remuneration rates ranging from low-teens to mid-twenties depending on the sublicense conclusion dates. Currently, we do not owe any sublicense remuneration payments to Eisai.

Unless terminated earlier, the Eisai Agreement will continue in full force and effect on a product-by-product and country-by-country basis until (i) the expiration of the royalty term in a country if a product is commercialized within 15 years of the date of the Eisai Agreement, or (ii) the 15th anniversary of this Eisai Agreement if there has not been a first commercial sale of a product in a country within 15 years of the date of the Eisai Agreement. After expiration of the Eisai Agreement, on a product-by-product, country-by-country basis, the rights and licenses granted to us or Eisai thereunder will become irrevocable, non-exclusive, royalty-free, fully paid-up, and non-terminable. The Eisai Agreement can be early terminated by either party because of the other party's uncured material breach, bankruptcy-related events, or proceedings, or patent challenge. We may terminate this agreement if competent regulatory authority in certain major countries decides to preclude clinical use of the Eisai Licensed Products on grounds of safety. This agreement may also be terminated by Eisai if we do not use commercially reasonable efforts to perform our obligations as per the Development Plan and achieve regulatory and commercial milestones under the Eisai Agreement and the JDC fails to resolve such issue.

Supply agreement with Roche

In November 2020, we entered into a master clinical supply agreement (the "Roche Agreement") with F. Hoffmann-La Roche Ltd ("Roche") for supply of atezolizumab for clinical trials to evaluate the triple combination of our AN2025 and AN0025 and atezolizumab (the "Study").

According to the Roche Agreement, Roche will supply its atezolizumab for use in the Study at no cost unless otherwise provided in the clinical supply agreement supplement (the "CSA Supplement"), which specifies the quantities and timelines for supply of atezolizumab. As of the date of this prospectus, we had not entered into a CSA Supplement that requires us to pay for the supplied atezolizumab.

We, as the sponsor of the Study, are required to prepare a protocol of the Study (which Roche is required to review), conduct the Study, provide written updates regarding the status of the Study, and summarize the

findings of the Study in a final study report, all in accordance with applicable regulatory authority rules, regulations, guidance, our protocol, and the Roche Agreement.

All clinical data generated in the performance of the Study in accordance with the Roche Agreement belong to us as the sponsor of the Study. Roche and its affiliates are granted certain use rights in relation to such data.

Unless terminated earlier, the Roche Agreement will continue in force for five years. Either party may terminate the Roche Agreement upon 60-day prior written notice to the other party. CSA Supplements continue in effect unless separately terminated. We may terminate CSA Supplements on 60 days' notice for any reason. Roche is only entitled to terminate CSA supplements (and therefore supply) for certain limited reasons, including patient safety issues, supply constraints and material breaches by us.

Supply agreement with MSD

In January 2019, we entered into a clinical trial collaboration and supply agreement with MSD (the "MSD Agreement") to collaborate for a clinical trial to evaluate the safety and preliminary efficacy of the combination of MSD's pembrolizumab, a PD-1 monoclonal antibody (the "MSD Compound"), and our AN0025, in subjects with locally advanced or metastatic solid tumor cancers which may include but not be limited to NSCLC, MSS CRC, bladder cancer, cervical cancer, and TNBC in the territory where we have exclusive license to AN0025 ("MSD Collaborative Study").

Each party will manufacture and supply its respective compound for use in the MSD Collaborative Study and conduct its sample testing at its own costs and expenses, and we will bear all other costs associated with the conduct of the MSD Collaborative Study. We will act as the sponsor of the MSD Collaborative Study, and the parties have formed a joint development committee with equal representation from each party to coordinate all regulatory and other activities under the agreement.

All clinical data shall be jointly owned by us and MSD. Each party retains the exclusive ownership of all rights to inventions relating solely to, or covering its compound and any improvements related thereto. The parties jointly own all rights to all inventions relating to, or covering the combined use of both parties' compounds that are not either party's inventions. The parties must consult and reasonably cooperate with one another in the preparation, filing, prosecution, and maintenance of each joint patent application and equally share the expenses associated therewith. In the event that one party wishes to file a joint patent application in respect of a jointly owned invention and the other party does not want to file, or that one party wishes to discontinue the prosecution and maintenance of a joint patent application or joint patent, the non-filing/opting-out party shall assign such jointly owned invention, joint patent application, or joint patent to the filing/continuing party, and the filing/continuing party shall thereafter solely own the jointly owned invention, joint patent application, or joint patent so assigned.

Unless terminated earlier, the term of the MSD Agreement will continue in full force and effect until delivery to MSD of the final study report for the MSD Collaborative Study. In addition to each party's certain customary termination rights such as the right to terminate for the other party's uncured material breach, MSD may terminate the agreement if it in good faith believes that the MSD Compound is being used in the MSD Collaborative Study in an unsafe manner and we fail to promptly incorporate changes into the protocol requested by MSD to address such issue or to otherwise address such issue reasonably and in good faith.

Collaboration with Biotime

On November 15, 2021, we entered into a collaboration agreement with Xiamen Biotime Biotechnology Co. Ltd ("Biotime"), a biotechnology company established in 2008, focusing on the R&D, manufacturing, and commercialization of *in vitro* diagnostic devices and reagents, with respect to five products, namely our drug candidates AN4005 and AN3025, and three other early-stage programs not included in our pipeline. Under this agreement, we assigned to Biotime a list of patents and related research material, know-how, and research results generated through studies of the five products to engage in preclinical and clinical development, registration, manufacturing, and commercialization of (a) AN4005 and AN3025 in China, and (b) three early-stage programs globally.

Under this agreement, Biotime is obligated to pay an aggregated down payment of up to RMB295.0 million (approximately US$46.0 million, based on the conversion rate of RMB6.4508 to US$1.00, which was the average daily exchange rate for the year ended December 31, 2021) in relation to the patents, patent applications, know-how, data, and information of the five products. Biotime also agreed to make milestone payments in the aggregate amount of RMB835.0 million (approximately US$129.0 million, based on the conversion rate of RMB6.4508 to US$1.00, which was the average daily exchange rate for the year ended December 31, 2021) conditioned upon the achievement of certain development and sales targets. Additionally, Biotime also agrees to make payments at remuneration rates ranging from mid-single digits to mid-teens depending on the net sales of the products. As of June 30, 2022, Biotime has made down payments totaling RMB295.0 million (approximately US$46.0 million) to us.

Unless terminated earlier, the term of the agreement will continue in full force and effect. Each party enjoys customary termination rights such as the right to terminate for the other party's material breach. Specifically, Biotime is entitled to suspend performance of the agreement or terminate the agreement if we make any materially false or misleading statement that causes Biotime to not be able to perform its obligations under the agreement.

Intellectual property

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

We have a global portfolio of patents to protect our drug candidates and technologies. As of December 31, 2022, we owned or had exclusive license rights to (i) 162 granted patents and 92 pending patent applications in jurisdictions such as the U.S., EPO, mainland China, Japan, South Korea, Canada, Australia, Taiwan, Mexico, and Brazil, and (ii) 11 patent applications under the PCT that has not been nationalized.

The patent portfolios for our clinical stage lead product and other products as of December 31, 2022 are summarized below:

- ***AN2025***: As of December 31, 2022, we in-licensed 86 granted patents, including seven in the U.S., six in EPO, five in China, and 68 in other jurisdictions, including Canada and Japan, and 13 pending patent applications directed to AN2025. The expected expiration date of granted patents directed to the potential approved use of the compound is 2032, taking into account of the possible 5-year patent term extension in jurisdictions where patent term extension is available, including but not limited to U.S., Europe, and China. The term of patent extension in each jurisdiction is estimated based on the patent filing date, the patent grant date, the IND enabling date, the estimated NDA date, and FDA/EMA/NMPA approval date according to relevant regulations in each jurisdiction. In addition to the in-licensed patents, we filed two more PCT applications claiming use of AN2025 in combination therapy, which have not been nationalized yet. Even if these patents can provide us with adequate protection, after patent term expires, we may face competition from generic manufacturers. For further details, see “Risk Factors — Risk related to our business — We may face competition from generic or biosimilar manufacturers after the patent protection is no longer valid.”
- ***AN0025***: As of December 31, 2022, we in-licensed 21 granted patents, including two in the U.S., one in EPO, two in China, and 16 in other jurisdictions, including Canada and Australia, and six pending patent applications directed to AN0025. The expected expiration date of granted patents directed to the potential approved use of the compound is 2036, taking into account of the possible 5-year patent term extensions in jurisdictions where patent term extension is available, including but not limited to the U.S., Europe, and China. Similar to AN2025, the term of patent extension in each jurisdiction is estimated based on the patent filing date, the patent grant date, the IND enabling date, the estimated NDA date, and FDA/EMA/NMPA approval date according to relevant regulations in each jurisdiction. Further to the in-licensed patents, we also filed two provisional patent applications directed to a new formulation of AN0025 and a series of biomarkers to predict patients’ responsiveness to the treatment with AN0025.

The following table summarizes the details of the material patents or patent applications in-licensed/ owned by us in connection with our clinical drug candidates:

Product	Scope of patent protection	Jurisdiction	Status	Applicant	Patent Expiration[1]	Our Rights
AN2025	Directed to combination therapy	PCT	Pending	Our Group	—	Ownership
		United States			2034-05-09	
		EPO			2034-05-06	
		Mainland China	Granted	Novartis	2034-05-06	Exclusive
		Japan			2034-05-06	
		Others[2]			2034-05-06	
	Directed to formulation	United States	Granted	Novartis	2034-03-04	Exclusive
		EPO			2034-03-04	
		Mainland China	Granted	Novartis	2034-03-04	Exclusive
		Japan			2034-03-04	
		Others[3]			2034-03-04	
	Directed to process	United States			2033-10-21	
		EPO			2033-10-21	
		Mainland China			2033-10-21	
		Japan			2033-10-21	
		Others[4]			2033-10-21	
	Directed to compound	United States	Granted	Novartis	2027-12-05	Exclusive
		EPO			2027-01-22	
		Mainland China			2027-01-22	
		Japan			2027-01-22	
		Others[5]			2027-01-22	
AN0025	Directed to Biomarkers	Mainland China	Pending	Our Group	—	Ownership
	Directed to formulation	Mainland China	Pending	Our Group	—	Ownership
	Directed to combination therapy	United States	Pending	Novartis	—	Exclusive
		EPO				
		Mainland China	Granted		2035-05-21	
		Australia				
		Others[6]	Pending		—	
	Directed to compound	United States	Granted	Eisai	2031-09-12	Exclusive
		EPO			2031-09-12	
		Mainland China			2031-09-12	
		Australia			2031-09-12	
		Others[7]			2031-09-12	
AN4005	Directed to compound	PCT	Pending	Our Group	—	Ownership
		United States, EPO, Mainland China, Japan, Taiwan				

Abbreviation: PCT = Patent Cooperation Treaty

Notes:

(1) Patent expiration date is estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity, and other government fees. Patent term extension is available in certain jurisdictions, such as in the U.S., Europe, and China. The patent term restored under patent term extension is estimated based on various factors in different jurisdictions, and subject to limitations. For example, in the U.S., the maximum extension that can be obtained for a patent is limited to five years, and the total remaining patent term (with PTE) is limited to fourteen years from the date of product approval by the FDA. The patent expiration date in the table is obtained from the commercial database of Patsnap.

(2) Four countries, which are Canada, Australia, South Korea, and Russia.

(3) 16 countries and/or territories, including Canada, Australia, New Zealand, South Korea, and Singapore.

(4) Seven countries, including Canada, Australia, South Korea, and Russia.

(5) 22 countries and/or territories, including Canada, Australia, New Zealand, South Korea, and Singapore.

(6) Israel and Russia. Except for the U.S. and EPO, patent applications of combination therapy are pending in Canada and Mexico. In addition to the combination therapy patent granted in mainland China, there is another patent application directed to the combination therapy pending before the China National Intellectual Property Administration.

(7) Nine countries and/or territories, including Canada, New Zealand, and Hong Kong.

The following table summarizes the details of the material patent applications owned by us in connection with our platforms:

Platform	Title of Patent Application	Jurisdiction	Status	Applicant	Patent Expiration	Our Rights
PAINT-2D™ platform	System and method for screening and evaluating tumor immunotherapy drugs	U.S., EPO, Mainland China, and Hong Kong	Pending	Our Group	—	Ownership
ANEAT-Id™ platform	Design and construction of fully human antibody yeast display technology	U.S., EPO, and Mainland China	Pending	Our Group	—	Ownership

The term of individual patents may vary based on the jurisdictions in which they are granted. In most jurisdictions in which we file patent applications, including the U.S. and China, the term of an issued patent is generally 20 years from the filing date of the earliest non-provisional patent application to which the patent claims priority. In the United States and China, a patent's term may be extended or adjusted to account for administrative delays during prosecution by the patent offices, in excess of a patent applicant's own delays during the prosecution process.

In addition, with respect to any issued patents in the U.S., Europe, and China, we may be entitled to an extension of the patent term for up to five years, provided we meet the applicable requirements for obtaining such patent term extensions. For example, in the U.S., we may apply for a patent term extension of up to five years as compensation for the patent term lost during clinical trials and the FDA regulatory review process under the Hatch-Waxman Amendments. The exact duration of the extension depends on the time we spend in clinical studies, as well as getting an NDA or BLA approval from the FDA. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. In addition, a patent may only be extended once, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Furthermore, a new chemical entity is granted five years of data exclusivity and a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In certain other foreign jurisdictions, similar extensions as compensation for regulatory delays are also available.

We conduct our business under the brand name "Adlai Nortye" or " ". As of December 31, 2022, we had registered 69 trademarks in total. Among them, we registered 18 "Adlai Nortye" or " "

trademarks in mainland China, five in Hong Kong, one in Macau, one in Taiwan, and applied for trademark registration of "Adlai Nortye" in other eleven jurisdictions including the U.S., Canada, Europe, U.K., Australia, Japan, and South Korea and have successfully obtained registrations in Europe, U.K., Australia, Japan, and other three jurisdictions. In addition, there are nine trademark applications of "Adlai Nortye" or " " pending potential registration in the U.S., mainland China, Japan, Singapore, Australia, and South Africa. As of December 31, 2022, we were also the registered owner of one domain name.

Pursuant to the license and collaboration agreements we entered into with our collaborators, we were granted certain exclusive licenses to develop and commercialize our drug candidates, including AN2025 and AN0025. For more details, please see the paragraphs headed "— License and collaboration agreements" in this section.

As of December 31, 2022, we had not been involved in any proceedings in respect of, and we had not received notice of any claims of infringement, misappropriation, or other violations of third-party intellectual property and we are not involved in any proceedings in respect of any intellectual property rights that may be threatened or pending and that may have an influence on its research and development for any drug candidates in which we may be a claimant or a respondent.

Employees

As of December 31, 2022, we had a total of 129 employees. The following table sets forth the number of our employees categorized by function as of December 31, 2022.

Function	Number	% of Total
Research and Development	90	70
Management, Finance, Administrative and Others	39	30
Total	129	100

Among our 129 employees, 103 are stationed in China, and 26 are based in the U.S. We have not established a labor union in our New Jersey office.

We enter into individual employment contracts with our employees covering matters such as salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause, and grounds for termination. We also enter into separate confidentiality and non-competition agreements with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information about our business.

To maintain the quality, knowledge, and skill levels of our workforce, we provide continuing education and training programs, including internal and external training, for our employees to improve their technical, professional, or management skills. We also provide 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 to our employees, particularly our key employees.

We have complied with the PRC law in respect of making contributions to statutory employee benefit plans (including pension insurance, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance, and housing funds) at a certain percentage of our employees' salaries.

We consider our relations with our employees to be good, and we have not experienced any strikes or labor disputes which had a material effect on our business.

Facilities

We do not own any property but instead lease certain properties in the United States and China in connection with our business operations. As of December 31, 2022, we rent a total of 623 sq.m. of combined office and laboratory space in New Jersey, the United States. We also leased two properties in Hangzhou and one property in Shanghai, China, with an aggregate gross floor area of 5,053 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 a summary of the properties leased by us in 2022:

Location	Usage	Address	Lease Term	Gross Floor Area (sq.m)
United States	Office and laboratory	New Jersey Biotechnology Development Center, 685 US Hwy 1, North Brunswick Township, NJ 08902	July 15, 2021 to July 14, 2024*	623.20
China	Office	Building 6, No. 1008, Xiangwang Street, Yuhang District, Hangzhou, Zhejiang Province	June 1, 2020 to September 30, 2025	2,236.26
China	Office and laboratory	Building 8, No. 1008, Xiangwang Street, Yuhang District, Hangzhou, Zhejiang Province	June 1, 2020 to September 30, 2025	2,303.9
China	Office	New Bund Oriental Plaza I, Room 1702, No. 512 Haiyang West Road, Pudong New District, Shanghai	January 1, 2022 to December 31, 2024	512.71

Note:

* Such lease commenced in July 2018. We renewed the lease agreement for another three years in July 2021.

Manufacturing and supply

Our CMC capability includes the following functions: (i) chemical process: our chemical process team focuses on developing and synthesizing active pharmaceutical ingredient ("API"), expediting scale up of compound for early developmental activities in drug safety and pharmaceutical sciences, and fulfilling in a timely and efficient manner the requests for drug substance supply to support preclinical and clinical studies; (ii) formulation development: our formulation development team focuses on developing dosage forms of toxicology evaluations and preclinical and clinical trials, evaluating the physicochemical properties and bioavailability of compounds; (iii) analytical sciences: our analytical science team implements a science-driven, clinical and commercial production oriented approach to the development and application of both classic and state-of-the-art analytical techniques and tools throughout the life cycle of each of our drug candidates, including but not limited to development and validation of analytical methods for API and drug product, technical transfer of process and analytical methods, establishment of specifications, testing and releasing of each batch of API and drug products to be used in preclinical and clinical studies; and (iv) quality control and assurance: with well-documented and comprehensive quality system, the quality control and assurance team is responsible for testing and verifying the product quality with predefined standards in effort to assure the quality of all the batches, manufactured at every stage of manufacturing/processing API and drug products.

Manufacturing

We currently work with qualified CMOs to manufacture and test drug candidates for preclinical and clinical supply. In the near future, we plan to continue outsourcing the manufacturing of our drug candidates, including commercial-scale manufacturing of any approved drugs, to industry-leading, highly reputable, and qualified CMOs/CDMOs globally and in China. We have adopted, and plan to continue to implement, robust procedures in effort to ensure that the production qualifications, facilities, and processes of our CMOs/CDMOs comply with the applicable regulatory requirements and our internal guidelines and quality standards.

We may also engage additional qualified CMOs/CDMOs in the future to help ensure that we will have sufficient supply of drug candidates for our clinical trials as well as for the commercial sales of our approved drugs. When selecting CMOs/CDMOs, we plan to focus on their qualifications, relevant expertise, production capacity, reputation, track record, product quality, and production cost.

Raw materials and suppliers

We procure raw materials and equipment for the development of our drug candidates from qualified suppliers. We also work with qualified CROs and CMOs to manage and conduct preclinical and clinical studies and of our pipeline candidates, as well as the manufacturing activities, in China and the United States. Our purchases mainly include licensor, third-party contracting services for research and development of our drug candidates, and manufacturing of certain drug substances for clinical supply, as well as raw materials, consumables, machines, and equipment.

In addition, we believe that adequate alternative sources for such supplies exist and we have developed alternative sourcing strategies for these supplies. We intend to establish necessary relationships with alternative sources based on supply continuity risk assessment. Other than the agreements with certain CROs, we order supplies and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements.

Legal proceedings

We may be subject to legal proceedings, investigations, and claims arising from the ordinary course of our business from time to time, and we may also initiate legal proceedings in order to protect our intellectual property and other rights. Currently, we are not a party to any actual or threatened legal or administrative proceedings which would have a material and adverse impact on our business, financial condition, or results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

REGULATION

We are subject to a variety of U.S. and PRC laws, rules, and regulations across a number of aspects of our business. This section sets forth a summary of the most significant laws and regulations that are applicable to our current business activities within the territory of U.S. and PRC that affect the dividends payment to our shareholders.

U.S. laws and regulations

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, and biologics under the FDCA and the Public Health Service Act, or PHSA, and its implementing regulations. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. Drugs and biologics are also subject to other federal, state, and local statutes and regulations. The FDA generally requires the following before drug candidates may be marketed in the United States:

- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with Good Laboratory Practices, or GLP, regulations, where applicable;
- submission to the FDA of an IND, which must become effective before human clinical studies may begin;
- approval by an independent institutional review board, or IRB or ethics committee representing each clinical site before each clinical study may be initiated;
- performance of adequate and well-controlled human clinical studies in accordance with GCP, requirements to establish the safety and efficacy, or with respect to biologics, the safety, purity and potency of the drug candidate for each proposed indication;
- preparation of and submission to the FDA of a NDA, or biologics license application, or BLA;
- potential review of the product application by an FDA advisory committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of the initial submission of an NDA or BLA to accept the application for formal review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the proposed product drug substance is produced to assess compliance with current Good Manufacturing Practices, or cGMP, and audits of selected clinical trial sites to ensure compliance with GCP; and
- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the drug in the United States.

An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and *in vitro* studies assessing the toxicology, PK, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls, information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. Upon the date of submission of the initial IND, the sponsor must wait 30 days to allow for FDA review and comment (e.g., protocol design, proposed starting dose) before dosing the first patient under the IND. If the FDA accepts the sponsor's response to all queries, the sponsor is given agency approval via an "OK to proceed letter" for the clinical trial. If questions are not answered appropriately or the FDA has concerns, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP, which includes the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in

monitoring safety and the effectiveness criteria to be evaluated. An amendment to the existing IND or initiation of a new, separate IND must be made for each successive clinical trial or amendment to the information contained in the IND for the existing clinical trial. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical study results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- **Phase 1**. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible.
- **Phase 2**. The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger Phase 3 clinical trials.
- **Phase 3.** The investigational product is administered to an expanded patient population to further evaluate potential dose regimen(s), to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

A clinical investigation may fail at any phase. In some cases, the FDA may conditionally approve an NDA or BLA for a drug candidate on the sponsor's agreement to conduct additional clinical studies after approval, called a post-marketing requirement, or PMR or a post-marketing commitment, or PMC. The stipulations of the PMR and/or PMCs are outlined in the FDA approval letter. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the drug candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, and purity of the final product, or for biologics, the safety, purity and potency.

NDA and BLA review process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for an indication. The NDA or BLA must include all relevant data available from pertinent preclinical studies and pivotal and supporting clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing and controls and proposed labeling. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The initial indication submission of an NDA or BLA requires payment per US regulatory under the Prescription Drug User Fee Act, or the PDUFA. Subsequent submissions for additional indications, called supplements, do not have a fee associated with the Agency review.

In addition, under the Pediatric Research Equity Act, or PREA, a NDA or BLA or supplement to an NDA or BLA must contain data to assess the safety and effectiveness of the biological drug candidate 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 FDA Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any drug or biological product for an indication for which orphan designation has been granted.

Within 60 days following submission of the application, the FDA will determine if the application is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA or BLA must be resubmitted with the additional information. Once an NDA or BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is sufficient to assure and preserve the product's identity, strength, quality, and purity. Ninety (90) days after submission, the FDA generally requires the Sponsor provide a safety update report which updates more recent safety information from the patients being evaluated in the NDA or BLA. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure, and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity, and potency. When reviewing an NDA or BLA, the FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

After the FDA evaluates the NDA or BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe deficiencies that the FDA identified in the NDA or BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the NDA or BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA or BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for the indication supported by the data included in the NDA or BLA and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA or BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace.

Expedited development and review programs

The FDA offers a number of expedited development and review programs for qualifying drug candidates. For example, the fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, drug candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the drug candidate and the specific indication for which it is being studied. The sponsor of a fast track drug candidate has opportunities for more frequent interactions with the review team during product development and, once an NDA or BLA is submitted, the application may be eligible for priority review. A fast track drug candidate is eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis, with the NDA or BLA being considered complete upon submission of the final module(s). The sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

A drug candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the drug candidate, including involvement of senior managers.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a drug candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A drug candidate is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For new-molecular-entity NDAs and original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, drug candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the drug candidate has an effect on 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, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Currently, the FDA granted fast track designation to AN2025 for the treatment of recurrent or metastatic HNSCC with disease progression on or after platinum-based therapy.

Post-approval requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping,

reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA or BLA. Drug and biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls; fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products and biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Drug product marketing exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. For example, the FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing

the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

Other U.S. healthcare laws

Pharmaceutical and medical device manufacturers are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, pricing reporting, and transparency laws and regulations, as well as similar foreign laws in the jurisdictions outside the United States, including but not limited to those discussed below:

The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program. A person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation.

The federal civil monetary penalties and false claims laws, including the civil False Claims Act, or FCA, prohibit individuals or entities from, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

The federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary, if the person knows or should know it

is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity need not have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The Physician Payments Sunshine Act imposes annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers including physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members.

Moreover, analogous state and foreign laws and regulations may be broader in scope than the provisions described above and may apply regardless of payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and relevant federal government compliance guidance; require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, many of which differ from each other in significant ways, are often not pre-empted, thus further complicating compliance efforts; and restrict marketing practices or require disclosure of marketing expenditures and pricing information.

Violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, additional reporting obligations and oversight if a manufacturer becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and imprisonment.

U.S. coverage and reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing reimbursements for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

U.S. healthcare reform

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each as amended, collectively known as the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. By way of example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;

- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, or AMP, beginning January 1, 2024. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, proposed and enacted legislation and executive orders issued by the President designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

PRC laws and regulations

PRC drug regulatory regime

China heavily regulates the development, approval, manufacturing, and distribution of drugs, including biologics. The specific regulatory requirements applicable depend on whether the drug is made and finished in China, which is referred to as a domestically manufactured drug, or made abroad and imported into China in a finished form, which is referred to as an imported drug, as well as the approval or "registration" category of the drug. For both imported and domestically manufactured drugs, China typically requires regulatory approval for a clinical trial application to conduct clinical trials in China and submit China clinical trial data, prior to submitting an application for marketing approval. For a domestically manufactured drug, there is also a requirement to have a drug manufacturing license for a facility in China.

In 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Office of the Central Committee of the Communist Party of China jointly issued an Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices, or the Innovation Opinions, in October 2017. The expedited programs, the record-filing system, the prioritized review mechanism, the acceptance of foreign clinical data under the Innovation Opinions and other recent reforms encourage drug manufacturers to seek marketing approval in China first to develop drugs in highly prioritized therapeutical areas, such as oncology.

To implement the regulatory reform introduced by Innovation Opinions, the National People's Congress, the National Medical Products Administration, or NMPA, a newly formed government authority as well as other authorities, has been revising the fundamental laws, regulations and rules regulating pharmaceutical products and the industry, which include the framework law known as the PRC Drug Administration Law. In

addition, the State Council issued the Regulations for Implementation of the Drug Administration Law of the PRC, which was promulgated in 2002 and latest amended in 2019, to further implement the PRC Drug Administration Law. NMPA also has its own set of regulations for the PRC Drug Administration Law, and the primary one governing clinical trial applications, marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation, which was latest amended by NMPA in 2020.

Regulatory authorities

In the PRC, NMPA is the primary regulatory agency for pharmaceutical products and businesses. The agency was formed from the prior China Food and Drug Administration, in 2018 as part of a government reorganization. NMPA is responsible for drawing up the laws and regulations related to pharmaceuticals and medical devices, making policy planning, formulating departmental regulations, organizing the development and issuance of pharmaceutical and medical device standards, classification, and management systems, such as national formulary, and supervising the implementation.

The Center for Drug Evaluation is the technical evaluation unit for drug registration with NMPA. It is mainly responsible for conducting technical evaluation on the drugs applying for registration and verifying the relevant drug registrations.

The National Health Commission (formerly known as the National Health and Family Planning Commission), is primary national regulator for public health and family planning management. It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of medical and health system, organizing the formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practicing of medical personnel.

Non-clinical research

NMPA requires preclinical data to support registration applications for imported and domestic drugs. According to the Drug Registration Regulation, nonclinical safety studies must comply with the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory. In 2003, NMPA promulgated the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory to improve the quality of non-clinical research and began to conduct the Good Laboratories Practice. Pursuant to the Circular on Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory issued by NMPA in 2007, NMPA is responsible for the certification of non-clinical research institutions nationwide and local provincial medical products administrative authorities is in charge of the daily supervision of non-clinical research institution. NMPA decides whether an institution is qualified for undertaking pharmaceutical non-clinical research by evaluating such institution’s organizational administration, its research personnel, its equipment and facilities, and its operation and management of non-clinical pharmaceutical projects. A Good Laboratory Practice Certification will be issued by NMPA if all the relevant requirements are satisfied, which will also be published on NMPA’s website.

Clinical trial application

According to the Administrative Measures for Drug Registration, which was promulgated in January 2020 and took effect in July 2020, the Center for Drug Evaluation under NMPA is responsible for the application of conducting new drug clinical trials. According to the Administrative Measures for Drug Registration, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. In accordance with the Circular on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs issued in 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the Center for Drug Evaluation within 60 business days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the Center for Drug Evaluation.

After obtaining the clinical trial authorization from NMPA, the applicant must register the clinical trial at the Drug Clinical Trial Information Platform for public disclosure in accordance with the Announcement

on Drug Clinical Trial Information Platform. The applicant shall complete the initial registration within one month after obtaining the clinical trial authorization and complete follow-up registrations before the first subject's enrollment in the trial.

Conducting clinical trial and the communication with Center for Drug Evaluation

NMPA promulgated the Administration of Quality of Drug Clinical Practice in August 2003. Pursuant to the Administration of Quality of Drug Clinical Practice, clinical trial means systematical investigation of drugs conducted on human subjects (patients or healthy volunteers) to prove or reveal the function, adverse reactions and/or absorption, distribution, metabolism, and excretion of the drug being investigated, of which the purpose is to determine the therapeutic efficacy and safety of the drug.

The conduct of clinical trials must adhere to GCP and the protocols approved by the ethics committees of each study site. The sponsor of clinical trials should provide insurance to the human subjects participating in the clinical trial and bear the cost of the treatment and the corresponding financial compensation for the human subjects who suffer harm or death related to the trial. To ensure authenticity and reliability of the clinical data, NMPA mandates applicants of the pending drug registration submissions to conduct self-inspection and verification of their clinical trial data. Based on the submitted self-inspection results, NMPA also regularly launches onsite clinical trial audits over selected applications and rejects those found with data forgery.

According to the Administrative Measures for Drug Registration, a clinical trial consists of Phases I, II, III and IV as well as the bioequivalence trial. Phase I refers to the initial clinical pharmacology and safety evaluation studies in humans. Phase II refers to the preliminary evaluation of a drug candidate's therapeutic effectiveness and safety for indications in patients, to provide evidence and support for the design of Phase III clinical trials and to settle the administrative dose regimen. Phase III refers to clinical trials undertaken to confirm the therapeutic effectiveness and safety on patients with target indications, to evaluate the overall benefit-risk relationships of the drug, and ultimately to provide sufficient evidence for the review of drug registration application. Phase IV refers to a new drug's post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used, to evaluate the overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose. Based on the characteristics of drugs and research objective, the research contents shall include clinical pharmacology research, exploratory clinical trial, confirmatory clinical trial, and post-marketing research.

According to the Technical Guiding Principles for Clinical Trials of Anti-tumor Drugs issued by the State FDA in May 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 State Food and Drug Administration.

Human genetic resources filing

The Interim Administrative Measures on Human Genetic Resources, promulgated by the Ministry of Science and Technology and the Ministry of Health in 1998, aimed at protecting and fair utilizing human genetic resources in the PRC. In July 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC, or the Service Guide, which provides that 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.

The Regulations of the PRC on the Administration of Human Genetic Resources promulgated by the State Council in 2019 and repealed the Interim Administrative Measures on Human Genetic Resources, and further stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China's human genetic resources

at clinical institutions without exporting of human genetic resource materials. However, the two parties shall file the type, quantity, and usage of the human genetic resource to be used with the administrative department of science and technology under the State Council before clinical trials.

Currently, we have obtained the human generic resources approvals for AN0025, AN1004, AN2025 and AN4005.

Acceptance of overseas clinical trial data

NMPA may reduce requirements for clinical trials and data, depending on the drug and the existing data. NMPA issued the Technical Guiding Principles for the Acceptance of Overseas Clinical Trial Data of Drugs, or the Overseas Data Guiding Principles, in July 2018, as one of the implementing rules for the Innovation Opinions, which provides that overseas clinical trial data can be submitted for clinical evaluation information in the process of drug marketing registration applications in China. According to the Overseas Data Guiding Principles, the overseas clinical trial data shall include, amongst others, the clinical trial data obtained overseas by the sponsor in its simultaneous R&D at home and abroad of innovative drugs, and sponsors must ensure the authenticity, integrity, accuracy and traceability of the overseas clinical trial data and such data must be obtained consistent with the relevant requirements under the Good Clinical Trial Practice of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. Moreover, sponsors shall ensure the scientific design of overseas clinical trials, the compliance of clinical trial quality management system requirements, and the accuracy and integrity of statistical analysis of data. To ensure that the clinical trial design and statistical analysis of the data are scientific and reasonable, for the drugs with simultaneous R&D at home and abroad and forthcoming clinical trials in China, the sponsors may, prior to implementing pivotal clinical trials, contact the Center for Drug Evaluation to ensure the compliance of pivotal clinical trials' design with the essential technical requirements for drug registration in China. Sponsors must also comply with other relevant sections of the Registration Measures when applying for drug marketing registrations in China using foreign clinical trial data. Currently, we have conducted some multi-center clinical trials overseas, and may apply for drug registrations in China by using overseas clinical trial data in the future.

International multi-center clinical trials regulations

According to the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (for Trial Implementation), or the Multi-Center Clinical Trial Guidelines, promulgated by NMPA in January 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 GCP, make reference to universal international principles such as the ICH-GCP, and comply with the laws and regulations of the countries involved in the international multi-center clinical trials. Where the applicants plan to use the data derived from the international multi-center clinical trials for approval of a drug registration in the PRC, it shall involve at least two countries, including China, and shall satisfy the requirements for clinical trials set forth in the Multi-Center Clinical Trial Guidelines and Administrative Measures for Drug Registration and other related laws and regulations. Currently, we have conducted certain multi-center clinical trials overseas for AN2025, AN0025 and AN4005. If we plan to implement the international multi-center clinical trials in the PRC, we shall comply with relevant laws and regulations accordingly.

New drug application

According to the Administrative Measures for Drug Registration, the applicant may apply for drug marketing registration to Center for Drug Evaluation upon completion of relevant research on pharmacy, pharmacology, toxicology and drug clinical trials, determination the quality standards of the drug, validation of commercial-scale production processes and preparation for acceptance of verification and inspection conducted by professional technical institution designated by competent NMPA. The Center for Drug Evaluation will organize pharmaceutical, medical, and other technicians to conduct comprehensive review of the safety, efficacy, and quality controllability, among others, of the drug according to the application materials

submitted by the applicant, the results of the verification and inspection conducted by professional technical institution, etc. If the comprehensive review conclusion is affirmative, the drug shall be approved for marketing and a drug registration certificate will be issued containing the information of the drug approval number, the marketing authorization holders, and the manufacturer.

In March 2016, the China Food and Drug Administration issued the Reform Plan for Registration Category of Chemical Medicine, which aims to reclass the registration application of chemical drugs stipulated by the Administrative Measures for Drug Registration promulgated in 2007. According to the Reform Plan for Registration Category of Chemical Medicine, Category 1 drugs refer to innovative chemical drugs that have not been marketed anywhere in the world. Improved new chemical drugs that are not marketed anywhere in the world fall into Category 2 drugs. Generic chemical drugs, that have equivalent quality and efficacy to the originator's drugs have been marketed abroad but not yet in China, can be classified as Category 3 drugs. Generic drugs, that have equivalent quality and efficacy to the originator's drugs and have been marketed in China, fall into Category 4 drugs. Category 5 drugs are drugs which have already been marketed abroad but are not yet approved in China.

As a support policy and implementing rule of the Administrative Measures for Drug Registration newly amended in 2020, NMPA issued the Chemical Drug Registration Classification and Application Data Requirements in June 2020, effective in July 2020, which reaffirmed the principles of the classification of chemical drugs set forth by the Reform Plan for Registration Category of Chemical Medicine and made minor adjustments to the subclassifications of Category 5. According to such regulation, Category 5.1 are innovative chemical drugs and improved new chemical drugs while Category 5.2 are generic chemical drugs, all of which shall have been already marketed abroad but not yet approved in China.

Special examination and fast track approval

NMPA has adopted several expedited review and approval mechanisms since 2009 and created additional expedited programs in recent years that are intended to encourage innovation. Applications for these expedited programs can be submitted together with the registration package or after the registration submission is admitted for review by the Center for Drug Evaluation. The Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovation promulgated by NMPA on December 21, 2017, clarified that fast track clinical trial applications or drug registration pathways will be available to the innovative drugs. It was further replaced by the Announcement on the Release of Three Documents including the Procedures for the Evaluation of Breakthrough Therapeutic Drugs (Trial) issued by the NMPA on July 7, 2020, the three documents are namely the Procedures for the Evaluation of Breakthrough Therapeutic Drugs (Trial), Procedures for the Evaluation and Approval of the Listing Application for Conditional Approval of Drugs (Trial) and Procedures for Prioritized Evaluation and Approval for Drug Marketing (Trial), among others, which allow the applicant to apply for the breakthrough therapy drug procedure during the Phase I and II clinical trials and normally no later than the commencement of Phase III clinical trials for the innovative or improved drugs which are used for the prevention and treatment of diseases that seriously endanger life or seriously affect quality of life and there is no effective means of prevention and treatment or there is sufficient evidence to show a significant clinical advantage over the existing treatments. In addition, when applying for the marketing licenses for the drugs with obvious clinical value, the applicant can apply for the prioritized evaluation and approval procedure.

If admitted to one of these expedited programs, an applicant will be entitled to more frequent and timely communication with reviewers at the Center for Drug Evaluation, expedited review and approval, and more agency resources throughout the review approval process.

NMPA also permits conditional approval of certain medicines based on early phase China clinical trial data or only on foreign approval clinical data. Post-approval the applicant may need to conduct one or more post-market studies. The agency has done this for drugs that meet unmet clinical needs for life-threatening illnesses and also for drugs that treat orphan indications. In 2018, NMPA established a conditional approval program for drugs designated by the Center for Drug Evaluation that have been approved in the US, EU and Japan within the last 10 years and that meet one of three criteria (1) orphan indications, (2) drugs that treat life threatening illnesses for which there are not effective treatment or preventive methods, and (3) drugs that treat life threatening illnesses and that have a clear clinical advantage over other approved therapies. In the future, we anticipate that we may seek expedited review and approval for certain of our drug candidates.

Drug manufacturing permit

Pursuant to the PRC Drug Administration Law and the Implement Measures of the PRC Drug Administration Law, a drug manufacturer must obtain a Drug Manufacturing Permit from the provincial Medical Products Administration before it starts to manufacture drug products. Prior to granting such a permit, the relevant government authority will inspect the applicant's production facilities and decide whether the sanitary conditions, QA system, management structure and equipment within the facilities have met the required standards. Each Drug Manufacturing Permit will be valid for a period of five years and the manufacturer is required to apply for renewal of the permit within six months prior to its expiration date and will be subject to reassessment by the authority in accordance with then prevailing legal and regulatory requirements for the purposes of such renewal.

Coverage and reimbursement

China's national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program issued by the State Council in 1998, under which all employers in urban cities are required to enroll their employees in the basic medical insurance program. The insurance premium is jointly contributed by the employers and employees. In 2007, the State Council promulgated Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. Participants of the national medical insurance program and their employers, if any, are required to contribute to the payment of insurance premiums on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the National Reimbursed Drugs List. A pharmaceutical product listed in the National Reimbursed Drugs List must be clinically needed, safe, effective, reasonably priced, easy to use, and available in sufficient quantity.

Factors that affect the inclusion of a pharmaceutical product in the National Reimbursed Drugs List include whether the product is consumed in large volumes and commonly prescribed for clinical use in the PRC and whether it is considered to be important in meeting the basic healthcare needs of the general public. Since 2016, special consideration has been given to, among others, innovative drugs with high clinical value and drugs for serious diseases. In addition, the PRC Ministry of Human Resources and Social Security has also been negotiating with manufacturers of expensive drugs with high clinical demands and proven effectiveness for price cuts in exchange for inclusion into the National Reimbursed Drugs List.

PRC laws and regulation in relation to Company Law and Foreign Investment

The establishment, operation, and management of corporate entities in China are governed by the Company Law of the PRC, or the Company Law. Pursuant to the Company Law, companies are classified into categories, namely limited liability companies and limited companies by shares. The Company Law shall also apply to foreign-invested limited liability companies and companies limited by shares. According to the Company Law, the provisions otherwise prescribed by the laws on foreign investment shall prevail.

On March 15, 2019, the National People's Congress promulgated the Foreign Investment Law of the PRC, which came into force on January 1, 2020 and repealed simultaneously the Law of PRC on Sino-foreign Equity Joint Ventures, the Wholly Foreign-owned Enterprise Law of the PRC, and the Law of the PRC on Sino-foreign Cooperative Joint Ventures. Subject to the Foreign Investment Law of the PRC, foreign-invested enterprises incorporated before the enforcement of the Foreign Investment Law of the PRC may keep their original organizational forms for five years after the enforcement of the Foreign Investment Law of the PRC. And the Implementation Regulations for the Foreign Investment Law of the PRC was promulgated by the State Council on December 26, 2019 and took effect on January 1, 2020. According to the Foreign Investment Law of the PRC, the State adopts the management system of pre-establishment national treatment and negative list for foreign investment. The negative list refers to special administrative measures for access of foreign investment in specific fields as stipulated by the State. The State will give national treatment to foreign investments outside the negative list.

The Provisions on Guiding Foreign Investment Direction, which was promulgated by the State Council on February 11, 2002, and came into effect on April 1, 2002, classify all foreign investment projects into four

categories: (i) encouraged projects, (ii) permitted projects, (iii) restricted projects, and (iv) prohibited projects. Investment activities in the PRC by foreign investors were principally governed by the Catalogue of Industries for Guiding Foreign Investment, which was promulgated by the Ministry of Commerce and the National Development and Reform Commission and was abolished by the Special Administrative Measures (Negative List) for Access of Foreign Investment (2021 version), or the Negative List and Catalogue of Industries for Encouraging Foreign Investment (2022 version), or the "Encouraging List". The Negative List, which came into effect on January 1, 2022, sets out special administrative measures in respect of the access of foreign investments in a centralized manner, and the Encouraging List, which will come into effect on January 1, 2023, sets out the encouraged industries for foreign investment.

Pursuant to the Interim Administrative for the Record-filling of the Establishment and Modification of Foreign-invested Enterprises, or the Interim Measures, promulgated by the Ministry of Commerce on October 8, 2016, establishment and modifications of foreign investment enterprises that are not subject to the approval under the special entry management measures shall be filed with the delegated commercial authorities. The Measures on Reporting of Foreign Investment Information was issued by the Ministry of Commerce and State Administration for Market Regulation on December 30, 2019. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to such measures.

PRC laws and regulations in relation to intellectual property rights

Patents

According to the Patent Law of the PRC promulgated by the National People's Congress of China, or the SCNPC, and the Implementation Rules of the Patent Law of the PRC, promulgated by the State Council, there are three types of patents in the PRC: invention patents, utility model patents and design patents. The protection period is 20 years for an invention patent, 10 years for a utility model patent and 15 years for a design patent, commencing from their respective application dates. Any individual or entity that utilizes a patent or conducts any other activity in infringement of a patent without prior authorization of the patent holder shall pay compensation to the patent holder and is subject to a fine imposed by relevant administrative authorities and, if constituting a crime, shall be held criminally liable in accordance with the law. According to the Patent Law of the PRC, for public health purposes, the State Intellectual Property Office of the PRC may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which PRC has acceded. In addition, according to the Patent Law of the PRC, any organization or individual that applies for a patent in a foreign country for an invention or utility model patent established in China is required to report to the State Intellectual Property Office for confidentiality examination.

For the purpose of compensating for the time taken to evaluate and approve a new drug to be put on market, the patent administrative department under the State Council shall grant compensation for duration of patent rights for invention of a new drug approved to be put on market in China upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent rights for a new drug approved to be put on market shall not exceed 14 years.

Trade secrets

According to the PRC Anti-Unfair Competition Law, promulgated by the SCNPC in September 1993, as amended in 2017 and 2019 respectively, the term "trade secrets" refers to technical, operational, or other business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others' trade secrets by: (1) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; (3) disclosing, using or permitting others to use the trade secrets, in violation of any confidentiality obligations or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (4) instigate, entice or help others to obtain, disclose, use or permit

others to use the trade secrets in violation of any confidentiality obligations or any requirements of the legal owners or holders to keep such trade secrets in confidence. 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 an infringement of the others' trade secrets. The parties whose trade secrets are being infringed 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, promulgated by the SCNPC, 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 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 case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided according to law.

Product liability

The Product Quality Law of the PRC promulgated by the SCNPC, is the principal governing law relating to the supervision and administration of product quality, which clarified liabilities of the manufacturers and sellers. Manufacturers shall not be liable when they are able to prove that: (1) the product has never been circulated; (2) the defects causing injuries or damage did not exist at the time when the product was circulated; or (3) the science and technology at the time when the product was circulated were at a level incapable of detecting the defects. A seller shall pay compensation if it can neither indicate the manufacturer nor the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim compensation from the manufacturer or the seller.

According to the Civil Code of the PRC, promulgated by the National People's Congress on May 28, 2020 and effective on January 1, 2021, manufacturers shall assume tort liability where the defects in relevant products cause damage to others. The aggrieved party may claim compensation from the manufacturer or the seller of the relevant product in which the defects have caused damage.

Regulations relating to foreign exchange control

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Administration Regulations of the PRC and the Regulations on the Administration of Foreign Exchange Settlement, Sale and Payment. Pursuant to these regulations and other PRC rules and regulations on currency conversion, Renminbi is freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan, or investment in securities outside China unless prior approval of the State Administration of Foreign Exchange or its local counterpart is obtained.

Foreign-invested enterprises are permitted to convert their after-tax dividends into foreign exchange and to remit such foreign exchange out of their foreign exchange bank accounts in the PRC. However, foreign exchange transactions involving overseas direct investment or investment and exchange in securities, derivative products abroad are subject to registration with SAFE, and approval from or filing with the relevant PRC government authorities (if necessary).

Regulations relating to dividend distribution

According to the PRC Company Law, Foreign Investment Law of the PRC and Regulation for Implementing the Foreign Investment Law of the PRC, 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. An enterprise is required to set aside at least 10% of its respective accumulated profits to its

statutory common reserve where it distributes its after-tax profits of the current year, until the accumulative amount of such reserve reaches 50% of its registered capital. If the aggregate balance of the enterprise's statutory common reserve is not enough to make up for the losses of the enterprise of the previous year, the current year's profits shall first be used for making up the losses before the statutory common reserve is drawn. After the enterprise has drawn statutory common reserve from the after-tax profits, it may, upon a resolution made by the shareholders' meeting, draw a discretionary common reserve from the after-tax profits. After the losses have been made up and common reserves have been drawn, the remaining profits shall be distributed to shareholders.

Regulations relating to employee stock incentive plan

On February 15, 2012, SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, 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 (which may be the Chinese affiliate of the overseas publicly listed company that participates in a 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.

Regulations on M&A rules and Overseas Listings

According to the Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors, or the M&A Rules, the merger and acquisition of domestic companies by foreign investors means that the foreign investors purchase or subscribe for the equity or shares of a non-foreign invested PRC company or that the foreign investors establish a foreign-invested PRC company to acquire or operate the assets of a non-foreign-invested PRC company by agreement. The M&A Rules require that an application be made to Ministry of Commerce for examination and approval in relation to the acquisition of any company inside China affiliated with a domestic company, enterprise, or natural person, which is made in the name of an overseas company lawfully established or controlled by such domestic company, enterprise, or natural person. The M&A Rules also provide that the overseas listing of a special purpose company controlled directly or indirectly by PRC companies or individuals on an overseas stock market must be approved by the China Securities Regulatory Committee.

The M&A Rules, and other recently adopted 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. For example, the M&A Rules require that Ministry of Commerce 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 impact or may impact 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.

On July 6, 2021, the General Office of the State Council, together with another regulatory authority, jointly promulgated the Opinions on Lawfully and Strictly Cracking Down Illegal Securities Activities, among which, it emphasizes the need to strengthen the administration over illegal securities activities and the supervision on overseas listings by China-based companies, and proposed to take effective measures, such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas-listed companies, and provided that the special provisions of the State Council on overseas offering and listing by those companies limited by shares will be revised and therefore the duties of domestic industry competent authorities and regulatory authorities will be clarified.

On February 17, 2023, with the approval of the State Council, the CSRC released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies, or the Trial Measures, and five supporting guidelines, which took effect on March 31, 2023. According to the Trial Measures, (1) domestic companies that seek to offer or list securities overseas, both directly and indirectly, should fulfill the filing procedure and report relevant information to the CSRC; if a domestic company fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, such domestic company may be subject to administrative penalties, such as order to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines; (2) if the issuer meets both of the following conditions, the overseas offering and listing shall be determined as an indirect overseas offering and listing by a domestic company: (i) any of the total assets, net assets, revenues or profits of the domestic operating entities of the issuer in the most recent accounting year accounts for more than 50% of the corresponding figure in the issuer's audited consolidated financial statements for the same period; (ii) its major operational activities are carried out in China or its main places of business are located in China, or the senior managers in charge of operation and management of the issuer are mostly Chinese citizens or are domiciled in China; and (3) where a domestic company seeks to indirectly offer and list securities in an overseas market, the issuer shall designate a major domestic operating entity responsible for all filing procedures with the CSRC, and where an issuer makes an application for listing in an overseas market, the issuer shall submit filings 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 Trial Measures, domestic companies that have already submitted valid applications for overseas 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 offering and listing; and (2) a six-month transition period will be granted to domestic companies which, prior to the effective date of the Trial Measures, have already obtained 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.

Regulations relating to information security and data privacy

On June 10, 2021, the SCNPC promulgated the PRC Data Security Law, which became effective from September 1, 2021. According to the PRC Data Security Law, a data classification protection system shall be established to protect data by classification. Entities engaged in data processing activities shall, in accordance with the laws and regulations, establish a sound whole-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security.

According to the Civil Code of the PRC, personal information of natural persons is protected by law. Any organization or individual that needs to obtain personal information of others shall obtain legally and ensure the information security, and shall not illegally collect, use, process, transmit, trade, provide or disclose personal information of others. The Personal Information Protection Law of the PRC promulgated by the SCNPC on August 20, 2021, and effective from November 1, 2021, further emphasized the duties and responsibilities of the processing personnel for the protection of personal information, and provided stricter protection measures for processing sensitive personal information.

On July 12, 2018, the National Health Commission issued the Administrative Measures on National Health and Medical Care Big Data Standards, Security and Services (Trial), or the Measures on Health and Medical Care Big Data, which became effective therefrom. The Measures on Health and Medical Care Big Data provided the guidelines and principles of health and medical big data standard management, security management and service management. According to the Measures on Health and Medical Care Big Data, the National Health Commission, together with other relevant departments, is responsible for the management of national health and medical care big data, while the authorities of health above the county level, together with

other relevant departments, are responsible for the management of health and medical care big data within their respective administrative regions. Medical institutions and relevant enterprises, including those engaged by medical institutions to store or operate health and medical care big data, shall take measures, such as data classification, important data backup and encryption, to ensure the security of health and medical care big data, and provide secured channels for the query and replication of information. Without authorization, no unit or individual shall use or disseminate any health and medical care big data or data beyond the scope of authorization, nor obtain any data in illegal ways. The responsible parties shall abide by the relevant regulations when disclosing health and medical care big data, shall not divulge state secrets, trade secrets or personal privacy, shall not infringe upon the interests of the state or the public, and shall not infringe upon the legitimate rights and interests of citizens, enterprise entities or other organizations.

On July 7, 2022, the CAC promulgated the Measures on Security Assessment of Cross-border Data Transfer which became effective on September 1, 2022. The data export measures require that any data processor who processes or exports personal information exceeding a certain volume threshold pursuant to the measures shall apply for a security assessment by the CAC before transferring any personal information abroad, including the following circumstances: (i) important data will be provided overseas by any data processor; (ii) personal information will be provided overseas by any operator of critical information infrastructure or any data processor who processes the personal information of more than 1,000,000 individuals; (iii) personal information will be provided overseas by any data processor who has provided the personal information of more than 100,000 individuals in aggregate or has provided the sensitive personal information of more than 10,000 individuals in aggregate since January 1 of last year; and (iv) other circumstances where the security assessment is required as prescribed by the CAC. A data processor shall, before applying for the security assessment of an outbound data transfer, conduct a self-assessment of the risks involved in the outbound data transfer. The security assessment of a cross-border data transfer shall focus on assessing the risks that may be brought about by the cross-border data transfer concerning national security, public interests, or the lawful rights and interests of individuals or organizations.

On February 24, 2023, the CSRC, jointly with other relevant governmental authorities, promulgated the Provisions on Strengthening Confidentiality and Archives Management of Overseas Securities Issuance and Listing by Domestic Enterprises, or the Confidentiality and Archives Management Provisions, which took effect on March 31, 2023. According to the Confidentiality and Archives Management Provisions, mainland China-based companies, whether offering and listing securities overseas directly or indirectly, must strictly abide the applicable laws and regulations when providing or publicly disclosing, either directly or through their overseas listed entities, documents and materials to securities services providers such as securities companies and accounting firms or overseas regulators in the process of their overseas offering and listing. If such documents or materials contain any state secrets or government authorities work secrets, the domestic companies must obtain the approval from competent governmental authorities according to the applicable laws, and file with the secrecy administrative department at the same level with the approving governmental authority. Furthermore, the Confidentiality and Archives Management Provisions provide that securities companies and securities service providers shall fulfill the applicable legal procedures when providing overseas regulatory institutions and other relevant institutions and individuals with documents or materials containing any state secrets or government authorities work secrets or other documents or materials that, if divulged, will jeopardize national security or public interest.

MANAGEMENT

Directors and executive officers

The following table sets forth information regarding our directors and executive officers as of the date of this prospectus.

Name	Age	Positions(s)
Yang Lu	43	Chief Executive Officer, Chairman of our Board of Directors
Hui Shao	50	Director
Yuan Sun	34	Director
Yuan Tian	68	Director
Shuqing Wu	36	Director
Ming Lun Alan Tse	43	Independent Director Nominee*
Lars Erik Birgerson	70	President, Chief Medical Officer, Chief Executive Officer of U.S. Subsidiary
Kaiyang Tang	59	Senior Vice President, Global Head of Clinical Operations
Wei (Vicky) Zhang	32	Chief Financial Officer
Victoria Elizabeth Demby	53	Senior Vice President, Global Head of Regulatory Affairs

* Ming Lun Alan Tse has accepted appointment as a director, which will be effective as of immediately prior and conditioned upon the closing of this offering.

The following is a biographical summary of the experience of our directors and executive officers.

Yang Lu co-founded our group and has served as our director since 2006. Currently he also serves as our chief executive officer and the chairman of our board of directors. Mr. Lu has 20 years of experience in the pharmaceutical industry. Prior to founding our company, Mr. Lu worked at Hybio Pharmaceutical Co., Ltd from April 2003 to March 2004. Mr. Lu obtained his bachelor's degree in biotechnology from Xiamen University in July 2002, and his EMBA-Executive Master of Business Administration from China Europe International Business School in September 2012.

Hui Shao has served as our director since January 2020. Mr. Shao has 15 years of experience in the investment industry. Mr. Shao has been serving as the chairman of the board at Beijing L'avion International Medical Investment and Management Limited Company and Beijing Youxiang International Travel Co., Ltd. since September 2014 and May 2006, respectively. Mr. Shao obtained his bachelor's degree in law from Northeast Normal University in July 1993 and was awarded fund qualification certification issued by the Asset Management Association of China in April 2017. He also received securities qualification from the Securities Association of China in June 2001.

Yuan Sun has served as our director since July 2021. Mr. Sun has over nine years of experience in the finance and investment industry. He currently serves as investment director at CS Capital Co., Ltd. Mr. Sun obtained his bachelor's degree in computer science from Tsinghua University in June 2010. He also obtained his master's degree in finance from Washington University in St. Louis in the United States in December 2012 and was qualified as a Chartered Financial Analyst (CFA) by the CFA Institute in November 2017.

Yuan Tian has served as our director since June 2018. He has 30 years of experience in the investment industry. Dr. Tian has been a partner of Yuanming Capital since he founded it in 2015. Dr. Tian established China International Futures Corporation, a PRC-based company mainly engaged in futures investment business, in 1992. He also served as the chairman of China Chengtong Holdings Group Limited from July 1997 to September 2002. He served as a director of Yado Wisdom (Beijing) Pharmaceutical Technology Co. since April 2017 and an independent director of Wuhan Zhongbang Bank Co., Ltd. since May 2017. Dr. Tian founded the China Entrepreneurs Forum in 2001 and serves as the chairman of the forum. He is the recipient of the China Economics Theory Innovation Award in 2011. From July 2018 to May 2022, Dr. Tian served as non-executive director of Ascentage Pharma Group International (HKEx: 6855). Since June 2018, he has served as a member on the Biotech Advisory Panel of the Hong Kong Stock Exchange, and he is responsible

for providing advice to assist the Hong Kong Stock Exchange in its review of listing applications from biotech companies. Dr. Tian obtained his master's degree and doctoral degree in economics from Wuhan University in January 1983 and August 1992, respectively.

Shuqing Wu has served as our director since August 2020. Ms. Wu has more than twelve years of experience in the investment industry. Since July 2015, Ms. Wu has served as the senior partner and president of financial business department of Shanghai Worth Asset Management Co., Ltd., a company wholly owned by Yingke Innovation Asset Management Co., Ltd., where Ms. Wu has served as a director since October 2020. Ms. Wu currently also serves as the chairman of supervisory board in Chengdu Kanghua Biological Products Co., Ltd. (SZSE: 300841) and Nanjing Aolian AE and EA Co., Ltd. (SZSE: 300585). From February 2009 to April 2012, she served as investment counsel and assistant to director of operations of Dongxing Securities Co., Ltd. (SSE: 601198). From April 2012 to September 2014, Ms. Wu served as an executive vice president of Zhongtuo Holding Group Co., Ltd. Ms. Wu obtained her bachelor's degree in international economy and trade from Yang-En University in July 2009.

Ming Lun Alan Tse will serve as our independent director effective as of immediately prior and conditioned upon the closing of this offering. Mr. Tse has more than 20 years of experience in financial management and accounting. Mr. Tse currently serves as a general manager at Jebsen Capital Ltd. and the independent non-executive director of Tian Ge Interactive Holdings Ltd. (HKEx: 1980). Previously, Mr. Tse has served as an accountant at KPMG from September 2002 to May 2005, a senior analyst at Techtronic Industries Co., Ltd from May 2005 to May 2007. Mr. Tse has also served as a senior manager of corporate planning and development, a senior manager of corporate planning and development at Next Horizon Company Limited from September 2007 to August 2009, and a project and business development manager of finance and administration department at Richemont Asia Pacific Limited from September 2009 to October 2011. Since November 2011, Mr. Tse has served as a general manager of Jebsen Automotive Technology Beijing Co., Ltd. Mr. Tse obtained his bachelor of business administration in accounting and finance from the University of Hong Kong in December 2002. He has been a fellow member of the Association of Chartered Certified Accountants (ACCA) since December 2005.

Lars Erik Birgerson has served as the president and chief executive officer of Adlai Nortye USA INC since July 2018 and has served as our chief medical officer since July 2021. Dr. Birgerson has more than 32 years of experience in the pharmaceutical industry. Prior to joining us, Dr. Birgerson served as the vice president and head of global and US medical affairs at Roche Pharmaceuticals in Basel, Switzerland; the vice president of medical affairs at Genentech in California, the United States; and the senior vice president of medical affairs at BMS in New Jersey, the United States. From January 2016 to date, Dr. Birgerson has served as the president and senior advisor of The Birgerson Group in New Jersey, the United States. Since February 2016, Dr. Birgerson has also served as the global medical consultant of Delcath Systems Inc. Dr. Birgerson received his Doctor of Medicine and doctorate of philosophy from Uppsala University at Uppsala, Sweden in June 1977 and June 1990 respectively. Dr. Birgerson has been a specialist of obstetrics and gynecology certified by the National Swedish Board of Health and Welfare since December 14, 1984. Further, he was certified as a licensed physician by the National Swedish Board of Health and Welfare in Sweden on February 19, 1980.

Kaiyang Tang has served as our senior vice president and global head of clinical operations since August 2018. Dr. Tang has more than 20 years of experience in the pharmaceutical industry. From 1990 to 1997, he served as study coordinator at Elizabeth General Medical Center. From 1997 to 1999, Dr. Tang served as global site coordinator and clinical research associate at Covance Inc. Dr. Tang served as senior clinical program manager at Pfizer Corporation from 1999 to 2003. From 2003 to 2007, he served as clinical program leader and medical monitor at Pliva Inc. From 2007 to 2010, he served as vice president and head of clinical and regulatory affairs at Hutchison MediPharma Ltd. From 2010 to date, he has served as chief medical officer, head of clinical and regulatory at Generon Inc. Dr. Tang obtained his medical doctor degree from Capital Institute of Medicine in the PRC in 1986. He obtained his MBA degree from Rutgers, the State University of New Jersey in 1999.

Wei (Vicky) Zhang joined us in June 2021 as our chief financial officer. From July 2014 to July 2015, Ms. Zhang served as an analyst at Nomura International Plc. She was in the role of executive director within the Corporate Finance Department of Goldman Sachs (Asia) L.L.C. and was employed by the firm from November 9, 2015 to June 12, 2021. Ms. Zhang obtained her Bachelor of Arts in accounting and economics

from Illinois Wesleyan University in the United States in April 2013. She obtained a Master of Science in financial economics from University of Oxford in the United Kingdom in July 2014.

Victoria Elizabeth Demby has served as our senior vice president and global head of regulatory affairs since March 2022. Dr. Demby has more than 30 years of pharmaceutical experience in various functional areas. From January 1992 to August 1996, Dr. Demby served at Wyeth-Ayerst Research as associate scientist. She later served at Dupont Pharmaceuticals as senior research investigator from May 2001 to January 2002, and then at Quest Pharmaceutical Services as senior research investigator from March 2002 to April 2003. From May 2003 to July 2008, she served at GSK, Inc. as section head of transport group in the preclinical department. After that, Dr. Demby served at BMS as senior research investigator of submission documents group from August 2008 to February 2010, as associate director of global regulatory strategy and safety from March 2010 to September 2012. Later, Dr. Demby served at MSD as a director from September 2012 to January 2019, as an executive director from January 2019 to May 2019. Then, she worked at Greenwich Biosciences as a senior director from May 2019 to October 2019. Recently, Dr. Demby has served at GlaxoSmithKline, Inc as executive director and team leader of global regulatory team since November 2019 and has also served as interim vice president of global regulatory affairs since July 2021. Dr. Demby obtained her bachelor's degree in biochemistry in University of Vermont in May 1991 and her doctoral degree in pharmacology and toxicology in University of Kansas in May 2001.

Board of directors

Our board of directors will consist of directors upon the SEC's declaration of effectiveness of our registration statement on Form F-1 of which this prospectus is a part. A director who is in any way, whether directly or indirectly, interested in a contract or transaction or proposed contract or transaction with our company is required to declare the nature of his interest at a meeting of our directors. Subject to the Nasdaq Stock Market rules and disqualification by the chairman of the relevant board meeting, a director may vote in respect of any contract or transaction or proposed contract or transaction notwithstanding that he may be interested therein, and if he does so his vote shall be counted and he shall be counted in the quorum at any meeting of our directors at which any such contract or transaction or proposed contract or transaction is considered, provided (i) such director, if his or her interest in such contract or arrangement is material, has declared the nature of his or her interest at the earliest meeting of the board at which it is practicable for him or her to do so, either specifically or by way of a general notice and (ii) if such contract or arrangement is a transaction with a related party, such transaction has been approved by the audit committee. Our directors may exercise all the powers of our company to raise or borrow money and to mortgage or charge its undertaking, property and assets (present and future) and uncalled capital or any part thereof, to issue debentures, debenture stock, bonds and other securities, whether outright or as collateral security for any debt, liability, or obligation of our company or of any third party.

Committees of the board of directors

We will establish three committees under the board of directors immediately upon the effectiveness of our registration statement on Form F-1, of which this prospectus is a part: an audit committee, a compensation committee, and a nominating and corporate governance committee. We will adopt a charter for each of the three committees. Each committee's members and functions are described below.

Audit Committee. Our audit committee will consist of , and . will be the chairman of our audit committee. We have determined that and satisfy the "independence" requirements of *Rule 5605(a)(2) of the Listing Rules of the Nasdaq Stock Market* and *Rule 10A-3 under the Exchange Act*. We have determined that qualifies as an "audit committee financial expert." The audit committee will oversee our accounting and financial reporting processes and the audits of the financial statements of our company. The audit committee will be responsible for, among other things:

- appointing the independent auditors and pre-approving all auditing and non-auditing services permitted to be performed by the independent auditors;
- reviewing with the independent auditors any audit findings or difficulties and management's response;
- discussing the annual audited financial statements with management and the independent auditors;

- reviewing the adequacy and effectiveness of our accounting and internal control policies and procedures and any steps taken to monitor and control major financial risk exposures;
- reviewing and approving all proposed related party transactions;
- meeting separately and periodically with management and the independent auditors; and
- monitoring compliance with our code of business conduct and ethics, including reviewing the adequacy and effectiveness of our procedures to ensure proper compliance.

Compensation Committee. Our compensation committee will consist of , and . will be the chairman of our compensation committee. We have determined that and satisfy the "independence" requirements of *Rule 5605(a)(2) of the Listing Rules of the Nasdaq Stock Market*. The compensation committee will assist the board in reviewing and approving the compensation structure, including all forms of compensation, relating to our directors and executive officers. Our chief executive officer may not be present at any committee meeting during which his compensation is deliberated. The compensation committee will be responsible for, among other things:

- reviewing and approving, or recommending to the board for its approval, the compensation for our chief executive officer and other executive officers;
- reviewing and recommending to the board for determination with respect to the compensation of our non-employee directors;
- reviewing periodically and approving any incentive compensation or equity plans, programs, or similar arrangements; and
- selecting compensation consultant, legal counsel, or other adviser only after taking into consideration all factors relevant to that person's independence from management.

Nominating and Corporate Governance Committee. Our nominating and corporate governance committee will consist of , and . will be the chairperson of our nominating and corporate governance committee. and satisfy the "independence" requirements of *Rule 5605(a)(2) of the Listing Rules of the Nasdaq Stock Market*. The nominating and corporate governance committee will assist the board of directors in selecting individuals qualified to become our directors and in determining the composition of the board and its committees. The nominating and corporate governance committee will be responsible for, among other things:

- selecting and recommending to the board nominees for election by the shareholders or appointment by the board;
- reviewing annually with the board the current composition of the board with regards to characteristics such as independence, knowledge, skills, experience, and diversity;
- making recommendations on the frequency and structure of board meetings and monitoring the functioning of the committees of the board; and
- advising the board periodically with regards to significant developments in the law and practice of corporate governance as well as our compliance with applicable laws and regulations, and making recommendations to the board on all matters of corporate governance and on any remedial action to be taken.

Duties of directors

Under Cayman Islands law, our directors owe fiduciary duties to our company, including a duty of loyalty, a duty to act honestly and a duty to act in what they consider in good faith to be in our best interests. Our directors must also exercise their powers only for a proper purpose. Our directors also owe to our company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. However, English and Commonwealth Courts have moved toward an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands. In fulfilling their duty of care to us, our directors must ensure compliance with our memorandum and articles of

association, as amended, and restated from time to time. We have the right to seek damages if a duty owed by our directors is breached. In certain limited exceptional circumstances, a shareholder may have the right to seek damages in our name if a duty owed by our directors is breached.

Our board of directors has all the powers necessary for managing, and for directing and supervising, our business affairs. The functions and powers of our board of directors include, among others:

- convening shareholders' annual and extraordinary general meetings and reporting its work to shareholders at such meetings;
- declaring dividends and distributions;
- appointing officers and determining the term of office of the officers;
- exercising the borrowing powers of our company and mortgaging the property of our company; and
- approving the transfer of shares in our company, including the registration of such shares in our share register.

Terms of directors and officers

Our directors may be appointed by an ordinary resolution of our shareholders. Alternatively, our board of directors may, by the affirmative vote of a simple majority of the directors present and voting at a board meeting appoint any person as a director to fill a casual vacancy on our board or as an addition to the existing board. Our directors are not automatically subject to a term of office and hold office until such time as they are removed from office by an ordinary resolution of our shareholders. In addition, a director will cease to be a director if he (i) becomes bankrupt or makes any arrangement or composition with his creditors; (ii) dies or is found to be or becomes of unsound mind; (iii) resigns his office by notice in writing; (iv) without special leave of absence from our board, is absent from meetings of our board for three consecutive meetings and our board resolves that his office be vacated; or (v) is removed from office pursuant to any other provision of our articles of association.

Our officers are appointed by and serve at the discretion of the board of directors and may be removed by our board of directors.

Employment agreements and indemnification agreements

We have entered into employment agreements with each of our executive officers. Under these agreements, each of our executive officers is employed for a specified time period. We may terminate employment for cause, at any time, for certain acts of the executive officer, such as continued failure to satisfactorily perform, willful misconduct or gross negligence in the performance of agreed duties, conviction or entry of a guilty or nolo contendere plea of any felony or any misdemeanor involving moral turpitude, or dishonest act that results in material harm to our interests or material breaches of the employment agreement. We may also terminate an executive officer's employment without cause upon 60-day advance written notice. In such case of termination by us, we will provide severance payments to the executive officer as may be agreed between the executive officer and us. The executive officer may resign at any time with a 60-day advance written notice.

Each executive officer has agreed to hold, both during and after the termination or expiry of his or her employment agreement, in strict confidence and not to use, except as required in the performance of his or her duties in connection with the employment or pursuant to applicable law, any of our confidential information or trade secrets, any confidential information or trade secrets of our clients or prospective clients, or the confidential or proprietary information of any third party received by us and for which we have confidential obligations. The executive officers have also agreed to disclose in confidence to us all inventions, designs, and trade secrets which they conceive, develop or reduce to practice during the executive officer's employment with us and to assign all right, title, and interest in them to us, and assist us in obtaining and enforcing patents, copyrights, and other legal rights for these inventions, designs, and trade secrets.

In addition, each executive officer has agreed to be bound by non-competition and non-solicitation restrictions during the term of his or her employment and typically for one year following the last date of employment. Specifically, each executive officer has agreed not to (i) solicit from any customer doing business with us during the effective term of the employment agreement business of the same or of a similar nature to our business; (ii) solicit from any of our known potential customer business of the same or of a similar nature to that which has been the subject of our known written or oral bid, offer or proposal, or of substantial preparation with a view to making such a bid, proposal or offer; (iii) solicit the employment or services of, or hire or engage, any person who is known to be employed or engaged by us; or (iv) otherwise interfere with our business or accounts, including, but not limited to, with respect to any relationship or agreement between any vendor or supplier and us.

We have also entered into indemnification agreements with each of our directors and executive officers. Under these agreements, we agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being a director or officer of our company.

Compensation of directors and executive officers

In 2022, we paid an aggregate of approximately US$2.5 million in cash and benefits to our directors and executive officers. For stock option grants to our executive officers and directors, see "— Share incentive plans." We have not set aside or accrued any amount to provide pension, retirement or other similar benefits to our executive officers and directors. Our operating subsidiary in the PRC is required by law to make contributions equal to certain percentages of each employee's salary for his or her pension insurance, medical insurance, unemployment insurance, and other statutory benefits and a housing provident fund.

Share incentive plans

We adopted a share incentive plan in June 2020 and amended it in May 2021. We refer to this share incentive plan as our 2020 Share Incentive Plan in this prospectus. Under such 2020 Share Incentive Plan, we are authorized to issue no more than 15,000,000 ordinary shares. To manage this share incentive plan, we set up two holding vehicles, Nortye Talent Limited and Nortye International Limited, and issued 9,000,000 and 6,000,000 ordinary shares to these two entities respectively in July 2021. Nortye Talent Limited and Nortye International Limited are holding these shares through a trust for the benefit of our existing and future share award grantees, and will transfer these shares upon the vesting and exercise of share awards. As of the date of this prospectus, awards for an aggregate of 9,713,421 ordinary shares have been granted.

The following paragraphs describe the principal terms of our 2020 Share Incentive Plan:

Type of awards. The 2020 Share Incentive Plan permits awards of options, restricted shares, restricted share units or other types of awards as the case may require.

Plan administration. The 2020 Share Incentive Plan is administered by the board of directors of the Company (the "**Administrator**"). The Administrator determines, among other things, the participant eligible to receive awards, the type and number of the awards to be granted to each eligible participants and the terms and conditions of each award.

Eligibility. Awards may be granted to our employees, directors, or consultants, or trusts or companies established in connection with any employee benefit plan of the Company.

Award agreement. Awards granted will be evidenced by an award agreement in the forms approved by the Administrator. The award agreement contains the terms established by the Administrator for that award, as well as any other additional terms, provisions, or restrictions that the Administrator may impose on the award.

Terms of the share incentive. The 2020 Share Incentive Plan as amended commenced on June 8, 2020 (the "**Effective Date**") and will terminate at the close of business on the day before the 10th anniversary of the Effective Date.

Vesting schedule. In general, the Administrator determines the vesting schedule, which is specified in the relevant award agreement.

Rights on death or termination of employment. If the participant's employment is terminated for cause other than death, all of the options and awards granted shall be terminated on the date of the termination of employment for cause, regardless of whether they are vested and/or exercisable or not. If the participant's employment is terminated by reason of disability, the participant may exercise any options or awards granted that are exercisable at the time of the termination within 12 months of such date of termination of employment. If the participant's employment is terminated as a result of death, the participant's executors or administrators of estate may exercise any options or awards granted that are exercisable at the time of the termination of employment within 6 months of such date of termination of employment. If the participant's employment is terminated for any reason other than those referred to above, the participant may exercise any options or awards granted that are exercisable at the time of the termination within 3 months of such date of termination of employment.

Transfer restriction. Awards may not be transferred in any manner by the participant other than in accordance with the exceptions provided in the 2020 Share Incentive Plan or the relevant award agreement, such as transfers by will or the laws of descent and distribution.

Amendment, termination and suspension. The board of the directors of the Company may at any time amend, alter, suspend, or terminate the 2020 Share Incentive Plan, subject to applicable laws and articles of association of the Company. Termination shall not affect the Administrator's ability to exercise the powers granted to it under the 2020 Share Incentive Plan prior to such termination.

The following table summarizes, as of the date of this prospectus, the number of ordinary shares underlying outstanding options that we granted to our directors and executive officers:

Name	Ordinary Shares Underlying Options	Exercise Price (US$/Share)	Date of Grant	Date of Expiration
Yang Lu	3,200,000	2.0	31/05/2021	31/05/2031
Lars Erik Birgerson	*	1.1	08/09/2020	08/09/2030
	*	2.2	01/04/2022	01/04/2032
Kaiyang Tang	*	1.1	08/09/2020	08/09/2030
	*	1.8	01/11/2020	01/11/2030
	*	2.2	01/04/2022	01/04/2032
Wei (Vicky) Zhang	*	2.0	01/10/2021	01/10/2031
Victoria Elizabeth Demby	*	2.2	01/07/2022	01/07/2032
All directors and executive officers as a group	4,350,000			

* Less than 1% of our total outstanding shares on an as-converted basis as of the date of this prospectus.

PRINCIPAL SHAREHOLDERS

Except as specifically noted, the following table sets forth information with respect to the beneficial ownership of our ordinary shares as of the date of this prospectus by:

- each of our directors and executive officers; and
- each person known to us to own beneficially more than 5% of our ordinary shares.

The calculations in the table below are based on 97,983,414 ordinary shares on an as-converted basis outstanding as of the date of this prospectus and Class A ordinary shares and Class B ordinary shares outstanding immediately after the completion of this offering.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to such securities. Except as otherwise indicated, all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

	Ordinary Shares Beneficially Owned Prior to This Offering		Ordinary Shares Beneficially Owned After This Offering			
	Ordinary Shares	% of Beneficial Ownership	Class A ordinary shares	Class B ordinary shares	% of Beneficial Ownership (of total Class A ordinary shares and Class B ordinary shares)	% of aggregate voting power
Directors and Executive Officers*:						
Yang Lu[(1)]	37,530,000	38.3				
Hui Shao[(2)]	6,868,657	7.0				
Yuan Sun	—	—				
Yuan Tian	—	—				
Shuqing Wu	—	—				
Ming Lun Alan Tse	—	—				
Lars Erik Birgerson	—	—				
Kaiyang Tang	—	—				
Wei (Vicky) Zhang	—	—				
Victoria Elizabeth Demby	—	—				
All Directors and Executive Officers as a Group	44,398,657	45.3				
Principal Shareholders						
Archer Future Limited[(1)]	16,990,000	17.3				
Nortye Talent Limited[(3)]	9,000,000	9.2				
ATCG Holding Limited[(2)]	6,868,657	7.0				
JIN YIN (BVI) LIMITED[(4)]	6,060,000	6.2				
Nortye International Limited[(5)]	6,000,000	6.1				
UNIQUE MARK VENTURES LIMITED[(6)]	5,750,790	5.9				
PECO International Limited[(1)]	5,000,000	5.1				

Notes:

* The business address of Yang Lu and Wei (Vicky) Zhang is c/o P.O. Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands; the business address of Yuan Sun is Floor 20, No.2 Fuchengmen North Street, Xicheng District, Beijing, China; the business address of Shuqing Wu is Building G1, Lian Yang Constellation, No. 2433, Yanggao Road, Pudong New District, Shanghai, China; the business address of Yuan Tian is 1106, Tower A, Global Trade Center, No 36 North 3rd Rising East Road, Dongcheng District, Beijing, China; the business address of Hui Shao is Building A5, Junhao Central Park Plaza, Chaoyang District, Beijing, China; the business address of Ming Lun Alan Tse is 21/F, Hysan Place, 500 Hennessy Road, Causeway Bay, Hong Kong; the business address of Lars Erik Birgerson, Kaiyang Tang, and Victoria Elizabeth Demby is 685 US Hwy 1, 2nd floor, North Brunswick Township, NJ 08902 U.S.

† For each person and group included in this column, percentage voting power is calculated by dividing voting power beneficially owned by such person or group by voting power of all of our Class A ordinary shares and Class B ordinary shares as a single class. Each holder of Class A ordinary shares is entitled to one vote per share and each holder of Class B ordinary shares is entitled to fifteen votes per share on all matters subject to vote at our general meeting. Our Class A ordinary shares and Class B ordinary shares vote together as a single class on all matters submitted to a vote of our shareholders, except as may otherwise be required by law or provided for in our post-offering memorandum and articles of association. Each Class B ordinary share is convertible into one Class A ordinary share at the option of the holder thereof at any time upon written notice to our company, while Class A ordinary shares cannot be converted into Class B ordinary shares under any circumstances.

(1) Represents (i) 16,990,000 ordinary shares held by Archer Future Limited, a British Virgin Islands company wholly owned by Sagitta Future Limited, which is in turn wholly owned by Trident Trust Company (HK) Limited. Trident Trust Company (HK) Limited is holding these shares as the trustee for the benefit of Mr. Yang Lu and his family members. Mr. Lu is the settlor of the trust. Under the terms of this trust, Mr. Lu is able to exercise voting rights and dispositive rights attached to the ordinary shares held by Archer Future Limited. The registered address of Archer Future Limited is Trident Chambers, P.O. Box 146, Road Town, Tortola, British Virgin Islands. The registered address of Trident Trust Company (HK) Limited is 14th floor, Golden Centre, 188 des Voeux Road Central, Hong Kong; (ii) 5,000,000 ordinary shares held by PECO International Limited, a British Virgin Islands company wholly owned by PECO Innovation Limited, which is in turn wholly owned by PraxisIFM Fiduciaries (Hong Kong) Limited. PraxisIFM Fiduciaries (Hong Kong) Limited is holding these shares as the trustee for the benefit of Mr. Lu and certain of our former and existing employees and consultants. Under the terms of this trust, Mr. Lu has the power to direct the trustee with respect to the retention or disposal of, and the exercise of any voting and other rights attached to the ordinary shares held by PECO International Limited. The registered address of PraxisIFM Fiduciaries (Hong Kong) Limited is 20/F, 88 Gloucester Road, Wan Chai, Hong Kong. The registered address of PECO International Limited is Nerine Chambers, P.O. Box 905, Road Town, Tortola, British Virgin Islands; (iii) 2,550,000 ordinary shares held by DH Future Limited, a British Virgin Islands company wholly owned by DH Accrescent Limited, which is in turn wholly owned by Trident Trust Company (HK) Limited. Trident Trust Company (HK) Limited is holding these shares as the trustee for the benefit of Mr. Donghui Yang and his family members. Mr. Yang is the settlor of the trust. Under the terms of this trust, Mr. Yang is able to exercise voting rights and dispositive rights attached to the ordinary shares held by DH Future Limited. The Registered address of DH Future Limited is P.O. Box 146, Road Town, Tortola, British Virgin Islands. Mr. Lu and Mr. Yang entered into an acting-in-concert agreement, pursuant to which Mr. Lu is able to exercise voting power entrusted from Mr. Yang; and (iv) 12,990,000 ordinary shares issuable upon the conversion of 6,060,000 Series A preferred shares held by JIN YIN (BVI) LIMITED, 3,500,000 Series A preferred shares held by LAI NUO (BVI) LIMITED and 3,430,000 Series A preferred shares held by LV YI (BVI) LIMITED. Mr. Lu and these three Series A preferred investors entered into an acting-in-concert agreement, pursuant to which Mr. Lu is able to exercise voting rights entrusted from the other signing parties. (a) For more information regarding JIN YIN (BVI) LIMITED, please see Note (4) below; (b) LAI NUO (BVI) LIMITED is a British Virgin Islands company wholly owned by Hangzhou Lainuo Investment Limited Partnership. Shanghai Haomo Investment and Management Co., Ltd. is the general partner of Hangzhou Lainuo Investment Limited Partnership. Mi Yin and Yan Jiang hold 80% and 20% equity interests in Shanghai Haomo Investment and Management Co., Ltd., respectively. The registered address of LAI NUO (BVI) LIMITED is Craigmuir Chambers, Road Town, Tortola, VG 1110, Virgin Islands (British). The registered address of Hangzhou Lainuo Investment Limited Partnership is Room 328, Building 6, No. 88, Jiangling Road, Binjiang District, Hangzhou, China. The registered address of Shanghai Haomo Investment and Management Co., Ltd. is Room 399, 3rd Floor, Building 5, No.2801-2809, Tiancheng Road, Qingpu District, Shanghai, China; and (c) LV YI (BVI) LIMITED is a British Virgin Islands company wholly owned by Hangzhou Lvyi Investment and Management Limited Partnership. Congcong Wang is the general partner of Hangzhou Lvyi Investment and Management Limited Partnership. The registered address of LV YI (BVI) LIMITED is Craigmuir Chambers, Road Town, Tortola, VG 1110, Virgin Islands (British). The registered address of Hangzhou Lvyi Investment and Management Limited Partnership is Room 102, 2nd Floor, Building 6, No. 202, Zhenzhong Road, Xihu District, Hangzhou, China. All the preferred shares held by JIN YIN (BVI) LIMITED, LAI NUO (BVI) LIMITED and LV YI (BVI) LIMITED will be converted into Class A ordinary shares immediately upon the effective date of our registration statement relating to this offering.

(2) Represents 6,868,657 ordinary shares issuable upon the conversion of 4,600,632 Series C preferred shares and 2,268,025 Series D preferred shares held by ATCG Holding Limited, a limited company incorporated in British Virgin Islands. ATCG Holdings Limited is controlled by Mr. Hui Shao through a trust and of which Mr. Shao and his family members are the beneficiaries. The registered address of ATGC Holding Limited is Start Chambers, Wickham's Cay II, P.O. Box 2221, Road Town, Tortola, British Virgin Islands. All the preferred shares held by ATCG Holding Limited will be converted into Class A ordinary shares immediately upon the effective date of our registration statement relating to this offering.

(3) Represents 9,000,000 ordinary shares held by Nortye Talent Limited, a British Virgin Islands company wholly owned by Trident Trust Company (HK) Limited. Trident Trust Company (HK) Limited is holding these shares as the trustee for the benefit of certain employees of the Company in the trust. We are the settlor of this trust. Under the terms of this trust, the sole member of the advisory committee, Mr. Jun Zhou, is able to exercise voting rights and dispositive rights attached to the ordinary shares held by Nortye Talent Limited as of the date of this prospectus. The registered address of Nortye Talent Limited is P.O. Box 146, Road Town, Tortola, British Virgin Islands.

(4) Represents 6,060,000 ordinary shares issuable upon the conversion of Series A preferred shares held by JIN YIN (BVI) LIMITED, a British Virgin Islands company wholly owned by Shanghai Gaopei Duwei Biotechnology Co. Hangzhou Jingyin Investment Partnership (Limited Partnership) and Hangzhou Jingfeng Investment Management Company hold 99.0% and 1.0% equity interests in Shanghai Gaopei Duwei Biotechnology Co., respectively. The general partner of Hangzhou Jingyin Investment Partnership (Limited Partnership) is Hangzhou Jingfeng Investment Management Company. Hangzhou Jingfeng Investment Management Company is wholly-owned by Shijun Feng. The registered address of JIN YIN (BVI) LIMITED is Craigmuir Chambers, Road Town, Tortola, VG 1110, British Virgin Islands. The registered address of Shanghai Gaopei Duwei Biotechnology Co. is Room 2207A, No. 28, Maji Road, China (Shanghai) Pilot Free Trade Zone, Shanghai, China. The registered address of Hangzhou Jinyin Investment Partnership (Limited Partnership) is Room 357, No.88-2, Yuanshuaimiaohou, Shangcheng District, Hangzhou, China. The registered address of Hangzhou Jingfeng Investment Management Company is Room 606-47, Building 1, No. 217, Wujiang Road, Shangcheng District, Hangzhou, China.

(5) Represents 6,000,000 ordinary shares held by Nortye International Limited, a British Virgin Islands company wholly owned by Trident Trust Company (HK) Limited. Trident Trust Company (HK) Limited is holding these shares as the trustee for the benefit of certain employees of the Company in the trust. We are the settlor of this trust. Under the terms of this trust, the sole member of the advisory committee, Mr. Xiao Zhang, is able to exercise voting rights and dispositive rights attached to the ordinary shares held by Nortye International Limited as of the date of this prospectus.. The registered address of Nortye International Limited is P.O. Box 146, Road Town, Tortola, British Virgin Islands.

(6) Represents 5,750,790 ordinary shares issuable upon the conversion of Series C preferred shares held by UNIQUE MARK VENTURES LIMITED, a British Virgin Islands company wholly owned by RONGXI HONGKONG INVESTMENT MANAGEMENT LIMITED, which is in turn wholly owned by Zhuhai Rongxi Capital Investment LLP. Zhuhai Rongxi Capital Investment LLP is ultimately controlled by the Industrial and Commercial Bank of China Limited, a PRC state-owned bank and a public company, and the voting and/or dispositive power with respect to the shares owned by UNIQUE MARK VENTURES LIMITED is exercised jointly by members of the asset management department of the Industrial and Commercial Bank of China Limited, rather than any specific individuals. The registered address of UNIQUE MARK VENTURES LIMITED is Wickhams Cay II, Road Town, Tortola, VG1110, British Virgin Islands. The registered address of RONGXI HONGKONG INVESTMENT MANAGEMENT LIMITED is Room 1005, 10/F., Champion Tower, 3 Garden Road, Central, Hong Kong. The registered address of Zhuhai Rongxi Capital Investment LLP is Room 105, No. 6, Baohua Road, Hengqin New District, Zhuhai, China. The registered address of the Industrial and Commercial Bank of China Limited is No. 55, Fuxingmennei Street, Xicheng District, Beijing, China. All the preferred shares held by UNIQUE MARK VENTURES LIMITED will be converted into Class A ordinary shares immediately upon the effective date of our registration statement relating to this offering.

As of the date of this prospectus, 0.9% of our ordinary shares are held by record holders in the United States. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

RELATED PARTY TRANSACTIONS

Shareholders agreement

See “Description of Share Capital — Shareholders agreement.”

Employment agreements and indemnification agreements

See “Management — Employment agreements and indemnification agreements.”

DESCRIPTION OF SHARE CAPITAL

We are a Cayman Islands exempted company incorporated with limited liability and our affairs are governed by our memorandum and articles of association, the Companies Act (As Revised) of the Cayman Islands, which we refer to as the Companies Act below, and the common law of the Cayman Islands.

As of the date of this prospectus, our authorized share capital is US$50,000 divided into 500,000,000 ordinary shares with a par value of US$0.0001 each. As of the date of this prospectus, (i) 40,440,000 ordinary shares, (ii) 14,560,000 Series A preferred shares, (iii) 13,607,896 Series B preferred shares, (iv) 14,653,013 Series C preferred shares and (v) 14,722,505 Series D preferred Shares are issued and outstanding.

Immediately prior to the completion of this offering, we will have 80,993,414 Class A ordinary shares and 16,990,000 Class B ordinary shares issued and outstanding, assuming the underwriters do not exercise the option to purchase additional ADSs. All of our shares issued and outstanding prior to the completion of the offering are and will be fully paid, and all of our shares to be issued in the offering will be issued as fully paid.

Our post-offering memorandum and articles of association

We have adopted a seventh amended and restated memorandum and articles of association, which will become effective and replace our sixth amended and restated memorandum and articles of association in its entirety immediately prior to the completion of this offering. The following are summaries of material provisions of the post-offering memorandum and articles of association that we have adopted and of the Companies Act, insofar as they relate to the material terms of our ordinary shares.

Objects of our company. Under our post-offering memorandum and articles of association, the objects of our company are unrestricted, and we have the full power and authority to carry out any object not prohibited by the laws of the Cayman Islands.

Ordinary shares. Our ordinary shares are divided into Class A ordinary shares and Class B ordinary shares. Holders of our Class A ordinary shares and Class B ordinary shares will have the same rights except for voting and conversion rights. Each Class A ordinary share shall entitle the holder thereof to one (1) vote on all matters subject to vote at our general meetings, and each Class B ordinary share shall entitle the holder thereof to fifteen (15) votes on all matters subject to vote at our general meetings. Our ordinary shares are issued in registered form and are issued when registered in our register of members.

Conversion. Each Class B ordinary share is convertible into one (1) Class A ordinary share at the option of the holder thereof at any time upon written notice to our company, while Class A ordinary shares cannot be converted into Class B ordinary shares under any circumstances. Upon any sale, transfer, assignment or disposition of any Class B ordinary share by a shareholder, or any affiliate of the founder to any person who is not the founder, or an affiliate of the founder, or upon a change of ultimate beneficial ownership of any Class B ordinary share to any person who is not the founder, or an affiliate of the founder, such Class B ordinary share shall be automatically and immediately converted into one Class A ordinary share.

Dividends. Our directors may from time to time declare dividends (including interim dividends) and other distributions on our shares in issue and authorize payment of the same out of the funds of our company lawfully available therefor. In addition, our shareholders may declare dividends by ordinary resolution, but no dividend may exceed the amount recommended by our directors. Our post-offering memorandum and articles of association provide that dividends may be declared and paid out of the profits of the Company or, if permitted by the Companies Act, out of capital. Under the laws of the Cayman Islands, our company may declare and pay a dividend out of either profit or share premium account; provided that in no circumstances may a dividend be paid if that would result in our company being unable to pay its debts as they fall due in the ordinary course of business.

Voting rights. Our Class A ordinary shares and Class B ordinary shares vote together as a single class on all matters submitted to a vote of our shareholders, except as may otherwise be required by law or provided for in our post-offering memorandum and articles of association. In respect of matters requiring shareholders' vote, each Class A ordinary share is entitled to one vote, and each Class B ordinary share is entitled to fifteen votes. At any general meeting a resolution put to the vote of the meeting shall be decided on by way of a poll

save that the chairman of the meeting may, in good faith, allow a resolution which relates purely to a procedural or administrative matter to be voted on by a show of hands.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast at a meeting, while a special resolution requires the affirmative vote of no less than two-thirds of the votes cast attaching to the issued and outstanding ordinary shares at a meeting. A special resolution will be required for important matters such as a change of name or making changes to our post-offering memorandum and articles of association. Our shareholders may, among other things, divide and combine their shares by ordinary resolution.

General meetings of shareholders. As a Cayman Islands exempted company, we are not obliged by the Companies Act to call shareholders' annual general meetings. Our post-offering memorandum and articles of association provide that we may (but are not obliged to) in each year hold a general meeting as our annual general meeting in which case we will specify the meeting as such in the notices calling it, and the annual general meeting will be held at such time and place as may be determined by our directors.

Shareholders' general meetings may be convened by the chairman or a majority of our board of directors. Advance notice of at least seven (7) calendar days is required for the convening of our annual general shareholders' meeting (if any) and any other general meeting of our shareholders. A quorum required for any general meeting of shareholders consists of one or more of our shareholders holding shares which carry in aggregate (or representing by proxy) not less than ten percent (10%) of all votes attaching to the issued and outstanding shares in our company entitled to vote at such general meeting.

The Companies Act provides shareholders with only limited rights to requisition a general meeting and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our post-offering memorandum and articles of association provide that upon the requisition of any one or more of our shareholders holding shares which carry in aggregate not less than ten percent (10%) of the votes attaching to the outstanding shares of our company entitled to vote at general meetings, our board will convene an extraordinary general meeting and put the resolutions so requisitioned to a vote at such meeting. However, our post-offering memorandum and articles of association do not provide our shareholders with any right to put any proposals before annual general meetings or extraordinary general meetings not called by such shareholders.

Transfer of ordinary shares. Subject to the restrictions set out below, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in writing and in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any ordinary share which is not fully paid up or on which we have a lien. Our board of directors may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of ordinary shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four; and
- a fee of such maximum sum as the Nasdaq Stock Market may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer they must, within one calendar month after the date on which the instrument of transfer was lodged, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, after compliance with any notice required of the Nasdaq Stock Market, be suspended and the register closed at such times and for such periods as our board of directors may from

time to time determine, provided, however, that the registration of transfers may not be suspended nor the register closed for more than 30 calendar days in any year as our board may determine.

Liquidation. On the winding up of our company, if the assets available for distribution amongst our shareholders will be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus will be distributed amongst our shareholders in proportion to the par value of the shares held by them at the commencement of the winding up, subject to a deduction from those shares in respect of which there are monies due, of all monies payable to our company for unpaid calls or otherwise. If our assets available for distribution are insufficient to repay all of the paid-up capital, such assets will be distributed so that, as nearly as may be, the losses are borne by our shareholders in proportion to the par value of the shares held by them.

Calls on shares and forfeiture of shares. Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their shares in a notice served to such shareholders [at least 14 days] prior to the specified time and place of payment. The shares that have been called upon and remain unpaid are subject to forfeiture.

Redemption, repurchase and surrender of shares. We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders of these shares, on such terms and in such manner as may be determined, before the issue of such shares, by our board of directors or by the shareholders by ordinary resolution. Our company may also repurchase any of our shares on such terms and in such manner as have been approved by our board of directors or by an ordinary resolution of our shareholders. Under the Companies Act, the redemption or repurchase of any share may be paid out of our company's profits or out of the proceeds of a new issue of shares made for the purpose of such redemption or repurchase, or out of capital (including share premium account and capital redemption reserve) if our company can, immediately following such payment, pay its debts as they fall due in the ordinary course of business. In addition, under the Companies Act no such share may be redeemed or repurchased (a) unless it is fully paid up, (b) if such redemption or repurchase would result in there being no shares outstanding or (c) if the company has commenced liquidation. In addition, our company may accept the surrender of any fully paid share for no consideration.

Variation of rights of shares. Whenever the capital of our company is divided into different classes, the rights attached to any such class may, subject to any rights or restrictions for the time being attached to any class, only be materially adversely varied with the consent in writing of the holders of no less than two-thirds of the issued shares of that class or with the sanction of a resolution passed at a separate meeting of the holders of the shares of the class by a majority of two-thirds of the votes cast at such meeting. The rights conferred upon the holders of the shares of any class issued will not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation, allotment, or issue of further shares ranking *pari passu* with such existing class of shares.

Issuance of additional shares. Our post-offering memorandum and articles of association authorize our board of directors to issue additional ordinary shares from time to time as our board of directors may determine, to the extent of available authorized but unissued shares.

Inspection of books and records. Holders of our ordinary shares will have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records (other than our memorandum and articles of association, special resolutions which have been passed by our shareholders, and our register of mortgages and charges). Under Cayman Islands law, the names of our current directors can be obtained from a search conducted at the Registrar of Companies. However, we intend to provide our shareholders with annual audited financial statements. See "Where You Can Find Additional Information."

Anti-takeover provisions. Some provisions of our post-offering memorandum and articles of association may discourage, delay, or prevent a change of control of our company or management that shareholders may consider favorable, including provisions that:

- authorize our board of directors to issue additional ordinary shares from time to time as our board of directors may determine, to the extent of available authorized but unissued shares; and
- limit the ability of shareholders to requisition and convene general meetings of shareholders.

However, under Cayman Islands law, our directors may only exercise the rights and powers granted to them under our post-offering memorandum and articles of association for a proper purpose and for what they believe in good faith to be in the best interests of our company.

Changes in capital. Our shareholders may from time to time by ordinary resolution:

- increase our share capital by such sum, to be divided into shares of such classes and amount, as the resolution shall prescribe;
- consolidate and divide all or any of our share capital into shares of a larger amount than our existing shares;
- sub-divide our existing shares, or any of them into shares of a smaller amount, provided that in the subdivision the proportion between the amount paid and the amount, if any, unpaid on each reduced share shall be the same as it was in case of the share from which the reduced share is derived; or
- cancel any shares which, at the date of the passing of the resolution, have not been taken or agreed to be taken by any person and diminish the amount of our share capital by the amount of the shares so canceled.

Our shareholders may, by special resolution, subject to confirmation by the Grand Court of the Cayman Islands on an application by our company for an order confirming such reduction, reduce our share capital or any capital redemption reserve in any manner permitted by law.

Exempted company. We are an exempted company with limited liability under the Companies Act. The Companies Act distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue negotiable or bearer shares or shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- may register as a segregated portfolio company.

“Limited liability” means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company (except in exceptional circumstances, such as involving fraud, the establishment of an agency relationship or an illegal or improper purpose or other circumstances in which a court may be prepared to pierce or lift the corporate veil).

Exclusive forum. Unless we consent in writing to the selection of an alternative forum, the United States District Court for the Southern District of New York (or, if the United States District Court for the Southern District of New York lacks subject matter jurisdiction over a particular dispute, the state courts in New York County, New York) shall be the exclusive forum within the United States for the resolution of any complaint asserting a cause of action arising under the Securities Act and the Exchange Act. Any person or entity purchasing or otherwise acquiring any of our shares, ADSs or other securities shall be deemed to have notice of and consented to the provisions of our post-offering memorandum and articles of association. See “Risk Factors — Risks relating to the ADSs — You may face difficulties in protecting your interests, and your ability to protect your rights through U.S. courts may be limited, because we are incorporated under Cayman Islands law” and “Risk Factors — Risks relating to the ADSs — Forum selection provisions in our post-offering memorandum and articles of association and our deposit agreement with the depositary bank could limit the

ability of holders of our ordinary shares, ADSs, or other securities to obtain a favorable judicial forum for disputes with us, our directors and officers, the depositary bank, and potentially others."

Differences in corporate law

The Companies Act is derived, to a large extent, from the older Companies Acts of England but does not follow recent English statutory enactments and, accordingly, there are significant differences between the Companies Act and the current Companies Act of England. In addition, the Companies Act differs from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain significant differences between the provisions of the Companies Act applicable to us and the laws applicable to companies incorporated in the United States and their shareholders.

Mergers and Similar Arrangements. The Companies Act permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (i) "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 (ii) a "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 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 the shareholders 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 surviving or consolidated 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. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

A merger between a Cayman parent company and its Cayman subsidiary or subsidiaries does not require authorization by a resolution of shareholders of that Cayman subsidiary if a copy of the plan of merger is given to every member of that Cayman subsidiary to be merged unless that member agrees otherwise. For this purpose, a subsidiary is a company of which at least ninety percent (90%) of the issued shares entitled to vote at a general meeting of such subsidiary are owned by the parent company.

The consent of each holder of a fixed or floating security interest over a constituent company is required unless this requirement is waived by a court in the Cayman Islands.

Save in certain circumstances, a dissenting shareholder of a Cayman constituent company is entitled to payment of the fair value of his shares upon dissenting to a merger or consolidation. The exercise of appraisal rights will preclude the exercise of any other rights save for the right to seek relief on the grounds that the merger or consolidation is void or unlawful.

In addition, there are statutory provisions that facilitate the reconstruction and amalgamation of companies, provided that the arrangement is approved by a majority in number of each class of shareholders and creditors with whom the arrangement is to be made, and who must in addition represent three-fourths in value of each such class of shareholders or creditors, as the case may be, that are present and voting either in person or by proxy at a meeting, or meetings, convened for that purpose. The convening of the meetings and subsequently the arrangement must be sanctioned by the Grand Court of the Cayman Islands. While a dissenting shareholder has the right to express to the court the view that the transaction ought not to be approved, the court can be expected to approve the arrangement if it determines that:

- the statutory provisions as to the required majority vote have been met;
- the shareholders have been fairly represented at the meeting in question and the statutory majority are acting bona fide without coercion of the minority to promote interests adverse to those of the class;
- the arrangement is such that may be reasonably approved by an intelligent and honest man of that class acting in respect of his interest; and

- the arrangement is not one that would more properly be sanctioned under some other provision of the Companies Act.

When a takeover offer is made and accepted by holders of 90.0% of the shares within four months, the offeror may, within a two-month period commencing on the expiration of such four-month period, require the holders of the remaining shares to transfer such shares on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion.

If an arrangement and reconstruction by way of scheme of arrangement is thus approved and sanctioned, or if a tender offer is made and accepted in accordance with the foregoing statutory procedures, a dissenting shareholder would have no rights comparable to appraisal rights, which would otherwise ordinarily be available to dissenting shareholders of Delaware corporations, providing rights to receive payment in cash for the judicially determined value of the shares.

Shareholders' Suits. In principle, we will normally be the proper plaintiff and as a general rule a derivative action may not be brought by a minority shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority in the Cayman Islands, the Cayman Islands court can be expected to follow and apply the common law principles (namely the rule in Foss v. Harbottle and the exceptions thereto) so that a non-controlling shareholder may be permitted to commence a class action against or derivative actions in the name of the company to challenge actions where:

- a company acts or proposes to act illegally or ultra vires;
- the act complained of, although not ultra vires, could only be effected duly if authorized by more than a simple majority vote that has not been obtained; and
- those who control the company are perpetrating a "fraud on the minority."

Indemnification of directors and executive officers and limitation of liability. Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of directors and officers, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against the consequences of committing a crime, or against the indemnified person's own fraud or dishonesty.

This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation. In addition, we have entered into indemnification agreements with our directors and executive officers that provide such persons with additional indemnification beyond that provided in our post-offering amended and restated memorandum and articles of association.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or persons controlling us under the foregoing provisions, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Directors' fiduciary duties. Under Delaware corporate law, a director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components: the duty of care and the duty of loyalty. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director acts in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer, or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, the director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.

As a matter of Cayman Islands law, a director of a Cayman Islands company is in the position of a fiduciary with respect to the company and therefore it is considered that he owes the following duties to the company — a duty to act in good faith in the best interests of the company, a duty not to make a personal profit based on his position as director (unless the company permits him to do so), a duty not to put himself in a position where the interests of the company conflict with his personal interest or his duty to a third party, and a duty to exercise powers for the purpose for which such powers were intended. A director of a Cayman Islands company owes to the company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands.

Shareholder action by written consent. Under the Delaware General Corporation Law, a corporation may eliminate the right of shareholders to act by written consent by amendment to its certificate of incorporation. The Companies Act and our post-offering memorandum and articles of association provide that shareholders may approve corporate matters by way of a unanimous written resolution signed by or on behalf of each shareholder who would have been entitled to vote on such matter at a general meeting without a meeting being held, and any such resolution in writing shall be as valid and effective as if the same had been passed at a general meeting of our company duly convened and held.

Shareholder proposals. Under the Delaware General Corporation Law, a shareholder has the right to put any proposal before the annual meeting of shareholders; provided that it complies with the notice provisions in the governing documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.

The Companies Act provides shareholders with only limited rights to requisition a general meeting, and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. [Our post-offering memorandum and articles of association allow our shareholders holding shares which carry in aggregate not less than one-third of the total number of votes attaching to all issued and outstanding shares of our company entitled to vote at general meetings to requisition an extraordinary general meeting of our shareholders, in which case our board is obliged to convene an extraordinary general meeting and to put the resolutions so requisitioned to a vote at such meeting. Other than this right to requisition a shareholders' meeting, our post-offering amended and restated articles of association do not provide our shareholders with any other right to put proposals before annual general meetings or extraordinary general meetings. As an exempted Cayman Islands company, we are not obliged by law to call shareholders' annual general meetings.]

Cumulative voting. Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation's certificate of incorporation specifically provides for it. Cumulative voting potentially facilitates the representation of minority shareholders on a board of directors since it permits the minority shareholder to cast all the votes to which the shareholder is entitled on a single director, which increases the shareholder's voting power with respect to electing such director.

Under the Companies Act of the Cayman Islands, cumulative voting for the election of directors is not permitted unless so provided in the memorandum and articles of association. There are no prohibitions in relation to cumulative voting under the laws of the Cayman Islands, but our post-offering memorandum and articles of association do not provide for cumulative voting. As a result, our shareholders are not afforded any less protections or rights on this issue than shareholders of a Delaware corporation.

Removal of directors. Under the Delaware General Corporation Law, a director of a corporation with a classified board may be removed only for cause with the approval of a majority of the issued and outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under our post-offering memorandum and articles of association, directors may be removed by an ordinary resolution of our shareholders or by the board of directors. A director will also cease to be a director if he (i) becomes bankrupt or makes any arrangement or composition with his creditors; (ii) dies or is found to be or becomes of unsound mind; (iii) resigns his office by notice in writing; (iv) is prohibited by any applicable law or designated stock exchange rules from being a director; (v) without special leave of absence from our board, is absent from

meetings of our board for three consecutive meetings and our board resolves that his office be vacated; or (vi) is removed from office pursuant to any other provision of our articles of association.

Transactions with interested shareholders. The Delaware General Corporation Law contains a business combination statute applicable to Delaware corporations whereby, unless the corporation has specifically elected not to be governed by such statute by amendment to its certificate of incorporation, it is prohibited from engaging in certain business combinations with an "interested shareholder" for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or a group who or which owns or owned 15% or more of the target's outstanding voting shares within the past three years. This has the effect of limiting the ability of a potential acquirer to make a two-tiered bid for the target in which all shareholders would not be treated equally. The statute does not apply if, among other things, prior to the date on which such shareholder becomes an interested shareholder, the board of directors approves either the business combination or the transaction which resulted in the person becoming an interested shareholder. This encourages any potential acquirer of a Delaware corporation to negotiate the terms of any acquisition transaction with the target's board of directors.

Cayman Islands law has no comparable statute. As a result, we cannot avail ourselves of the types of protections afforded by the Delaware business combination statute. However, although Cayman Islands law does not regulate transactions between a company and its significant shareholders, it does provide that such transactions must be entered into bona fide in the best interests of the company and not with the effect of constituting a fraud on the minority shareholders.

Dissolution; winding up. Under the Delaware General Corporation Law, unless the board of directors approves the proposal to dissolve, dissolution must be approved by shareholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by either an order of the courts of the Cayman Islands or by the board of directors.

Under Cayman Islands law, a company may be wound up by either an order of the courts of the Cayman Islands or by a special resolution of its members or, if the company is unable to pay its debts as they fall due, by an ordinary resolution of its members. The court has authority to order winding up in a number of specified circumstances including where it is, in the opinion of the court, just and equitable to do so. Under the Companies Act, our company may be dissolved, liquidated, or wound up by a special resolution of our shareholders.

Variation of rights of shares. Under the Delaware General Corporation Law, a corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise. Under our post-offering memorandum and articles of association, if our share capital is divided into more than one class of shares, the rights attached to any such class may only be materially adversely varied with the consent in writing of the holders of not less than two-thirds of the issued shares of that class or with the sanction of a resolution passed at a separate meeting of the holders of the shares of that class by a majority of two-thirds of the votes cast at such a meeting. The rights conferred upon the holders of the shares of any class issued with preferred or other rights shall not, subject to any rights or restrictions for the time being attached to the shares of that class, be deemed to be materially adversely varied by the creation, allotment or issue of further shares ranking *pari passu* with or subsequent to them or the redemption or purchase of any shares of any class by our company.

Amendment of governing documents. Under the Delaware General Corporation Law, a corporation's governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under the Companies Act and our post-offering memorandum and articles of association, our memorandum and articles of association may only be amended by a special resolution of our shareholders.

Rights of non-resident or foreign shareholders. There are no limitations imposed by our post-offering memorandum and articles of association on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our shares. In addition, there are no provisions in our post-offering memorandum and articles of association that require our company to disclose shareholder ownership above any particular ownership threshold.

History of share capital

The following is a summary of changes in our share capital in the past three years.

Ordinary shares

On May 28, 2021, Mr. Yang Lu transferred 900,000 ordinary shares through an entity controlled by him to Lucy Zhang for consideration of USD2,833,574 due to debt-to-equity swap for settlement of a convertible loan between Mr. Yang Lu and Lucy Zhang's father, each of Lucy Zhang and her father is an independent third party to Mr. Lu and us. Such convertible loan was provided by Lucy Zhang's father to Mr. Lu for the purpose of investing on our company. On July 5, 2021, we issued (i) 9,000,000 ordinary shares to Nortye Talent Limited and (ii) 6,000,000 ordinary shares to Nortye International Limited for nominal consideration as reservation for future transfers to employees upon their exercise of share incentive awards. On the same day, we issued (i) 5,000,000 ordinary shares to PECO International Limited for nominal consideration as compensation to certain management personnel and (ii) 16,990,000 ordinary shares to Archer Future Limited and 2,550,000 ordinary shares to DH Future Limited, for Mr. Yang Lu and Mr. Donghui Yang's family trust, respectively.

Preferred shares

Our ultimate holding company was incorporated in the Cayman Islands on May 9, 2018. Before the completion of the restructuring in 2019, we completed the Series A investments. From January 2020 to April 2020, Series A investors exercised the options and converted their equity interests in Adlai Hangzhou to Series A preferred shares of the Company. As a result, we issued (i) 3,500,000 Series A preferred shares to LAI NUO (BVI) LIMITED; (ii) 6,060,000 Series A preferred shares to JIN YIN (BVI) LIMITED; (iii) 3,430,000 Series A preferred shares to LV YI (BVI) LIMITED; and (iv) 1,570,000 Series A preferred shares to Yingzhi International Limited.

In parallel with our reorganization, we also completed our series B financing issuing certain convertible loans by Hangzhou Adlai. Meanwhile, we also entered into a forward contract with Series B investors to grant them an option to convert their convertible loans of Hangzhou Adlai to Series B preferred shares of the Company. During April 2020 to May 2020, Series B investors had exercised the option, and we issued (i) 1,000,000 Series B preferred shares to BJKR Management Ltd. for consideration of RMB25,000,000; (ii) 960,000 Series B preferred shares to Ningbo Meishan Bonded Port Area Yahui Xinrun Investment Management Center (Limited Partnership) for consideration of RMB24,000,000; (iii) 640,000 Series B preferred shares to Beijing Yahui Qianfeng Equity Investment Partnership (Limited Partnership) for consideration of RMB16,000,000; (iv) 2,000,000 Series B preferred shares to QHYM Investment Ltd. for consideration of RMB50,000,000; and (v) 2,000,000 Series B preferred shares to Dexuan (Shanghai) Enterprise Management Center (Limited Partnership) for consideration of RMB50,000,000. On May 20, 2019, we entered into a warrant agreement with China Equities HK Limited under the condition of a bank facility agreement. In July 2021, China Equities HK Limited elected to exercise cashless exchange of such warrants, and we issued 100,000 Series B preferred shares to China Equities HK Limited.

Since the end of 2019, we attracted another round of investment and entered into a series of share purchase agreements, by, among others, with six investors pursuant to which the investors agreed to subscribe for a total of 14,653,013 Series C preferred shares. During December 2019 to August 2020, we issued (i) 1,150,158 Series C preferred shares to Hongkong Tigermed Co., Limited for consideration of USD5,000,000; (ii) 4,600,632 Series C preferred shares to ATCG Holdings Limited for consideration of USD20,000,000; (iii) 230,032 Series C preferred shares to Pingtan Hongtu No. 5 Venture Capital Partnership (Limited Partnership) for consideration of USD1,000,000; (iv) 2,300,316 Series C preferred shares to Pingtan Yingke Shengxin Chuangye Partnership (Limited Partnership) for consideration of USD10,000,000; (v) 621,085 Series C preferred shares to Pingtan Puxin Yingke Ruiyuan Venture Capital Partnership (Limited Partnership) for consideration of USD2,700,000; and (vi) 5,750,790 Series C preferred shares to UNIQUE MARK VENTURES LIMITED for consideration of USD25,000,000.

Since early 2021, pursuant to a series of share purchase agreements entered into by, among others, our ultimate holding company, our founders and more than ten investors, the investors agreed to subscribe for 14,722,505 Series D preferred shares. As a result, from May to July of 2021, we issued (i) 2,268,025 Series D

preferred shares to ATCG Holdings Limited for consideration of USD15,000,000; (ii) 756,008 Series D preferred shares to Hangzhou Tigermed Equity Investment Partnership (Limited Partnership) for consideration of USD5,000,000; (iii) 2,066,927 Series D preferred shares to Triwise Kangnuo Investment Limited for consideration of USD13,670,000; (iv) 1,239,854 Series D preferred shares to Qingdao Mukui Equity Investment Partnership (Limited Partnership) for consideration of USD8,200,000; (v) 680,407 Series D preferred shares to Wuxi Guolian Guokang Health Industry Investment Centre (Limited Partnership) for consideration of USD4,500,000; (vi) 453,605 Series D preferred shares to Week8 Holdings (HK) Limited for consideration of USD3,000,000; (vii) 302,403 Series D preferred shares to Ningbo Menovo Ruihe Equity Investment Partnership (Limited Partnership) for consideration of USD2,000,000; (viii) 4,536,050 Series D preferred shares to Xianjin Zhizao Industry Investment Fund II (Limited Partnership) for consideration of USD30,000,000; (ix) 226,802 Series D preferred shares to Adlai Nortye Investment Limited for consideration of USD1,500,000; (x) 453,605 Series D preferred shares to Legendstar Fund IV, L.P. for consideration of USD3,000,000; (xi) 1,512,017 Series D preferred shares to Phantom Capital Fund L.P. for consideration of USD10,000,000 and (xii) 226,802 Series D preferred shares to WuXi Biologics Healthcare Venture for consideration of USD1,500,000.

Immediately prior to the completion of this offering, issued and outstanding ordinary shares held by Archer Future Limited will be re-designated as Class B ordinary shares on a one-for-one basis, and the remaining issued and outstanding ordinary shares will be re-designated as Class A ordinary shares on a one-for-one basis.

Grant of share incentive awards

We have granted options to purchase our ordinary shares to certain of our directors, executive officers, employees, and consultants. See “Management — Share incentive plans.”

Shareholders agreement

Our currently effective shareholders agreement was entered into on April 15, 2021 by and among us, our shareholders, and certain other parties named therein.

The current shareholders agreement provides for certain special rights, including registration right, right of first refusal and right of co-sale, and contains provisions governing the board of directors and other corporate governance matters. Those special rights as well as the corporate governance provisions will terminate upon the completion of this offering.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

American Depositary Shares

The Bank of New York Mellon, as depositary, will register and deliver American Depositary Shares, also referred to as ADSs. Each ADS will represent Class A ordinary shares (or a right to receive Class A ordinary shares) deposited with The Hong Kong and Shanghai Banking Corporation Limited, as custodian for the depositary in Hong Kong. Each ADS will also represent any other securities, cash or other property that may be held by the depositary. The deposited shares, together with any other securities, cash or other property held by the depositary, are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC. If you hold ADSs directly, you are a registered ADS holder, also referred to as an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. Cayman Islands law governs shareholder rights. The depositary will be the holder of the Class A ordinary shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR. For directions on how to obtain copies of those documents, see "Where You Can Find Additional Information."

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of Class A ordinary shares your ADSs represent.

Cash. The depositary will convert any cash dividend or other cash distribution we pay on the Class A ordinary shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. See "Taxation." The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.*

Shares. The depositary may distribute additional ADSs representing any Class A ordinary shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell Class A ordinary shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new Class A ordinary shares. The depositary may sell a portion of the distributed Class A ordinary shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

Rights to purchase additional shares. If we offer holders of our Class A ordinary shares any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. *In that case, you will receive no value for them.* The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of Class A ordinary shares, new ADSs representing the new Class A ordinary shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you*.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits Class A ordinary shares or evidence of rights to receive Class A ordinary shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the Class A ordinary shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited share or other security. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do you vote?

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of the Cayman Islands and the provisions of our memorandum and articles of association or similar documents, to vote or to have its agents vote the Class A ordinary shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

Except by instructing the depositary as described above, you will not be able to exercise voting rights unless you surrender your ADSs and withdraw the Class A ordinary shares. However, you may not know about the meeting enough in advance to withdraw the Class A ordinary shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote the Class A ordinary shares represented by your ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise voting rights and there may be nothing you can do if the Class A ordinary shares represented by your ADSs are not voted as you requested.*

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to depository securities, if we request the Depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:	**For:**
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
	Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	Depositary services

Persons depositing or withdrawing shares or ADS holders must pay:	For:
Registration or transfer fees	Transfer and registration of Class A ordinary shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw Class A ordinary shares
Expenses of the depositary	Cable (including SWIFT) and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or Class A ordinary shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates, or the custodian or we may convert currency and pay U.S. dollars to the depositary. Where the depositary converts currency itself or through any of its affiliates, the depositary acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained by it or its affiliate in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligation to act without negligence or bad faith. The methodology used to determine exchange rates used in currency conversions made by the depositary is available upon request. Where the custodian converts currency, the custodian has no obligation to obtain the most favorable rate that could be obtained at the time or to ensure that the method by which that rate will be determined will be the most favorable to ADS holders, and the depositary makes no representation that the rate is the most favorable rate and will not be liable for any direct or indirect losses associated with the rate. In certain instances, the depositary may receive dividends or other distributions from us in U.S. dollars that represent the proceeds of a conversion of foreign currency or translation from foreign currency at a rate that was obtained or determined by us and, in such cases, the depositary will not engage in, or be responsible for, any foreign currency transactions and neither it nor we make any representation that the rate obtained or determined by us is the most favorable rate and neither it nor we will be liable for any direct or indirect losses associated with the rate.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do so by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADSs in exchange for new ADSs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.*

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;

- we delist the ADSs from an exchange in the United States on which they were listed and do not list the ADSs on another exchange in the United States or make arrangements for trading of ADSs on the U.S. over-the-counter market;
- we delist our shares from an exchange outside the United States on which they were listed and do not list the shares on another exchange outside the United States;
- the depositary has reason to believe the ADSs have become, or will become, ineligible for registration on Form F-6 under the Securities Act of 1933;
- we appear to be insolvent or enter insolvency proceedings;
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind that have not settled if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to ADS holders (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;
- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its ability to prevent or counteract with reasonable care or effort from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;

- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depositary has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of Class A ordinary shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any Class A ordinary shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Shares Underlying your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying Class A ordinary shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our Class A ordinary shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of Class A ordinary shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and

delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder Communications; Inspection of Register of Holders of ADSs

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

Jury Trial Waiver

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our Class A ordinary shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law.

You will not, by agreeing to the terms of the deposit agreement, be deemed to have waived our or the depositary's compliance with U.S. federal securities laws or the rules and regulations promulgated thereunder.

SHARES ELIGIBLE FOR FUTURE SALE

Upon completion of this offering, we will have ADSs outstanding, representing Class A ordinary shares, or approximately % of our outstanding ordinary shares. All of the ADSs sold in this offering will be freely transferable by persons other than by our "affiliates" without restriction or further registration under the Securities Act. Sales of substantial amounts of the ADSs in the public market could adversely affect prevailing market prices of the ADSs. Prior to this offering, there has been no public market for our ordinary shares or the ADSs. We intend to apply to list the ADSs on the Nasdaq Stock Market, but we cannot assure you that a regular trading market will develop in the ADSs. We do not expect that a trading market will develop for our ordinary shares not represented by the ADSs.

Lock-up agreements

We, [our directors and executive officers and our existing shareholders and holders of share-based awards] have agreed, subject to some exceptions, not to transfer or dispose of, directly or indirectly, any of our ordinary shares, in the form of ADSs or otherwise, or any securities convertible into or exchangeable or exercisable for our ordinary shares, in the form of ADSs or otherwise, for a period of 180 days after the date of this prospectus. After the expiration of the 180-day period, the ordinary shares or ADSs held by our directors, executive officers, and our existing shareholders and holders of share-based awards may be sold subject to the restrictions under Rule 144 under the Securities Act or by means of registered public offerings.]

Rule 144

All of our ordinary shares that will be outstanding upon the completion of this offering, other than those ordinary shares sold in this offering, are "restricted securities" as that term is defined in Rule 144 under the Securities Act and may be sold publicly in the United States only if they are subject to an effective registration statement under the Securities Act or pursuant to an exemption from the registration requirement such as those provided by Rule 144 and Rule 701 promulgated under the Securities Act. In general, beginning 90 days after the date of this prospectus, a person who at the time of a sale is not, and has not been during the three months preceding the sale, an affiliate of ours and has beneficially owned our restricted securities for at least six months will be entitled to sell the restricted securities without registration under the Securities Act, subject only to the availability of current public information about us, and will be entitled to sell restricted securities beneficially owned for at least one year without restriction. Persons who are our affiliates and have

beneficially owned our restricted securities for at least six months may sell a number of restricted securities within any three-month period that (together with any sales aggregated with them) does not exceed the greater of the following:

- 1% of the then outstanding ordinary shares of the same class, in the form of ADSs or otherwise, which immediately after this offering will equal Class A ordinary shares; or
- the average weekly trading volume of our ordinary shares of the same class, in the form of ADSs or otherwise, during the four calendar weeks preceding the date on which notice of the sale is filed with the SEC.

Sales by our affiliates under Rule 144 are also subject to certain requirements relating to manner of sale, notice, and the availability of current public information about us.

Rule 701

In general, under Rule 701 of the Securities Act as currently in effect, each of our employees, consultants or advisors who purchases our ordinary shares from us in connection with a compensatory stock plan or other written agreement executed prior to the completion of this offering is eligible to resell those ordinary shares in reliance on Rule 144, but without compliance with some of the restrictions, including the holding period, contained in Rule 144.

TAXATION

The following summary of Cayman Islands, PRC, and U.S. federal income tax considerations of an investment in the ADSs or ordinary shares is based upon laws and relevant interpretations thereof in effect as of the date of this registration statement, all of which are subject to change. This summary does not deal with all possible tax considerations relating to an investment in the ADSs or ordinary shares, such as the tax considerations under U.S. state and local tax laws or under the tax laws of jurisdictions other than the Cayman Islands, the People's Republic of China, and the United States. To the extent that the discussion relates to matters of Cayman Islands tax law, it represents the opinion of Maples and Calder (Hong Kong) LLP, our Cayman Islands legal counsel; to the extent it relates to PRC tax law, it is the opinion of Han Kun Law Offices, our PRC legal counsel.

Cayman Islands 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 certain stamp duties which may be applicable, from time to time, on certain instruments executed in or brought within the jurisdiction of the Cayman Islands. The Cayman Islands is not a party to any double tax treaties that are applicable to any payments made to or by the Company.

Further, no stamp duty is payable in respect of the issue of our ordinary shares or on an instrument of transfer in respect of our ordinary shares, unless the relevant instruments are executed in, or after execution brought within, the jurisdiction of the Cayman Islands or our company holds interests in land in the Cayman Islands.

Payments of dividends and capital in respect of the ADSs will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of a dividend or capital to any holder of the ADSs, nor will gains derived from the disposal of the ADSs be subject to Cayman Islands income or corporate tax.

People's Republic of China taxation

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside China with "de facto management body" within China is considered a resident enterprise. The implementation rules define the term "de facto management body" as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts, and properties of an enterprise. In April 2009, the SAT issued a circular, known as SAT Circular 82, which provides certain specific criteria for determining whether the "de facto management body" of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the SAT's general position on how the "de facto management body" test should be applied in determining the tax resident status of all offshore enterprises. According to SAT Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its "de facto management body" in China only if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in China; (ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in China; (iii) the enterprise's primary assets, accounting books, and records, company seals, and board and shareholder meeting minutes are located or maintained in China; and (iv) at least 50% of voting board members or senior executives habitually reside in China.

Our company is incorporated outside the PRC. As a holding company, its key assets are its ownership interests in its subsidiaries, and its key assets are located, and its records (including the resolutions of its board of directors and the resolutions of its shareholders) are maintained, outside the PRC. As such, we do not believe that our company meets all of the conditions above or is a PRC resident enterprise for PRC tax purposes. For the same reasons, we believe our other entities outside China are not PRC resident enterprises either. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities

and uncertainties remain with respect to the interpretation of the term "de facto management body." There can be no assurance that the PRC government will ultimately take a view that is consistent with us.

If the PRC tax authorities determine that our Cayman Islands holding company is a PRC resident enterprise for PRC enterprise income tax purposes, a 10% withholding tax would be imposed on dividends we pay to our non-PRC enterprise shareholders (including the ADS holders) if such dividends are deemed to be sourced within the PRC. In addition, non-PRC resident enterprise shareholders (including the ADS holders) may be subject to PRC tax on gains realized on the sale or other disposition of ADSs or ordinary shares at a rate of 10% if such income is treated as sourced from within the PRC. Furthermore, if we are deemed a PRC resident enterprise, dividends paid to our non-PRC individual shareholders (including the ADS holders) and any gain realized on the transfer of ADSs or ordinary shares by such shareholders may be subject to PRC tax at a rate of 20% (which, in the case of dividends, may be withheld at source by us) if such dividends or gains are deemed to be sourced within the PRC. These rates may be reduced by an applicable tax treaty, but it is unclear whether non-PRC shareholders of our company would be able to claim the benefits of any tax treaties between their country of tax residence and the PRC in the event that we are treated as a PRC resident enterprise.

Pursuant to the PRC Enterprise Income Tax Law and its implementation rules, if a non-resident enterprise has not set up an organization or establishment in China, or has set up an organization or establishment but the income derived has no actual connection with such organization or establishment, it will be subject to a withholding tax on its PRC-sourced income at a rate of 10%. Pursuant to the Arrangement between Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income, the tax rate in respect to dividends paid by a PRC enterprise to a Hong Kong enterprise is reduced to 5% from a standard rate of 10% if the Hong Kong enterprise directly holds at least 25% of the PRC enterprise. Pursuant to the Notice of the State Administration of Taxation on the Issues concerning the Application of the Dividend Clauses of Tax Agreements, or SAT Circular 81, a Hong Kong resident enterprise must meet the following conditions, among others, in order to enjoy the reduced tax rate: (i) it must directly own the required percentage of equity interests and voting rights in the PRC resident enterprise; and (ii) it must have directly owned such percentage in the PRC resident enterprise throughout the 12 months prior to receiving the dividends. Furthermore, in accordance with the Measures for Non-resident Taxpayers' Enjoyment of Treaty Benefits, which became effective in January 2020, where non-resident enterprises determine through self-assessment that they meet the conditions for entitlement of reduced tax rate according to tax treaties, they may enjoy such entitlement after reporting required information to competent tax authorities provided that they shall collect and retain relevant documents for future reference and inspections. Accordingly, our subsidiary Adlai Nortye (HK) Limited may be able to enjoy the 5% tax rate for the dividends it receives from its PRC incorporated subsidiaries if they satisfy the conditions prescribed under SAT Circular 81 and other relevant tax rules and regulations and complete necessary government formalities. However, according to SAT Circular 81, if the relevant tax authorities determine our transactions or arrangements are for the primary purpose of enjoying a favorable tax treatment, the relevant tax authorities may adjust the favorable tax rate on dividends in the future.

Provided that our Cayman Islands holding company is not deemed to be a PRC resident enterprise, holders of the ADSs and ordinary shares who are not PRC residents will not be subject to PRC income tax on dividends distributed by us or gains realized from the sale or other disposition of our ordinary shares or ADSs. However, under SAT Circular 7 and SAT Circular 37, where a non-resident enterprise conducts an "indirect transfer" by transferring taxable assets, including, in particular, equity interests in a PRC resident enterprise, indirectly by disposing of the equity interests of an overseas holding company, the non-resident enterprise, being the transferor, or the transferee or the PRC entity which directly owned such taxable assets may report to the relevant tax authority such indirect transfer. Using a "substance over form" principle, the PRC tax authority may disregard the existence of the overseas holding company if it lacks a reasonable commercial purpose and was established for the purpose of reducing, avoiding or deferring PRC tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax, and the transferee or other person who is obligated to pay for the transfer is obligated to withhold the applicable taxes, currently at a rate of 10% for the transfer of equity interests in a PRC resident enterprise. However, sales of shares and ADSs by investors through a public stock exchange where such shares or ADSs are acquired on a public stock exchange are currently exempt from these indirect transfer rules under SAT Circular 7 and SAT Circular 37. We and our non-PRC resident investors may be at risk of being required to file a return and being

taxed under SAT Circular 7 and SAT Circular 37, and we may be required to expend valuable resources to comply with SAT Circular 7 and SAT Circular 37, or to establish that we should not be taxed under these Circulars.

United States federal income tax considerations

The following discussion is a general discussion of certain U.S. federal income tax considerations relating to the ownership and disposition of the ADSs or Class A ordinary shares by U.S. Holders (as defined below) that acquire the ADSs in this offering and holds the ADSs as "capital assets" (generally, property held for investment) under the U.S. Internal Revenue Code of 1986, as amended, or the Code. This discussion does not address any aspect of U.S. federal gift or estate tax, alternative minimum tax, the Medicare tax on net investment income, or the state, local or non-U.S. tax consequences of an investment in the ADSs or Class A ordinary shares. This discussion is based on the Code, its legislative history, existing and proposed regulations promulgated thereunder, published rulings, court decisions, and the income tax treaty between the U.S. and the PRC, or the Treaty, all as of the date hereof. These laws are subject to change, possibly on a retroactive basis. No ruling has been obtained and no ruling will be requested from the U.S. Internal Revenue Service, or the IRS, with respect to any of the U.S. federal income tax consequences described below, and as a result, there can be no assurance that the IRS will not disagree with or challenge any of the statements provided below.

This discussion is not a complete description of all tax considerations that may be relevant to particular investors in light of their individual circumstances or investors subject to special tax rules, such as:

- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of tax accounting for securities holdings;
- banks or certain financial institutions;
- insurance companies;
- tax-exempt organizations, "individual retirement accounts" or "Roth IRAs";
- partnerships or other entities treated as partnerships or other pass-through entities for U.S. federal income tax purposes or persons holding the ADSs or ordinary shares through any such entities;
- regulated investment companies or real estate investment trusts;
- persons that hold the ADSs or ordinary shares as part of a hedge, straddle, constructive sale, conversion transaction, or other integrated investment;
- persons whose functional currency for tax purposes is not the U.S. dollar;
- U.S. expatriates;
- persons liable for alternative minimum tax; or
- persons that actually or constructively own 10% or more of (i) the total combined voting power of all classes of our voting stock or (ii) the total value of all classes of our stock (including the ADSs or ordinary shares).

Each prospective investor is urged to consult its tax advisor regarding the application of U.S. federal taxation to its particular circumstances, and the state, local, non-U.S., and other tax considerations of the ownership and disposition of the ADSs or ordinary shares.

General

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of the ADSs or ordinary shares that is:

- an individual citizen or resident of the United States for U.S. federal income tax purposes;
- a corporation, or other entity classified as a corporation for U.S. federal income tax purposes, that was created or organized in or under the laws of the United States, any state thereof or the District of Columbia;

- an estate the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all substantial decisions of the trust, or (ii) the trust has a valid election in effect to be treated as a U.S. person.

For U.S. federal income tax purposes, income earned through an entity or arrangement classified as a partnership for U.S. federal income tax purposes is attributed to its owners. Accordingly, if a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) is a beneficial owner of the ADSs or ordinary shares, the tax treatment of a partner in the partnership will generally depend upon the status of the partner and the activities of the partnership. Partnerships holding the ADSs or ordinary shares and their partners are urged to consult their tax advisors regarding an investment in the ADSs or ordinary shares.

For U.S. federal income tax purposes, it is generally expected that a U.S. Holder of ADSs will be treated as the beneficial owner of the underlying shares represented by the ADSs. The remainder of this discussion assumes that a U.S. Holder of the ADSs will be treated in this manner. Accordingly, deposits or withdrawals of ordinary shares for ADSs will generally not be subject to U.S. federal income tax.

Dividends

The following discussion is subject to the discussion under “Passive Foreign Investment Company” below. If we make cash distributions and you are a U.S. Holder, the gross amount of any distributions with respect to your ADSs or ordinary shares (including the amount of any taxes withheld therefrom) will be includible in your gross income on the day you actually or constructively receive such income as dividend income if the distributions are made from our current or accumulated earnings and profits, calculated according to U.S. federal income tax principles. We do not intend to calculate our earnings and profits according to U.S. federal income tax principles. Accordingly, you should expect that distributions on the ADSs or ordinary shares, if any, will generally be treated as dividend income for U.S. federal income tax purposes. Dividends received on the ADSs or ordinary shares will not be eligible for the dividends received deduction generally allowed to U.S. corporations. Dividends received by individuals and certain other non-corporate U.S. Holders may be subject to tax at the lower capital gain tax rate applicable to “qualified dividend income,” provided that certain conditions are satisfied, including that (1) the ADSs or ordinary shares on which the dividends are paid are readily tradeable on an established securities market in the United States, or, in the event that we are deemed to be a PRC resident enterprise under the PRC tax law, we are eligible for the benefits of the Treaty, (2) we are neither a PFIC nor treated as such with respect to such a U.S. Holder for the taxable year in which the dividend was paid and the preceding taxable year, and (3) certain holding period requirements are met. We expect the ADSs (but not our ordinary shares), which we intend to apply to list on the Nasdaq Stock Market will be considered readily tradeable on an established securities market in the United States, although there can be no assurance in this regard.

In the event that we are deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law. For details, see “— People’s Republic of China taxation”. We may be eligible for the benefits of the Treaty. If we are eligible for such benefits, dividends we pay on our ordinary shares, regardless of whether such shares are represented by the ADSs, would be eligible for the reduced rate of taxation described in the preceding paragraph (subject to the satisfaction of the other conditions described therein).Dividends paid on the ADSs or ordinary shares, if any, will generally be treated as income from foreign sources and will generally constitute passive category income for U.S. foreign tax credit purposes. As described under “Taxation — People’s Republic of China taxation,” we may be classified as a “resident enterprise” of China. This classification could result in unfavorable tax consequences to us and our non-PRC shareholders and dividends paid by us may be subject to PRC withholding tax. Any amount withheld in respect of PRC withholding tax will be treated as distributed to you for purposes of determining the amount of any taxable dividend. Depending on the U.S. Holder’s individual facts and circumstances, a U.S. Holder may be eligible, subject to a number of complex limitations, to claim a foreign tax credit in respect of any nonrefundable PRC withholding taxes imposed on dividends received on the ADSs or ordinary shares. A U.S. Holder who does not elect to claim a foreign tax credit for foreign taxes withheld may instead claim a deduction, for U.S. federal income tax purposes, in respect of such withholding, but only for a year in which such holder elects to do so for all creditable foreign income taxes. The rules governing the foreign tax credit are complex and their outcome

depends in large part on the U.S. Holder's individual facts and circumstances. Accordingly, U.S. Holders are urged to consult their tax advisors regarding the availability of the foreign tax credit under their particular circumstances.

Sale or other disposition

The following discussion is subject to the discussion under "Passive Foreign Investment Company" below. A U.S. Holder will generally recognize capital gain or loss upon the sale or other disposition of the ADSs or ordinary shares in an amount equal to the difference between the amount realized upon the disposition and the holder's adjusted tax basis in such ADSs or ordinary shares. The holder's adjusted tax basis will generally equal the amount the holder paid (including the offering price for the ADS or ordinary shares and trading fee, transaction levy and brokerage fee paid in connection with such purchase). Any gain or loss the U.S. Holder recognizes will generally be long-term capital gain or loss if the ADSs or ordinary shares have been held for more than one year and will generally be U.S.-source gain or loss for U.S. foreign tax credit purposes. Long-term capital gain of individuals and certain other non-corporate U.S. Holders will generally be eligible for a more favorable rate of taxation. The deductibility of a capital loss may be subject to limitations.

Gains from dispositions of the ADSs or ordinary shares may be subject to PRC tax if such gains are deemed as income derived from sources within China for PRC tax purposes or result from an "indirect transfer" (see "— People's Republic of China taxation.") In that case, the amount realized would include the gross amount of the proceeds of the sale or disposition before deduction of the PRC tax. Any gain generally would constitute U.S.-source income. However, a U.S. Holder that is eligible for the benefits of the Treaty may be able to elect to treat its gain as PRC-source gain for foreign tax credit purposes. If a U.S. Holder is not eligible for the benefits of the Treaty or fails to treat any such gain as PRC-source, then such U.S. Holder would generally not be able to use any foreign tax credit arising from any PRC tax imposed on the disposition of the ADSs or ordinary shares unless such credit can be applied (subject to applicable limitations) against U.S. federal income tax due on other income derived from foreign sources in the same income category (generally, the passive category). Recently finalized Treasury regulations may also impose additional limitations on the creditability of any PRC tax on sales or dispositions of the ADSs or ordinary shares. For instance, such Treasury regulations generally preclude a U.S. Holder from claiming a foreign tax credit with respect to PRC income taxes on gains on dispositions of the ADSs or ordinary shares if the U.S. Holder does not elect to apply the benefits of the Treaty. However, in that case it is possible that any PRC taxes on disposition gains may either be deductible or reduce the amount realized on the disposition. We also note that any PRC VAT will not be creditable for foreign tax credit purposes. U.S. Holders are urged to consult their tax advisors regarding the tax consequences if a foreign tax is imposed on a disposition of the ADSs or ordinary shares, including the availability of the foreign tax credit under their particular circumstances.

Passive foreign investment company

In connection with this offering, we are evaluating whether we will be classified as a "passive foreign investment company" for U.S. federal income tax purposes. We will complete this analysis prior to the effectiveness of the registration statement for which this prospectus forms a part.

If we were classified as a PFIC for any taxable year during which a U.S. Holder holds the ADSs or ordinary shares, the U.S. Holder would generally be subject to adverse U.S. tax consequences, in the form of increased tax liabilities (unless certain elections described below are timely made) and special U.S. tax reporting requirements.

A non-U.S. corporation is a PFIC for U.S. federal income tax purposes for any taxable year in which (i) at least 75% of its gross income is "passive" income, generally including interest and income from financial investments (the "income test") or (ii) at least 50% of the average value of its assets (generally determined on a quarterly basis) consists of assets that produce or are held to produce passive income (the "asset test"). For purposes of making a PFIC determination, the non-U.S. corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the gross income of any other corporation of which it owns, directly or indirectly, 25% or more (by value) of the stock. For purposes of the asset test, any cash and cash invested in short-term, interest bearing, debt instruments, or bank deposits that are readily convertible into cash will generally count as producing passive income or held for the production of

passive income, and goodwill should be treated as a non-passive asset to the extent that it is associated with activities that produce or are intended to produce non-passive income.

There can be no assurance that we will not be a PFIC for 2022 or any future taxable year as PFIC status is tested for each taxable year and will depend on the composition of our assets and income and the value of our assets (which may fluctuate significantly with our market capitalization) in such taxable year. For instance, we could be a PFIC for any taxable year if our market capitalization were to decrease significantly while we hold substantial cash and cash equivalents, or if the gross income that we and our subsidiaries earn from investing the portion of the cash raised in the offering is substantial in comparison with the gross income from our business operation. Furthermore, the application of the PFIC rules is subject to uncertainty in several respects, and there can be no assurance that the IRS will not challenge our application of the PFIC rules. *Our special U.S. counsel expresses no opinion with respect to our expectations contained in this paragraph.*

If we are a PFIC for any taxable year during which a U.S. Holder holds the ADSs or ordinary shares, we generally will continue to be treated as a PFIC with respect to such U.S. Holder for all succeeding years during which the U.S. Holder holds the ADSs or ordinary shares, unless we cease to be a PFIC and the U.S. Holder makes a "deemed sale" election with respect to the ADSs or ordinary shares. If such election is timely made, the U.S. Holder will be deemed to have sold the ADSs and ordinary shares held by the U.S. Holder at their fair market value on the last day of the last taxable year in which we were a PFIC and any gain from such deemed sale would be subject to the consequences described in the following two paragraphs. In addition, a new holding period would be deemed to begin for the ADSs and ordinary shares for purposes of the PFIC rules. After the deemed sale election, the U.S. Holder's ADSs or ordinary shares with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

If we were a PFIC for any taxable year during which you held the ADSs or ordinary shares, certain adverse U.S. federal income tax rules would apply. You would generally be subject to additional taxes and interest charges on certain "excess distributions" we make and on any gain realized on the disposition or deemed disposition of your ADSs or ordinary shares, regardless of whether we continue to be a PFIC in the year in which you receive an "excess distribution" or dispose of or are deemed to have disposed of, your the ADSs or ordinary shares. Distributions in respect of the ADSs or ordinary shares during a taxable year in which we are a PFIC would generally constitute "excess distributions" if, in the aggregate, they exceed 125% of the average amount of distributions with respect to your ADSs or ordinary shares over the three preceding taxable years or, if shorter, the portion of your holding period before such taxable year.

To compute the tax on "excess distributions" or any gain, (i) the "excess distribution" or the gain would be allocated ratably to each day in your holding period, (ii) the amount allocated to the current year and any tax year prior to the first taxable year in which we were a PFIC would be taxed as ordinary income in the current year, (iii) the amount allocated to other taxable years would be taxable at the highest applicable marginal rate in effect for that year, and (iv) an interest charge at the rate for underpayment of taxes for any period described under (iii) above would be imposed on the resulting tax liability on the portion of the "excess distribution" or gain that is allocated to such period. In addition, if we were a PFIC (or treated as a PFIC with respect to you) for any taxable year in which we make a distribution or the preceding taxable year, such distribution would not qualify for taxation at the more favorable tax rate if we are deemed to be a PRC resident enterprise under PRC tax law, as discussed in the "Dividends" section above.

Under certain attribution rules, if we were a PFIC for any taxable year in which you hold the ADSs or ordinary shares, you would be deemed to own your proportionate share of lower-tier PFICs, and would be subject to U.S. federal income tax under the PFIC rules described in the preceding paragraphs on (i) a distribution on the shares of a lower-tier PFIC and (ii) a disposition of shares of a lower-tier PFIC, both as if such U.S. Holder directly held the shares of such lower-tier PFIC.

You might be able to make a "mark-to-market" election with respect to the ADSs, but not our ordinary shares, in order to elect out of the tax treatment discussed above. If you make a valid mark-to-market election, you will include in gross income for each taxable year that we are treated as a PFIC an amount equal to the excess, if any, of the fair market value of your ADSs as of the close of such taxable year over your adjusted basis in such ADSs. You will be permitted a deduction for the excess, if any, of the adjusted basis of your ADSs over their fair market value as of the close of the taxable year. However, deductions are allowable only to the extent of any net mark-to-market gains on the ADSs included in your income for prior taxable years.

Amounts included in your income under a mark-to-market election, as well as gain on any sale or other disposition of the ADSs, will be treated as ordinary income. Ordinary loss treatment also will apply to the deductible portion of any mark-to-market loss on the ADSs, as well as to any loss realized on a sale or disposition of the ADSs, to the extent that the amount of such loss does not exceed the net mark-to-market gains previously included for such ADSs. Your basis in your ADSs will be adjusted to reflect any such income or loss amounts. If you make a valid mark-to-market election, the tax rules that apply to distributions by corporations that are not PFICs generally will apply to distributions by us, except that the favorable rate discussed in the "Dividends" section above that may apply if we are deemed to be a PRC resident enterprise under PRC tax law will not apply to any distribution if we are a PFIC (or treated as a PFIC with respect to you) in the taxable year of the distribution or the preceding taxable year. If a U.S. Holder makes a mark-to-market election in respect of the ADSs and we cease to be classified as a PFIC, the holder will not be required to take into account the gain or loss described above during any period that we are not classified as a PFIC.

The mark-to-market election is available only for "marketable stock," which is stock that is traded in other than de minimis quantities on at least 15 days during each calendar quarter, or regularly traded, on a qualified exchange or other market, as defined in applicable U.S. Treasury regulations. For those purposes, we expect that the ADSs will each be treated as marketable stock upon their listing on the Nasdaq Stock Market, which we expect to be a qualified exchange for these purposes. We anticipate that the ADSs should qualify as being regularly traded, although there can be no assurance in this regard. U.S. Holders of ordinary shares are advised to consult their own tax advisor regarding their eligibility to make such election. Because a mark-to-market election cannot technically be made for equity interests in lower-tier PFICs that we own, if we are a PFIC for any taxable year, a U.S. Holder generally will continue to be subject to the general PFIC rules with respect to the holder's indirect interest in any investments held by us that are treated as equity interest in a PFIC for U.S. federal income tax purposes. You should consult your tax advisor as to the availability and desirability of a mark-to-market election if we were a PFIC, as well as the impact of such election on interests in any lower-tier PFICs. The PFIC rules provide for a separate election, referred to as a qualified electing fund election, which, if available, results in a tax treatment different from (and generally less adverse than) the general PFIC tax treatment described above. That election, however, will not be available to you as we do not intend to provide the information you would need to make or maintain that election.

If you own the ADSs or ordinary shares during any taxable year that we are a PFIC, you will generally be required to file an annual report containing such information as the United States Treasury Department may require. You should consult your own tax advisor regarding the application of the PFIC rules to your investment in the ADSs or ordinary shares and the elections discussed above.

U.S. information reporting and backup withholding rules

Dividend payments with respect to the ADSs or ordinary shares and the proceeds received on the sale or other disposition of the ADSs or ordinary shares may be subject to information reporting to the IRS and to backup withholding, unless you are an exempt recipient. Backup withholding will not apply, however, if you provide a taxpayer identification number certifying that you are not subject to backup withholding and make any other required certification or if you are otherwise exempt from backup withholding. Any amounts withheld under the backup withholding rules from a payment to you will be refunded or credited against your U.S. federal income tax liability, provided that you timely file an appropriate claim for refund with the IRS and provide any required information. Certain U.S. Holders who hold "specific foreign financial assets," including stock of a non-U.S. corporation that is not held in an account maintained by a U.S. "financial institution" may be required to attach to their tax returns for the year certain specified information. A U.S. Holder who fails to timely furnish the required information may be subject to a penalty. You are advised to consult with your tax advisor regarding the application of the U.S. information reporting and backup withholding rules to your particular circumstances.

PROSPECTIVE INVESTORS IN THE ADSs OR ORDINARY SHARES SHOULD CONSULT WITH THEIR TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES RESULTING FROM OWNING OR DISPOSING THE ADSs OR ORDINARY SHARES, INCLUDING THE APPLICABILITY AND EFFECT OF THE TAX LAWS OF ANY STATE, LOCAL, NON-US JURISDICTION, OR ANY INCOME TAX TREATY, AND ESTATE, GIFT AND INHERITANCE LAWS

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , between us and Cantor Fitzgerald & Co., 499 Park Avenue, New York, New York 10022 and CLSA Limited, 18/F One Pacific Place, 88 Queensway, Hong Kong, as representatives of the underwriters named below (the "Representatives") and the sole book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the ADSs shown opposite its name below:

Underwriter	Number of ADSs
Cantor Fitzgerald & Co.	
CLSA Limited	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the ADSs subject to their acceptance of the ADSs from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

The underwriters are expected to make offers and sales both inside and outside the U.S. through their respective selling agents. Any offers or sales in the U.S. will be conducted by broker-dealers registered with the SEC. CLSA Limited is not a broker-dealer registered with the SEC and may not make sales in the United States or to U.S. persons. CLSA Limited has agreed that it does not intend to and will not offer or sell any of the ADSs in the United States or to U.S. persons in connection with this offering.

Option to purchase additional ADSs

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of ADSs from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. To the extent the option is exercised, each underwriter will be obligated, subject to certain conditions, to purchase a number of additional ADSs approximately proportionate to that underwriter's initial purchase commitment as indicated in the table above.

Commission and expenses

The underwriters have advised us that they propose to offer the ADSs to the public at the public offering price set forth on the cover page of this prospectus and to certain dealers. After the initial offering, the Representatives may change the offering price and other selling terms.

The following table shows the public offering price, underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional ADSs.

	Per ADS		Total	
	Without Option to Purchase Additional ADSs	With Option to Purchase Additional ADSs	Without Option to Purchase Additional ADSs	With Option to Purchase Additional ADSs
Public offering price	$	$	$	$
Underwriting discounts and commissions	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $. We have also agreed to reimburse the underwriters for up to $ million of certain of their counsels' fees and expenses.

Listing

We intend to list the ADSs on the Nasdaq Stock Market under the trading symbol "ANL." At this time, the Nasdaq Stock Market has not yet approved our application to list the ADSs. The closing of this offering is conditioned upon the Nasdaq Stock Market's final approval of our listing application, and there is no guarantee or assurance that the ADSs will be approved for listing on the Nasdaq Stock Market.

No sales of similar securities

We and [our directors, executive officers and all of our existing shareholders and holders of share-based awards] (collectively, the "Lock-Up Parties") have agreed, subject to certain exceptions, not to directly or indirectly, for a period of 180 days after the date of the underwriting agreement:

- sell, offer to sell, contract to sell or lend, effect any short sale or establish or increase a "put equivalent position" (as defined in Rule 16a-1(h) under the Exchange Act) or liquidate or decrease any "call equivalent position" (as defined in Rule 16a-1(b) under the Exchange Act), pledge, hypothecate or grant any security interest in, or in any other way transfer or dispose of, any ADSs or any securities convertible into or exchangeable or exercisable for ADSs, in each case whether now owned or hereafter acquired by the Lock-Up Parties or with respect to which the Lock-Up Parties have or hereafter acquire the power of disposition (collectively, the "Lock-Up Securities"),
- make any demand for, or exercise any right with respect to the registration of any of the Lock-Up Securities, or the filing of any registration statement, prospectus or prospectus (or an amendment or supplement thereto) in connection therewith, under the Securities Act of 1933, as amended,
- enter into any swap, hedge or any other agreement or any transaction that transfers, in whole or in part, the economic consequence of ownership of the Lock-Up Securities, whether any such swap or transaction is to be settled by delivery of ordinary shares, ADSs or other securities, in cash or otherwise, or
- publicly announce the intention to do any of the foregoing.

In addition, we and each such person agrees that, without the prior written consent of the Representatives, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any of our ordinary shares or ADSs or any security convertible into or exercisable or exchangeable for our ordinary shares or ADSs.

The Lock-Up Parties may transfer the Lock-Up Securities in certain circumstances, including:

- as a bona fide gift or gifts;
- to any trust for the direct or indirect benefit of the Lock-Up Parties or the immediate family of the Lock-Up Parties (for the purposes of the lock-up agreement, "immediate family" shall mean any relationship by blood, marriage or adoption, not more remote than first cousin);
- pursuant to a qualified domestic order or in connection with a divorce settlement; or
- by will or intestate succession to the legal representative, heir, beneficiary or immediate family of the Lock-Up Parties upon the death of the Lock-Up Parties;

provided that, (1) prior to any such transfer, the Representative receives a signed lock-up agreement, substantially in the form of the lock-up agreement, for the balance of the lock-up period from each donee, trustee, distributee or transferee, as the case may be, (2) any such transfer shall not involve a disposition for value, (3) in the case of the first three bullet points above, such transfers are not required to be reported with the SEC under the Exchange Act, and (4) the Lock-Up Parties do not otherwise voluntarily effect any public filing or report regarding such transfers.

Each of the Representatives may, in its sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements.

Market making, stabilization and other transactions

The underwriters may make a market in the ADSs as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the ADSs, that you will be able to sell any of the ADSs held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters have advised us that they, pursuant to Regulation M under the Exchange Act, may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the ADSs at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional ADSs in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional ADSs or purchasing the ADSs in the open market. In determining the source of ADSs to close out the covered short position, the underwriters will consider, among other things, the price of ADSs available for purchase in the open market as compared to the price at which they may purchase ADSs through the option to purchase additional ADSs.

"Naked" short sales are sales in excess of the option to purchase additional ADSs. The underwriters must close out any naked short position by purchasing ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of ADSs on behalf of the underwriters for the purpose of fixing or maintaining the price of the ADSs. A syndicate covering transaction is the bid for or the purchase of ADSs on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of the ADSs or preventing or retarding a decline in the market price of the ADSs. As a result, the price of the ADSs may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the ADSs originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the ADSs. The underwriters are not obligated to engage in these activities and, if commenced, may end any of these activities at any time. These transactions may be effected on the NASDAQ in the over-the-counter market or otherwise.

Passive market making

The underwriters may also engage in passive market making transactions in the ADSs on the [Nasdaq Global Market] in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of the ADSs in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded. Passive market making may cause the price of the ADSs to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriters are not required to engage in passive market making and, if commenced, may end passive market making activities at any time.

Electronic distribution

A prospectus in electronic format may be made available by e-mail or on the websites or through online services maintained by one or more of the underwriters, selling group members (if any) or their affiliates. The underwriters may agree with us to allocate a specific number of ADSs for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' websites and any information contained in any other website maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other activities and relationships

The underwriters and certain of their respective affiliates are full service financial institutions engaged in a wide range of activities for their own accounts and the accounts of customers, which may include, among other things, corporate finance, mergers and acquisitions, merchant banking, equity and fixed income sales, trading and research, derivatives, foreign exchange, futures, asset management, custody, clearance and securities lending. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their business, the underwriters and their respective affiliates may, directly or indirectly, hold long or short positions, trade and otherwise conduct such activities in or with respect to debt or equity securities and/or bank debt of, and/or derivative products. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Stamp taxes

If you purchase ADSs offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Directed share program

At our request, the underwriters have reserved [•]% of the ADSs being offered by this prospectus for sale, at the initial public offering price, to our directors, officers, employees, business associates and related persons. If purchased by these persons, these ADSs will be subject to a 180-day lock-up restriction. The number of ADSs available for sale to the general public will be reduced to the extent these individuals purchase such reserved ADSs. Any reserved ADSs that are not so purchased will be offered by the underwriters to the general public on the same basis as the other ADSs offered by this prospectus.

Selling restrictions

No action has been taken in any jurisdiction (except in the U.S.) that would permit a public offering of the ADSs, or the possession, circulation or distribution of this prospectus or any other material relating to us or the ADSs in any jurisdiction where action for that purpose is required. Accordingly, the ADSs may not be offered or sold, directly or indirectly, and neither this prospectus nor any other material or advertisements in connection with the ADSs may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable laws, rules and regulations of any such country or jurisdiction.

United Arab Emirates

The ADSs have not been offered or sold, and will not be offered or sold, directly or indirectly, in the United Arab Emirates, except: (1) in compliance with all applicable laws and regulations of the United Arab Emirates; and (2) through persons or corporate entities authorized and licensed to provide investment advice

and/or engage in brokerage activity and/or trade in respect of foreign securities in the United Arab Emirates. The information contained in this prospectus does not constitute a public offer of securities in the United Arab Emirates in accordance with the Commercial Companies Law (Federal Law No. 8 of 1984 (as amended)) or otherwise and is not intended to be a public offer and is addressed only to persons who are sophisticated investors.

Canada

This prospectus constitutes an "exempt offering document" as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the ADSs. No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this prospectus or on the merits of the ADSs and any representation to the contrary is an offence.

Canadian investors are advised that this prospectus has been prepared in reliance on section 3A.3 of National Instrument 33-105 Underwriting Conflicts ("NI 33-105"). Pursuant to section 3A.3 of NI 33-105, this prospectus is exempt from the requirement that the issuer and the underwriters provide investors with certain conflicts of interest disclosure pertaining to "connected issuer" and/or "related issuer" relationships that may exist between the issuer and the underwriters as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

Resale restrictions

The offer and sale of the ADSs in Canada is being made on a private placement basis only and is exempt from the requirement that the issuer prepares and files a prospectus under applicable Canadian securities laws. Any resale of the ADSs acquired by a Canadian investor in this offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, pursuant to a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the ADSs outside of Canada.

Representations of purchasers

Each Canadian investor who purchases the ADSs will be deemed to have represented to the issuer and the underwriters that the investor (i) is purchasing the ADSs as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) is an "accredited investor" as such term is defined in section 1.1 of National Instrument 45-106 *Prospectus Exemptions* ("NI 45-106") or, in Ontario, as such term is defined in section 73.3(1) of the *Securities Act* (Ontario); and (iii) is a "permitted client" as such term is defined in section 1.1 of National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*.

Taxation and eligibility for investment

Any discussion of taxation and related matters contained in this prospectus does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the ADSs and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the ADSs or with respect to the eligibility of the ADSs for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

Rights of action for damages or rescission

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum (such as this prospectus), including where the distribution involves an "eligible foreign security" as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration Exemptions* and in Multilateral Instrument 45-107 *Listing Representation and*

Statutory Rights of Action Disclosure Exemptions, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a "misrepresentation" as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defenses under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

Language of documents

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the ADSs described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur Canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

Australia

This document does not constitute a prospectus, product disclosure statement or other disclosure document under the Australia's Corporations Act 2001 (Cth) (the "Corporations Act") of Australia. This document has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this document in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor or professional investor under the Corporations Act any offer made to you under this document is void and incapable of acceptance.

You warrant and agree that you will not offer any of the ADSs issued to you pursuant to this document for resale in Australia within 12 months of those ADSs being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

European Economic Area

In relation to each member state of the European Economic Area (each a "Member State"), no ADSs have been offered or will be offered pursuant to the offer described herein in that Member State prior to the publication of a prospectus in relation to the ADSs which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that the ADSs may be offered to the public in that Member State at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer; or

(iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of ADSs shall require the issuer or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Member State who acquires any ADSs in the offer or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the issuer and the underwriters that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any ADSs being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed to and with the issuer and the underwriters that the ADSs acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Member State to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale. Neither the issuer nor the underwriters have authorised, nor do they authorise, the making of any offer of ADSs through any financial intermediary, other than offers made by the underwriters which constitute the final placement of securities contemplated in this document.

The issuer and the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to any ADSs in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any ADSs to be offered so as to enable an investor to decide to purchase, or subscribe for, any ADSs and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

In Member States, this document is being distributed only to, and is directed only at, persons who are "qualified investors" within the meaning of Article 2(e) of the Prospectus Regulation ("Qualified Investors"). This document must not be acted on or relied on in any Member State by persons who are not Qualified Investors. Any investment or investment activity to which this document relates is available in any Member State only to Qualified Investors and will be engaged in only with such persons.

France

The ADSs are being issued and sold outside the Republic of France and that, in connection with their initial distribution, the underwriters have not offered or sold and will not offer or sell, directly or indirectly, any ADSs to the public in the Republic of France, and that they has not distributed and will not distribute or cause to be distributed to the public in the Republic of France this prospectus or any other offering material relating to the ADSs, and that such offers, sales and distributions have been and will be made in the Republic of France only to qualified investors (investisseurs qualifiés) in accordance with Article L.411-2 of the Monetary and Financial Code and decrét no. 98-880 dated October 1, 1998.

Germany

Each person who is in possession of this prospectus is aware that no German sales prospectus (Verkaufsprospekt) within the meaning of the Securities Sales Prospectus Act (Wertpapier-Verkaufsprospektgesetz, the "Act") of the Federal Republic of Germany has been or will be published with respect to the ADSs. In particular, the underwriters have represented that they have not engaged and have agreed that they will not engage in a public offering (offentliches Angebot) within the meaning of the Act with respect to any of the ADSs otherwise then in accordance with the Act and all other applicable legal and regulatory requirements.

Peoples' Republic of China

This prospectus may not be circulated or distributed in the PRC and the ADSs may not be offered or sold, and will not offer or sell to any person for re-offering or resale directly or indirectly to any resident of the

PRC except pursuant to applicable laws, rules and regulations of the PRC. For the purpose of this paragraph only, the PRC does not include Taiwan and the special administrative regions of Hong Kong and Macau.

Hong Kong

No ADSs have been, may be or will be offered or sold in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell ADSs or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong (the "SFO") and any rules made thereunder; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong (the "C(WUMP)O"), or which do not constitute an offer to the public within the meaning of the C(WUMP)O. No document, invitation or advertisement relating to the ADSs has been issued or may be issued or will be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to ADSs which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made thereunder.

This document has not been and will not be registered with the Registrar of Companies in Hong Kong. Accordingly, this document may not be issued, circulated or distributed in Hong Kong, and the ADSs may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the ADSs will be required, and is deemed by the acquisition of the ADSs, to confirm that he is aware of the restriction on offers of the ADSs described in this document and the relevant offering documents and that he is not acquiring, and has not been offered any ADSs in circumstances that contravene any such restrictions.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948 of Japan, as amended) (the "FIEA"). The ADS may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEA and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This document has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this document and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the ADSs may not be circulated or distributed, nor may the ADSs be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA")) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the ADSs are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the ADSs under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the

transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore ("Regulation 32")

Where the ADSs are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the ADSs under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Switzerland

The ADSs may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the ADSs or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the issuer or the ADSs have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of ADSs will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, or FINMA, and the offer of ADSs has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this document is being distributed only to, and is directed only at, and any offer of the ADSs is directed only at, investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals", each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors will be required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

United Kingdom

In relation to the United Kingdom, no ADSs have been offered or will be offered pursuant to the offer described herein to the public in the United Kingdom prior to the publication of a prospectus in relation to the securities which has been approved by the UK Financial Conduct Authority, except that the ADSs may be offered to the public in the United Kingdom at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer; or

(iii) in any other circumstances falling within Section 86 of the Financial Services and Markets Act 2000 (as amended) (the "FSMA"),

provided that no such offer of the ADSs shall require the issuer or any underwriter to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

Each person in the United Kingdom who acquires any ADSs in the offer or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the issuer and the underwriters that it is a qualified investor within the meaning of the UK Prospectus Regulation.

In the case of any ADSs being offered to a financial intermediary as that term is used in Article 5(1) of the UK Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed to and with the issuer and the underwriters that the ADSs acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in the United Kingdom to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale. Neither the issuer nor the underwriters have authorised, nor do they authorise, the making of any offer of ADSs through any financial intermediary, other than offers made by the underwriters which constitute the final placement of ADSs contemplated in this document.

The issuer and the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to the securities in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase or subscribe for any securities and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of United Kingdom law by virtue of the European Union (Withdrawal) Act 2018.

In the United Kingdom, this document is being distributed only to, and is directed only at, persons who are "qualified investors" within the meaning of Article 2(e) of the UK Prospectus Regulation who are also: (i) persons who fall within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order"); (ii) persons falling within Article 49(2) of the Order; or (iii) persons to whom it may otherwise lawfully be communicated (all such persons together being referred to as "relevant persons"). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. Any investment or investment activity to which this document relates is available in the United Kingdom only to relevant persons and will be engaged in only with such persons.

Any invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) may only be communicated or caused to be communicated in connection with the issue or sale of the ADSs in circumstances in which Section 21(1) of the FSMA does not apply. All applicable provisions of the FSMA and the Order must be complied with in respect of anything done by any person in relation to the ADSs in, from or otherwise involving the United Kingdom.

EXPENSES RELATED TO THIS OFFERING

Set forth below is an itemization of the total expenses, excluding underwriting discounts and commissions, that we expect to incur in connection with this offering. With the exception of the SEC registration fee, the FINRA filing fee, and the stock exchange market entry and listing fee, all amounts are estimates.

SEC Registration Fee	**US$**
FINRA filing fee	
Stock exchange market entry and listing fee	
Printing and engraving expenses	
Legal fees and expenses	
Accounting fees and expenses	
Miscellaneous	
Total	**US$**

LEGAL MATTERS

We are being represented by O'Melveny & Myers LLP with respect to certain legal matters as to United States federal securities and New York State law. The underwriters are being represented by Latham & Watkins LLP with respect to certain legal matters as to United States federal securities and New York State law. The validity of the Class A ordinary shares represented by the ADSs offered in this offering will be passed upon for us by Maples and Calder (Hong Kong) LLP. Certain legal matters as to PRC law will be passed upon for us by Han Kun Law Offices and for the underwriters by Zhong Lun Law Firm. O'Melveny & Myers LLP may rely upon Maples and Calder (Hong Kong) LLP with respect to matters governed by Cayman Islands law and Han Kun Law Offices with respect to matters governed by PRC law.

EXPERTS

The consolidated financial statements of Adlai Nortye Ltd. as of and for the years ended December 31, 2020, 2021, and 2022 have been included herein and in the registration statement in reliance upon the report of Mazars USA LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

The offices of Mazars USA LLP located at 135 West 50th Street, New York, New York 10020.

ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the Cayman Islands as an exempted company with limited liability. We are incorporated in the Cayman Islands to take advantage of certain benefits associated with being a Cayman Islands exempted company, such as:

- political and economic stability;
- an effective judicial system;
- a favorable tax system;
- the absence of exchange control or currency restrictions; and
- the availability of professional and support services.

However, certain disadvantages accompany incorporation in the Cayman Islands. These disadvantages include but are not limited to:

- the Cayman Islands has a less developed body of securities laws as compared to the United States and these securities laws provide significantly less protection to investors as compared to those of the United States; and
- Cayman Islands companies may not have standing to sue before the federal courts of the United States.

Our memorandum and articles of association does not contain provisions requiring that disputes, including those arising under the securities laws of the United States, between us, our officers, directors, and shareholders, be arbitrated.

A majority of our directors and officers are nationals or residents of jurisdictions other than the United States and a substantial portion of their assets are located outside the United States. As a result, it may be difficult for a shareholder to effect service of process within the United States upon these individuals, or to bring an action against us or these individuals in the United States, or to enforce against us or them judgments obtained in United States courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state in the United States.

Our subsidiary, located at New Jersey Biotechnology Development Center, 685 US Hwy 1, 2nd floor, North Brunswick Township, NJ 08902, acts as our agent upon whom process may be served in any action brought against us under the securities laws of the United States.

Maples and Calder (Hong Kong) LLP, our legal counsel as to Cayman Islands law, and Han Kun Law Offices, our legal counsel as to PRC law, have advised us, respectively, that there is uncertainty as to whether the courts of the Cayman Islands and China, respectively, would:

- recognize or enforce judgments of United States courts obtained against us or our directors or officers predicated upon the civil liability provisions of the federal securities laws of the United States or the securities laws of any state in the United States; or
- entertain original actions brought in the Cayman Islands against us or our directors or officers that are predicated upon the federal securities laws of the United States or the securities law of any state in the United States.

We have also been advised by Maples and Calder (Hong Kong) LLP that although there is no statutory enforcement in the Cayman Islands of judgments obtained in a U.S. court (and the Cayman Islands are not a party to any treaties for the reciprocal enforcement or recognition of such judgments), the courts of the Cayman Islands will, at common law, recognize and enforce a foreign monetary judgment of a foreign court of competent jurisdiction without any re-examination of the merits of the underlying dispute based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the a liquidated sum for which such judgment has been given, provided such judgment, provided such judgment (i) is given by a foreign court of competent jurisdiction, (ii) imposes on the judgment debtor a liability to pay a liquidated sum for which the judgment has been given, (iii) is final and conclusive, (iv) is not in respect of taxes, a fine or a penalty, and (v) was not obtained in a manner and is not of a kind the enforcement of which is contrary to natural justice or the public policy of the Cayman Islands.

However, the Cayman Islands courts are unlikely to enforce a judgment obtained from the United States courts under civil liability provisions of the securities laws if such judgment is determined by the courts of the Cayman Islands to give rise to obligations to make payments that are penal or punitive in nature. A Cayman Islands court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere.

Han Kun Law Offices has further advised us that the recognition and enforcement of foreign judgments are provided for under the PRC Civil Procedures Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedures Law based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other form of reciprocity with the United States or the Cayman Islands that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, courts in China will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of PRC law or national sovereignty, security, or social public interest. As a result, it is uncertain whether and on what basis a PRC court would enforce a judgment rendered by a court in the United States or in the Cayman Islands. Under the PRC Civil Procedures Law, foreign shareholders may originate actions based on PRC law against a company in China for disputes if they can establish sufficient nexus to the PRC for a PRC court to have jurisdiction, and meet other procedural requirements, including, among others, the plaintiff must have a direct interest in the case, and there must be a concrete claim, a factual basis and a cause for the suit. However, it would be difficult for foreign shareholders to establish sufficient nexus to China by virtue only of holding the ADSs or ordinary shares. In addition, it will be difficult for U.S. shareholders to originate actions against us in China in accordance with PRC laws because we are incorporated under the laws of the Cayman Islands and it will be difficult for U.S. shareholders, by virtue only of holding the ADSs or ordinary shares, to establish a connection to China for a PRC court to have jurisdiction as required under the PRC Civil Procedures Law.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement, including relevant exhibits, with the SEC on Form F-1 under the Securities Act with respect to the underlying Class A ordinary shares represented by the ADSs to be sold in this offering. We have also filed a related registration statement on Form F-6 with the SEC to register the ADSs. This prospectus, which constitutes a part of the registration statement on Form F-1, does not contain all of the information contained in the registration statement. You should read our registration statements and their exhibits and schedules for further information with respect to us and the ADSs.

Immediately upon the effectiveness of the registration statement on Form F-1 of which this prospectus forms a part, we will become subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers. Accordingly, we will be required to file reports, including annual reports on Form 20-F, and other information with the SEC.

All information filed with the SEC can be obtained over the internet at the SEC's website at *www.sec.gov*.

ADLAI NORTYE LTD.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Shareholders of Adlai Nortye Ltd.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statements of financial position of Adlai Nortye Ltd. (the "Company") as of December 31, 2020, 2021 and 2022, and the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020, 2021 and 2022, and the results of its operations and its cash flows for each of the three years then ended in the period ended December 31, 2022, in conformity with International Financial Reporting Standards (IFRS) and its related interpretations as issued by the International Accounting Standards Board.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Mazars USA LLP

We have served as the Company's auditor since 2022.

New York, New York
April 13, 2023

ADLAI NORTYE LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020
(All amounts in thousands, except share and per share data, or as otherwise noted)

	Notes	Year ended December 31		
		2020	2021	2022
		$'000	$'000	$'000
REVENUE	4	—	45,726	—
Other operating income, net		50	183	259
Administrative expenses		(6,524)	(12,450)	(13,039)
Research and development expenses		(21,146)	(42,105)	(54,490)
Total operating loss		(27,620)	(8,646)	(67,270)
Other income and gains		559	213	2,079
Other expenses		(69)	(70)	(1,395)
Investment income		18	32	550
Fair value gain on financial assets at fair value through profit or loss ("FVTPL")		—	40	484
Fair value (loss)/gain on financial liabilities at FVTPL	15	(35,839)	(46,910)	7,195
Finance costs	5	(1,797)	(1,337)	(433)
LOSS BEFORE TAX		**(64,748)**	**(56,678)**	**(58,790)**
Income tax expense	6	—	—	—
LOSS FOR THE YEAR		**(64,748)**	**(56,678)**	**(58,790)**
Attributable to:				
Ordinary Equity Holders of the Parent		(64,748)	(56,678)	(58,790)
OTHER COMPREHENSIVE LOSS				
Exchange differences on translation of the financial statements of subsidiaries		(797)	(94)	(3,157)
Other comprehensive loss for the year, net of tax		(797)	(94)	(3,157)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		**(65,545)**	**(56,772)**	**(61,947)**
Attributable to:				
Ordinary Equity Holders of the Parent		(65,545)	(56,772)	(61,947)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT				
Basic and diluted				
Loss for the year ($ per share)	8	(2.55)	(2.23)	(2.31)
Weighted average common shares outstanding	8	25,440,000	25,440,000	25,440,000

The accompanying notes are an integral part of the Consolidated Financial Statements

ADLAI NORTYE LTD.
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION
AS OF DECEMBER 31, 2022, 2021 AND 2020
(All amounts in thousands, except share and per share data, or as otherwise noted)

	Notes	Year ended December 31		
		2020	2021	2022
		$'000	$'000	$'000
ASSETS				
Current assets				
Cash and cash equivalents		24,261	64,131	42,758
Financial assets at FVTPL	12	—	53,809	21,287
Prepayments, other receivables and other assets	11	5,502	6,604	2,258
Total current assets		**29,763**	**124,544**	**66,303**
Non-current assets				
Property, plant and equipment	9	3,730	3,655	3,713
Right-of-use assets	10(a)	3,834	2,934	2,162
Other intangible assets		11	97	89
Prepayments, other receivables and other assets	11	298	455	327
Total non-current assets		**7,873**	**7,141**	**6,291**
Total assets		**37,636**	**131,685**	**72,594**
LIABILITIES				
Current liabilities				
Trade payables		2,000	2,981	13,098
Other payables and accruals	13	2,464	3,224	3,877
Interest-bearing bank and other borrowings	14	8,296	10,457	4,307
Lease liabilities	10(b)	794	834	1,001
Financial liabilities at FVTPL	15	74,697	—	290,368
Total current liabilities		**88,251**	**17,496**	**312,651**
Non-current liabilities				
Lease liabilities	10(b)	2,841	2,054	1,236
Financial liabilities at FVTPL	15	78,586	297,563	—
Total non-current liabilities		**81,427**	**299,617**	**1,236**
Total liabilities		**169,678**	**317,113**	**313,887**
SHAREHOLDERS' (DEFICIT) EQUITY				
Ordinary shares (par value of $0.0001 per share; 442,456,586 shares authorized and 25,440,000 shares issued and outstanding as of December 31, 2020; 442,456,586 shares authorized and 40,440,000 shares issued and outstanding as of December 31, 2021 and 2022)	17	3	4	4
Series A convertible preferred shares (par value of US$0.0001 per share; 14,560,000, 14,560,000 and 14,560,000 shares authorized, issued and outstanding as of December 31, 2020, 2021 and 2022, respectively)		10,980	10,980	10,980
Additional paid-in capital	18	6,416	6,415	6,415
Share option reserve	18	4,220	7,606	13,688
Exchange fluctuation reserve	18	(908)	(1,002)	(4,159)
Accumulated deficit	18	(152,753)	(209,431)	(268,221)
Total shareholders' deficit		**(132,042)**	**(185,428)**	**(241,293)**
Total liabilities and shareholders' equity		**37,636**	**131,685**	**72,594**

The accompanying notes are an integral part of the Consolidated Financial Statements

ADLAI NORTYE LTD.
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020
(All amounts in thousands, except share and per share data, or as otherwise noted)

	Attributable to owners of the parent						
	Ordinary Shares	Additional paid-in capital	Series A convertible preferred shares	Share option reserve	Exchange fluctuation reserve	Accumulated losses	Total deficits
	$'000 (note 17)	$'000 (note 18)	$'000	$'000 (note 18)	$'000 (note 18)	$'000	$'000
At January 1, 2020	3	6,416	10,980	1,951	(111)	(88,005)	(68,766)
Loss for the year	—	—	—	—	—	(64,748)	(64,748)
Other comprehensive income for the year:							
Exchange differences on translation of the financial statements of subsidiaries	—	—	—	—	(797)	—	(797)
Share-based compensation	—	—	—	2,269	—	—	2,269
At December 31, 2020	3	6,416	10,980	4,220	(908)	(152,753)	(132,042)
Loss for the year	—	—	—	—	—	(56,678)	(56,678)
Other comprehensive income for the year:							
Exchange differences on translation of the financial statements of subsidiaries	—	—	—	—	(94)	—	(94)
Issuance of shares for the trust arrangement under the Share Incentive Plan	1	(1)	—	—	—	—	—
Share-based compensation	—	—	—	3,386	—	—	3,386
At December 31, 2021	4	6,415	10,980	7,606	(1,002)	(209,431)	(185,428)
Loss for the year	—	—	—	—	—	(58,790)	(58,790)
Other comprehensive income for the year							
Exchange differences on translation of the financial statements of subsidiaries	—	—	—	—	(3,157)	—	(3,157)
Issuance of shares for the trust arrangement under the Share Incentive Plan	—	—	—	—	—	—	—
Share-based compensation	—	—	—	6,082	—	—	6,082
At December 31, 2022	4	6,415	10,980	13,688	(4,159)	(268,221)	(241,293)

The accompanying notes are an integral part of the Consolidated Financial Statements

ADLAI NORTYE LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020
(All amounts in thousands, except share and per share data, or as otherwise noted)

	Notes	Year ended December 31		
		2020	2021	2022
		$'000	$'000	$'000
CASH FLOWS FROM OPERATING ACTIVITIES				
Loss before tax		(64,748)	(56,678)	(58,790)
Adjustments for:				
Finance costs	5	1,797	1,337	433
Investment income		(18)	(32)	(550)
Fair value loss/(gain) on financial liabilities at FVTPL	15	35,839	46,910	(7,195)
Fair value gain on financial assets at FVTPL		—	(40)	(484)
Loss on disposal of items of property, plant and equipment		57	5	(7)
Gain on termination of leases		(58)	—	—
Depreciation of property, plant and equipment	9	543	861	931
Amortization of intangible assets		13	16	20
Depreciation of right-of-use assets	10(a)	981	951	1,090
Equity-settled share-based payment expenses	19	2,269	3,386	6,082
(Increase)/Decrease in prepayments, other receivables and other assets		(3,837)	(419)	4,346
Increase in non-current assets		(225)	(157)	128
Increase in current assets		—	(390)	—
(Decrease)/Increase in trade payables		(3,260)	600	10,117
(Decrease)/Increase in other payables and accruals		(2,207)	619	656
Increase/(Decrease) in advances from customers		3	(3)	—
Net cash flows used in operating activities		**(32,851)**	**(3,034)**	**(43,223)**
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchases of property, plant and equipment		(1,787)	(1,018)	(1,249)
Purchases of intangible assets		—	(102)	(19)
Prepayments for right-of-use assets		(274)	—	
Proceeds from disposal of items of property, plant and equipment		11	—	17
Purchases of financial assets at FVTPL		(29,241)	(81,234)	(58,980)
Disposal of financial assets at FVTPL		29,241	27,465	88,057
Received investment income of financial assets at FVTPL		18	32	550
Net cash flows (used in)/provided from investing activities		**(2,032)**	**(54,857)**	**28,376**
CASH FLOWS FROM FINANCING ACTIVITIES				
Proceeds from issuance of financial instruments measured at FVTPL		58,700	97,370	—
Addition of bank and other borrowings		12,895	12,411	7,897
Bank and other borrowings interest paid		(652)	(427)	(292)
Repayment of bank and other borrowings		(15,499)	(10,430)	(13,315)
Transaction costs for issuance of convertible redeemable preferred shares		(1,076)	(758)	—
Payment for lease liabilities		(1,297)	(966)	(1,070)
Net cash flows from/(used in) financing activities		**53,071**	**97,200**	**(6,780)**
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS		**18,188**	**39,309**	**(21,627)**
Cash and cash equivalents at beginning of year		6,006	24,261	64,131
Effect of foreign exchange rate changes, net		67	561	254
CASH AND CASH EQUIVALENTS AT END OF YEAR		**24,261**	**64,131**	**42,758**

The accompanying notes are an integral part of the Consolidated Financial Statements

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020
(All amounts in thousands, except share and per share data, or as otherwise noted)

1. CORPORATE AND GROUP INFORMATION

Adlai Nortye Ltd. (the "Company") is a limited liability company incorporated in the Cayman Islands on 9 May 2018. The registered office of the Company is located at Harneys Fiduciary (Cayman) Limited, 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman, KY1-1002, Cayman Islands.

The Company is an investing holding company. The Company's subsidiaries were involved in the research and development of pharmaceutical products.

As of the date of this report, the Company had direct and indirect interests in its subsidiaries, all of which are private limited liability companies, the particulars of which are set out below:

Name	Notes	Date and place of incorporation / registration and place of operations	Issued ordinary share/ registered capital	Percentage of equity attributable to the Company		Principal activities
				Direct	Indirect	
Alpine Bioscience Ltd. ("Alpine BVI")		British Virgin Islands 8 January 2018	One share of par value $1	100%	—	Investment holding
Adlai Nortye (BVI) Ltd. ("Adlai BVI")		British Virgin Islands 10 May 2018	One share of par value $1	100%	—	Investment holding
Adlai Nortye USA Inc. ("Adlai US")		The United States 30 January 2018	10,000 shares of par value $0.0001 each	—	100%	Clinical studies and testing, and technology development and transfer
Adlai Nortye (Switzerland) AG ("Adlai Swiss")		Switzerland 21 June 2022	100 shares of par value CHF1'000 each	—	100%	Investment holding
Adlai Nortye PTE.LTD ("Adlai SGP")		Singapore 22 April 2022	One share of par value $1	—	100%	Investment holding
Adlai Nortye (HK) Limited ("Adlai HK")		Hong Kong 24 April 2018	HKD 0.001	—	100%	Investment holding
杭州阿诺生物医药科技有限公司 Hangzhou Adlai Nortye Biopharma Co., Ltd* ("Adlai Hangzhou")		the People's Republic of China ("PRC")/ Mainland China 14 September 2004	RMB 126,280	—	100%	Product research and development, technology transfer and consulting services business
上海阿德莱诺泰生物医药科技有限公司 Shanghai Adlai Nortye Biopharma Co., Ltd* ("Adlai Shanghai")		the People's Republic of China ("PRC")/ Mainland China 22 December 2021	RMB 10,000	—	100%	Produ and d techn and c servic
杭州塘创未来科技有限公司 Hangzhou Changchuang Weilai Technolegy Co., Ltd		the People's Republic of China ("PRC")/ Mainland China 2 November 2022	RMB 10,000	—	100%	Product research and development, technology transfer and consulting services business

* The English name of the subsidiary registered in the PRC represents the best efforts made by management of the Company to translate its Chinese name as the subsidiary does not have an official English name.

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

2.1 BASIS OF PRESENTATION

The consolidated financial statements of the Group include the financial statements of the Company and its subsidiaries. All significant intercompany balances and transactions have been eliminated upon consolidation.

2.2 BASIS OF PREPARATION

Notwithstanding that the Group recorded net liabilities of $241,293 as of December 31, 2022 and continually incurred losses from operations, the Consolidated Financial Statements have been prepared on a going concern basis. The directors of the Company are of the opinion that the Group will have sufficient working capital to meet its financial liabilities and obligations as and when they fall due and to sustain its operations for the next 12 months from December 31, 2022 because the convertible redeemable preferred shares would not be contractually redeemable within the next 12 months.

The Consolidated Financial Statements have been prepared in accordance with International Financial Reporting Standards ("IFRSs"), which comprise all standards and interpretations approved by the International Accounting Standards Board (the "IASB"). All IFRSs effective for the accounting period commencing from January 1, 2020, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the Consolidated Financial Statements throughout the Relevant Periods and in the period covered by the Interim Comparative Financial Information.

Recently issued accounting pronouncements:

In 2016, the IASB issued IFRS 16, which increases lease transparency and comparability among organizations. Under the new standard, lessees will be required to recognize all assets and liabilities arising from leases on the balance sheet, with the exception of leases with a term of 12 months or less, which permits a lessee to make an accounting policy election by class of underlying asset not to recognize lease assets and liabilities. IFRS 16 is effective for fiscal years beginning after January 1, 2019. The Company adopted the new lease accounting standard as of January 1, 2019. Adoption of this update increased the amounts of total assets and total liabilities on the Company's consolidated financial position, and did not have a material impact on the Company's consolidated results of operations and cash flows.

The Consolidated Financial Statements have been prepared under the historical cost convention except for certain financial liabilities which have been measured at fair value at the end of each of the Relevant Periods.

2.3 ISSUED BUT NOT YET EFFECTIVE IFRSs

The Group has not applied the following new and revised IFRSs that have been issued but are not yet effective in the Consolidated Financial Statements.

Amendments to IFRS 10 and IAS 28	*Sale or Contribution of Assets between an Investor and its Associate or Joint Venture*[(2)]
IFRS 17	*Insurance Contracts*[(1)]
Amendments to IFRS 17	*Insurance Contracts*[(1)(3)]
Amendments to IAS 1	*Classification of Liabilities as Current or Non-current*[(1)]
Amendments to IAS 1 and IFRS Practice Statement 2	*Disclosure of Accounting Policies*[(1)]
Amendments to IAS 8	*Definition of Accounting Estimates*[(1)]
Amendments to IAS 12	*Deferred Tax related to Assets and Liabilities arising from a Single Transaction*[(1)]
Amendments to IFRS 4	*Extension of the Temporary Exemption from Applying IFRS 9*[(1)]

2.3 ISSUED BUT NOT YET EFFECTIVE IFRSs (continued)

(1) Effective for annual periods beginning on or after 1 January 2023

(2) No mandatory effective date yet determined but available for adoption

(3) As a consequence of the amendments to IFRS 17 issued in October 2020, the effective date of IFRS 17 was deferred to January 1, 2023, and IFRS 4 was amended to extend the temporary exemption that permits insurers to apply IAS 39 rather than IFRS 9 for annual periods beginning before January 1, 2023

The Group is in the process of making an assessment of the impact of these new and revised IFRSs upon initial application. So far, the Group expects that these standards will not have a significant effect on the Group's financial performance and financial position.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Subsidiaries

A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee). When the Company has, directly or indirectly, less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

(a) contractual arrangements with other vote holders of the investee;

(b) rights arising from other contractual arrangements; and

(c) the Group's voting rights and potential voting rights.

The financial statements of subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

Fair value measurement

The Group measures certain financial instruments at fair value at the end of each of the Relevant Periods. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

All assets and liabilities for which fair value is measured or disclosed in the Consolidated Financial Statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1 — based on quoted prices (unadjusted) in active markets for identical assets or liabilities

Level 2 — based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly

Level 3 — based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognized in the Consolidated Financial Statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Relevant Periods.

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than financial assets), the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of the asset or cash-generating unit's value in use and its fair value less cost of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

An impairment loss is recognized only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each of the Relevant Periods as to whether there is an indication that previously recognized impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognized impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortization) had no impairment loss been recognized for the asset in prior years. A reversal of such an impairment loss is credited to profit or loss in the period in which it arises.

Related parties

A party is considered to be related to the Group if:

(a) the party is a person or a close member of that person's family and that person

(i) has control or joint control over the Group;

(ii) has significant influence over the Group; or

(iii) is a member of the key management personnel of the Group or of a parent of the Group;

or

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(b) the party is an entity where any of the following conditions applies:

(i) the entity and the Group are members of the same group;

(ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);

(iii) the entity and the Group are joint ventures of the same third party;

(iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;

(v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group; and the sponsoring employers of the post-employment benefit plan;

(vi) the entity is controlled or jointly controlled by a person identified in (a);

(vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and

(viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalized in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognizes such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used for this purpose are as follows:

Plant and machinery	10% to 19%
Office equipment	19% to 20%
Motor vehicles	19%
Electronic equipment	19% to 20%
Leasehold improvements	The shorter of remaining lease terms or estimated useful lives

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at the end of each of the Relevant Periods.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

An item of property, plant and equipment including any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognized in the statement of profit or loss and other comprehensive income in the year the asset is derecognized is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

Other intangible assets (other than goodwill)

Other intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least at the end of each of the Relevant Periods.

Computer software

Computer software is stated at cost less any impairment losses and amortized on a straight-line basis over its estimated useful life of 5 years.

The estimated useful life of software is determined by considering the period of the economic benefits to the Group, as well as by referring to industry practice.

Research and development costs

All research costs are charged to expense as incurred.

Expenditure incurred on projects to develop new products is capitalized and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the Group's ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognizes lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

Right-of-use assets are recognized at the commencement date of the lease (the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and any

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease terms and the estimated useful lives of the assets as follows:

Offices	2 to 5 years
Office equipment	2 to 5 years

If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

(b) Lease liabilities

Lease liabilities are recognized at the commencement date of the lease at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for termination of a lease, if the lease term reflects the Group exercising the option to terminate the lease. Variable lease payments that do not depend on an index or a rate are recognized as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in lease payments (e.g., a change to future lease payments resulting from a change in an index or rate) or a change in assessment of an option to purchase the underlying asset.

(c) Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of office equipment (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the recognition exemption for leases of low-value assets to leases of office equipment that are considered to be of low value.

Lease payments on short-term leases and leases of low-value assets are recognized as an expense on a straight-line basis over the lease term.

Financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortized cost, fair value through other comprehensive income, and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Group’s business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs.

In order for a financial asset to be classified and measured at amortized cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest ("SPPI") on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group's business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortized cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

All regular way purchases and sales of financial assets are recognized on the trade date, that is, the date that the Group commits to purchase or sell the asset. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace.

Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets at amortized cost (debt instruments)

Financial assets at amortized cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognized in the statement of profit or loss and other comprehensive income when the asset is derecognized, modified or impaired.

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognized in the statement of profit or loss and other comprehensive income.

This category includes derivative instruments and equity investments which the Group has not irrevocably elected to classify at fair value through other comprehensive income. Dividends on equity investments classified as financial assets at fair value through profit or loss are also recognized as other income in the statement of profit or loss and other comprehensive income when the right of payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably.

A derivative embedded in a hybrid contract, with a financial liability or non-financial host, is separated from the host and accounted for as a separate derivative if the economic characteristics and risks are not closely related to the host; a separate instrument with the same terms as the embedded derivative would meet the definition of a derivative; and the hybrid contract is not measured at fair value through profit or loss. Embedded derivatives are measured at fair value with changes in fair value recognized in the statement of profit or loss and other comprehensive income. Reassessment only occurs if there is either a change in the

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

terms of the contract that significantly modifies the cash flows that would otherwise be required or a reclassification of a financial asset out of the fair value through profit or loss category.

A derivative embedded within a hybrid contract containing a financial asset host is not accounted for separately. The financial asset host together with the embedded derivative is required to be classified in its entirety as a financial asset at fair value through profit or loss.

Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognized (i.e., removed from the Group's consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a "pass-through" arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognize the transferred asset to the extent of the Group's continuing involvement. In that case, the Group also recognizes an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognizes an allowance for expected credit losses ("ECLs") for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

General approach

ECLs are recognized in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At the end of each of the Relevant Periods, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as of the reporting date with the risk of a

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

default occurring on the financial instrument as of the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information.

The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Financial assets at amortized cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables and contract assets which apply the simplified approach as detailed below.

Stage 1 — Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs

Stage 2 — Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs

Stage 3 — Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

Simplified approach

For trade receivables that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognizes a loss allowance based on lifetime ECLs at the end of each of the Relevant Periods.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, payables, as appropriate.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group’s financial liabilities include trade and other payables, derivative financial instruments, interest-bearing bank and other borrowings and certain financial instruments designated at FVTPL.

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Financial liabilities at fair value through profit or loss

Financial liabilities at fair value through profit or loss include financial liabilities held for trading and financial liabilities designated upon initial recognition as at fair value through profit or loss.

Financial liabilities are classified as held for trading if they are incurred for the purpose of repurchasing in the near term. This category also includes derivative financial instruments entered into by the Group that are not designated as hedging instruments in hedge relationships as defined by IFRS 9. Separated embedded derivatives are also classified as held for trading unless they are designated as effective hedging instruments. Gains or losses on liabilities held for trading are recognized in the statement of profit or loss. The net fair value gain or loss recognized in the statement of profit or loss does not include any interest charged on these financial liabilities.

Financial liabilities designated upon initial recognition as at fair value through profit or loss are designated at the initial date of recognition, and only if the criteria in IFRS 9 are satisfied. Gains or losses on liabilities designated at fair value through profit or loss are recognized in the statement of profit or loss, except for the gains or losses arising from the Group's own credit risk which are presented in other comprehensive income with no subsequent reclassification to the statement of profit or loss. The net fair value gain or loss recognized in the statement of profit or loss does not include any interest charged on these financial liabilities.

The company assessed the contract characteristics of each series of convertible redeemable preferred shares to determine whether they should be classified as equity instruments or financial liabilities. The Series B, C, and D Preferred Shares and Series B Convertible Loans were classified as financial liabilities measured at fair value through profit or loss. The decision was based on the presence of a redemption feature and a conversion option with a price adjustment feature, which are considered financial liabilities under IAS 32.

The company also determined that the Series B Convertible Loans are a hybrid instrument that includes a non-derivative host contract and embedded derivatives, which should be accounted for at fair value through profit or loss.

Financial liabilities at amortized cost (loans and borrowings)

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognized in the statement of profit or loss and other comprehensive income when the liabilities are derecognized as well as through the effective interest rate amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortization is included in finance costs in the statement of profit or loss and other comprehensive income.

Derecognition of financial liabilities

A financial liability is derecognized when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognized in the statement of profit or loss and other comprehensive income.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Derivative financial instruments

Initial recognition and subsequent measurement

The Group uses derivative financial instruments, such as warrants. Such derivative financial instruments are initially recognized at fair value on the date on which a derivative contract is entered into and are subsequently remeasured at fair value. Derivatives are carried as assets when the fair value is positive and as liabilities when the fair value is negative.

Any gains or losses arising from changes in fair value of derivatives are taken directly to profit or loss.

Current versus non-current classification

Derivative instruments that are not designated as effective hedging instruments are classified as current or non-current or separated into current and non-current portions based on an assessment of the facts and circumstances (i.e., the underlying contracted cash flows):

- Where the Group expects to hold a derivative as an economic hedge (and does not apply hedge accounting) for a period beyond 12 months after the end of the reporting period, the derivative is classified as non-current (or separated into current and non-current portions) consistently with the classification of the underlying item.
- Embedded derivatives that are not closely related to the host contract are classified consistently with the cash flows of the host contract.
- Derivative instruments that are designated as, and are effective hedging instruments, are classified consistently with the classification of the underlying hedged item. The derivative instruments are separated into current portions and non-current portions only if a reliable allocation can be made.

Cash and cash equivalents

For the purpose of the consolidated statement of cash flows, cash and cash equivalents comprise cash on hand and demand deposits, and short term highly liquid investments that are readily convertible into known amounts of cash, are subject to an insignificant risk of changes in value, and have a short maturity of generally within three months when acquired.

For the purpose of the consolidated statement of financial position, cash and cash equivalents comprise cash on hand and at banks, including term deposits, and assets similar in nature to cash, which are not restricted as to use.

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains its cash and cash equivalents at high-quality and accredited financial institutions in amounts that could exceed the $250,000 maximum amount insured by the Federal Deposit Insurance Corporation (FDIC). The Company does not believe that its cash and cash equivalents are subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Provisions

A provision is recognized when a present obligation (legal or constructive) has arisen as a result of a past event and it is probable that a future outflow of resources will be required to settle the obligation, provided that a reliable estimate can be made of the amount of the obligation.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

When the effect of discounting is material, the amount recognized for a provision is the present value at the end of the reporting period of the future expenditures expected to be required to settle the obligation. The increase in the discounted present value amount arising from the passage of time is included in finance costs in the statement of profit or loss and other comprehensive income.

Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognized outside profit or loss is recognized outside profit or loss, either in other comprehensive income or directly in equity.

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of the reporting period between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognized for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of taxable temporary differences associated with investments in subsidiaries, associates and joint ventures, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognized for all deductible temporary differences, the carryforward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences and the carryforward of unused tax credits and unused tax losses can be utilized, except:

- when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of deductible temporary differences associated with investments in subsidiaries, associates and joint ventures, deferred tax assets are only recognized to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized.

The carrying amount of deferred tax assets is reviewed at the end of each of the Relevant Periods and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are reassessed at the end of each of the Relevant Periods and are recognized to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

In compliance with IFRIC 23, accruals for risk on income tax are part of the income tax within the statements of operations and comprehensive loss and income tax payable within the statements of financial position.

Government grants

Government grants are recognized at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed.

Revenue recognition

Sales of intellectual property

Revenue from sales of intellectual property is recognized when control of the intellectual property is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for the intellectual property.

When the consideration of sales of intellectual property includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the intellectual property to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

Milestone payments and sales-based royalties represent a form of variable consideration which is included in the transaction price to the extent that it is highly probable that a significant reversal of accumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. When the Group cannot conclude that it is highly probable that a significant revenue reversal of cumulative revenue under the contract will not occur, the Group constrains the related variable consideration resulting in its exclusion from the transaction price.

As part of the accounting for this arrangement, the Group must use significant judgement to determine: (a) the performance obligations; and (b) the method to estimate variable consideration.

At contract inception, the Group assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct.

The Group uses judgement to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Group recognizes revenue as or when the performance obligations under the contract are satisfied. If a milestone or other variable consideration relates specifically to the Group’s efforts to satisfy a single performance obligation or to a specific outcome from

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

satisfying the performance obligation, the Group generally allocates that milestone amount entirely to that performance obligation once it is highly probable that a significant revenue reversal would not occur.

The Group recognizes revenue only when it satisfies a performance obligation by transferring control of the promised goods or services. The transfer of control can occur over time or at a point in time. A performance obligation is satisfied over time if it meets one of the following criteria:

The counterparty simultaneously receives and consumes the benefits provided by the Group's performance as the Group performs; or

The Group's performance creates or enhances an asset that the counterparty controls as the asset is created or enhanced

The Group's performance does not create an asset with an alternative use to the Group and the Group has an enforceable right to payment for performance completed to date.

The portion of the transaction price that is allocated to performance obligations satisfied at a point in time is recognized as revenue when control of the goods or services is transferred to the counterparty. If the performance obligation is satisfied over time, the portion of the transaction price allocated to that performance obligation is recognized as revenue as the performance obligation is satisfied. The Group adopts an appropriate method of measuring progress for purposes of recognizing revenue. The Group evaluates the measure of progress at the end of each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Upfront fees

Upfront payment is allocated to the performance obligations based on the Group's best estimate of their relative stand-alone selling prices. The Group recognizes revenues from non-refundable upfront fees at a point in time when the transfer of control of the intellectual property to the counterparty occurs and the counterpary is able to use and benefit from the intellectual property.

Milestone payments

At the inception of each arrangement that includes milestone payments, the Group evaluates whether the milestones are considered highly probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is highly probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Group, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received. The Group evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgement involved in determining whether it is highly probable that a significant reversal of cumulative revenue would not occur. At the end of each subsequent reporting period, the Group re-evaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Milestone payments are allocated to performance obligations based on the Group's best estimate of their relative stand-alone selling prices unless the criteria under IFRS 15.85 are met, in which case the milestone payments are allocated entirely to the performance obligation which the milestone payments are specifically related to.

The Group assessed that achievement of all the remaining contractual milestones is highly uncertain and the related milestone payments are not included in the transaction price. Milestones are achieved when the triggering event described in the related agreement occurs.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Sales royalties

The Group recognizes revenue for a sales-based royalty promised in exchange for the sales of intellectual property only when (or as) the later of the following events occurs:

(a) the subsequent sale occurs; and

(b) the performance obligation to which some or all of the sales-based royalty has been allocated has been satisfied.

Revenue from other sources

Rental income is recognized on a time proportion basis over the lease terms. Variable lease payments that do not depend on an index or a rate are recognized as income in the accounting period in which they are incurred.

Interest income

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Share-based payments

The Company operates a share option scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group's operations. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments ("equity-settled transactions").

The cost of equity-settled transactions with employees for grants is measured by reference to the fair value at the date at which they are granted. The fair value is determined by an external valuer using a binomial model, further details of which are given in note 19 to the Consolidated Financial Statements.

The cost of equity-settled transactions is recognized in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognized for equity-settled transactions at the end of each of the Relevant Periods until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the statement of profit or loss and other comprehensive income for a period represents the movement in the cumulative expense recognized as of the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group's best estimate of the number of equity instruments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

Other employee benefits

Pension schemes

The employees of the Group's subsidiaries who operate in Mainland China are required to participate in a central pension scheme operated by the local municipal government. These subsidiaries are required to

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

contribute a certain percentage of their payroll costs to the central pension scheme. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme.

The subsidiary in the U.S. maintains multiple qualified contributory savings plans as allowed under Section 401(k) of the Internal Revenue Code in the U.S. These plans are defined contribution plans covering substantially all its qualifying employees and provide for voluntary contributions by employees, subject to certain limits. The contributions are made by both the employees and the employer. The employees' contributions are primarily based on specified dollar amounts or percentages of employee compensation. The only obligation of the subsidiary in the U.S. with respect to the retirement benefits plans is to make the specified contributions under the plans.

Housing fund — Mainland China

The Group contributes on a monthly basis to a defined contribution housing fund plan operated by the local municipal government. Contributions to this plan by the Group are expensed as incurred.

Borrowing costs

Borrowing costs directly attributable to the acquisition, construction or production of qualifying assets (i.e., assets that necessarily take a substantial period of time to get ready for their intended use or sale) are capitalized as part of the cost of those assets. The capitalization of such borrowing costs ceases when the assets are substantially ready for their intended use or sale. Investment income earned on the temporary investment of specific borrowings pending their expenditure on qualifying assets is deducted from the borrowing costs capitalized. All other borrowing costs are expensed in the period in which they are incurred. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

Foreign currencies

These consolidated financial statements are presented in United States dollars ("$"), which is the Company's functional currency. Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange at the end of the reporting period. Differences arising on settlement or translation of monetary items are recognized in the statement of operations and comprehensive loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognized in other comprehensive income or profit or loss is also recognized in other comprehensive income or profit or loss, respectively).

In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of the initial transaction is the date on which the Group initially recognizes the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of the advance consideration.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

The functional currencies of certain subsidiaries established in the PRC are currencies other than $. As of the end of the reporting period, the assets and liabilities of these entities are translated into $ at the exchange rates prevailing at the end of the reporting period and their statements of profit or loss and other comprehensive income are translated into $ at the weighted average exchange rates for the year.

The resulting exchange differences are recognized in other comprehensive income and accumulated in the exchange fluctuation reserve. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognized in the statement of profit or loss and other comprehensive income.

For the purpose of the consolidated statement of cash flows, the cash flows of the subsidiaries established in the PRC are translated into $ at the exchange rates at the dates of the cash flows. Frequently recurring cash flows of the subsidiaries established in the PRC which arise throughout the year are translated into $ at the weighted average exchange rates for the year.

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

Use of Estimates

The preparation of the Group's Consolidated Financial Statements requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of the reporting period that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are described below.

Fair value of financial liabilities measured at FVTPL

The fair value of the financial liabilities, including convertible redeemable preferred shares, convertible loans, forwards and warrants, are measured at FVTPL and determined using the valuation techniques, including the discounted cash flow method and the back-solve method. Such valuation requires the Group to make estimates of the key assumptions including the risk-free interest rate, discount for lack of marketability ("DLOM") and volatility, which are subject to uncertainty and might materially differ from the actual results. Further details are included in note 15 to the Consolidated Financial Statements.

Fair value of share-based payment

The fair value of the awarded shares is determined at the grant dates by the binomial option-pricing model. Significant estimates on assumptions, including the underlying equity value, discount rate, expected volatility, and dividend yield, are made by management. Further details are included in note 19 to the Consolidated Financial Statements.

The preparation of the consolidated financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the reporting amounts of assets and liabilities, and disclosure of contingent assets and liabilities, as of the date of the consolidated financial statements, and the reported

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES (continued)

amount of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include the valuation and accounting for financial liabilities at FVTPL and equity awards.

Impairment of non-financial assets (other than goodwill)

The Group assesses whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each of the Relevant Periods. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm's length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value-in-use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

Deferred tax assets

Deferred tax assets are recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgement is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and level of future taxable profits together with future tax planning strategies. Further details are contained in note 6 to the Consolidated Financial Statements.

Uncertain tax positions

In assessing any uncertainty over income tax treatments, the Group considers whether it is probable that the relevant tax authority will accept the uncertain tax treatment used, or proposed to be used, by individual group entities in their income tax filings. If it is probable, the current and deferred taxes are determined consistently with the tax treatment in the income tax filings. If it is not probable that the relevant taxation authority will accept an uncertain tax treatment, the effect of each uncertainty is reflected by using either the most likely amount or the expected value.

The Group has evaluated the uncertain tax position of each of the companies within the Group as of December 31, 2020, 2021 and 2022, the Group did not have any significant unrecognized uncertain tax positions.

Leases — Estimating the incremental borrowing rate

The Group cannot readily determine the interest rate implicit in a lease, and therefore, it uses an incremental borrowing rate ("IBR") to measure lease liabilities. The IBR is the rate of interest that the Group would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment. The IBR therefore reflects what the Group "would have to pay", which requires estimation when no observable rates are available (such as for subsidiaries that do not enter into financing transactions) or when it needs to be adjusted to reflect the terms and conditions of the lease (for example, when leases are not in the subsidiary's functional currency). The Group estimates the IBR using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates (such as the subsidiary's stand-alone credit rating).

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

4. REVENUE

An analysis of revenue is as follows:

	2020	2021	2022
	$'000	$'000	$'000
Revenue from contracts with customer			
Sales of intellectual property	—	45,726	—
Total	—	45,726	—

The Group entered into a collaboration agreement with one customer in the year ended December 31, 2021 for a list of patents and related research material, know-how, and research results generated through studies of the five products. The terms of the arrangement include: non-refundable upfront fees of RMB 295,000 (approximately equivalent to $45,726), milestone payments for the achievement of specified certain development and sales targets and sales-based royalties.

Revenue of $45,726 for the year ended December 31, 2021 was derived from the upfront fee for the sale of intellectual property to a single customer, recognized at a point in time, and there was no further performance obligation to be performed.

5. FINANCE COSTS

An analysis of finance costs is as follows:

	Year ended December 31,		
	2020	2021	2022
	$'000	$'000	$'000
Transaction cost for issuance of the Group's convertible redeemable preferred shares	1,076	758	—
Interest expenses on bank and other borrowings	592	421	295
Interest expenses on lease liabilities	129	158	138
Total	1,797	1,337	433

6. INCOME TAX

The Group is subject to income tax on an entity basis on profit arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains.

British Virgin Islands

The subsidiaries incorporated in British Virgin Islands are not subject to income tax under the current laws of British Virgin Islands.

Singapore

The subsidiary incorporated in Singapore is subject to Singapore corporate income tax effectively at the rate of 4.25%-17.00% on any estimated assessable profits arising in Singapore during the period presented. In the first three years since the establishment of the Singapore subsidiary, the first SGD100 of assessable profits

(All amounts in thousands, except share and per share data, or as otherwise noted)

6. INCOME TAX (continued)

of this subsidiary are taxed at an effective tax rate of 4.25% and the next SGD100 of assessable profits are taxed at an effective tax rate of 8.5%, and the remaining assessable profits are taxed at 17%.

Switzerland

The subsidiary incorporated in Switzerland is subject to a total corporate income tax rate of 11.9%, including 8.5% federal, and Zug cantonal and communal tax, during the Relevant Periods on the estimated assessable profits of the Swiss subsidiary. If the main business is operated in other cantons, the total corporate income tax, including federal, cantonal, and communal tax, could be up to 21.6%.

The United States

The subsidiary incorporated in the United States ("U.S.") is subject to U.S. federal income tax and New Jersey state income tax at the rates of 21% and 9%, respectively, during the Relevant Periods on the estimated assessable profits arising in the United States.

Hong Kong

The subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the rate of 16.5% on any estimated assessable profits arising in Hong Kong during the period presented. The first HKD2,000 of assessable profits of this subsidiary are taxed at 8.25% and the remaining assessable profits are taxed at 16.5%.

Mainland China

The provision for corporate income tax in Mainland China is based on the statutory rate of 25% of the assessable profits as determined in accordance with the PRC Corporate Income Tax Law, which was approved and became effective on January 1, 2008.

Pursuant to the relevant regulations on extension for expiries of unused tax losses of High and New Technology Enterprises and Small and Medium-sized Technological Enterprises issued in August 2018, the accumulated tax losses that did not expire from 2018 will have expiries extending from 5 years to 10 years from then on. Adlai Hangzhou qualified as a High and New Technology Enterprise during the years 2022-2024. In addition, Adlai Hangzhou a qualified as a Small and Medium-sized Technological Enterprise in 2019.

The income tax expense of the Group for the Relevant Periods is analyzed as follows:

	Year ended December 31,		
	2020	2021	2022
	$'000	$'000	$'000
Current	—	—	—
Deferred	—	—	—
Total	—	—	—

A reconciliation of the tax expense applicable to loss before tax at the statutory rate to the tax expense at the effective tax rate is as follows:

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

6. INCOME TAX (continued)

	Year ended December 31,		
	2020	2021	2022
	$'000	$'000	$'000
Loss before tax	(64,748)	(56,678)	(58,790)
Tax at the statutory tax rate (25%)	(16,187)	(14,169)	(14,698)
Lower tax rates for specific provinces or enacted by local authority	11,239	13,240	2,933
Expenses not deductible for tax	1,803	603	2,171
Income not subject to tax	(86)	(2,890)	(4)
Additional deductible allowance for qualified research and development costs	(306)	(1,109)	(1,681)
Valuation allowance	3,537	4,325	11,279
Current income tax expense	—	—	—
Tax charge at the Group's effective rate	—	—	—

The Group has accumulated tax losses arising in Adlai Hangzhou in Mainland China of $49,455, $50,612 and $83,103 as of December 31, 2020, 2021 and 2022, respectively, that will expire in five to ten years after the loss incurring year for offsetting against future taxable profits.

The Group also has accumulated tax losses in the U.S. of $26,217, $45,980 and $46,201 as of December 31, 2020, 2021 and 2022, respectively, that can be carried forward indefinitely to offset against future taxable profits of the companies in which losses were incurred, subject to 80% taxable income limitation annually.

Deferred tax assets have not been recognized in respect of these tax losses as they have been incurred in subsidiaries that were loss-making in the past and it is not probable that they will generate sufficient taxable income in the foreseeable future to utilize such tax losses.

According to the double tax avoidance arrangements and other applicable PRC 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, 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 current laws of the United States of America, dividends payable by a U.S. entity to non-U.S. resident enterprises shall be subject to 30% withholding tax, unless the respective non-U.S. resident enterprise's jurisdiction of incorporation has a tax treaty or arrangements with U.S. that provides for a reduced withholding tax rate or an exemption from withholding tax.

According to Swiss tax policy, a Swiss entity is subject to a 35% withholding tax when the entity pays dividends to a non-Swiss resident enterprise. However, according to the Agreement for the Avoidance of Double Taxation signed between Switzerland and Singapore, the withholding tax rate will be reduced to 5% if the non-Swiss resident enterprise is a Singapore resident enterprise.

7. DIVIDENDS

No dividends have been declared and paid by the Company or the Group during the Relevant Periods.

8. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic loss per share amount is based on the loss for the year attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 25,440,000, 25,440,000 and 25,440,000 in issue during the years ended December 31, 2020, 2021 and 2022, respectively.

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

8. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT (continued)

The calculation of the basic loss per share amount is based on the loss for the years attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares in issue or deemed to be in issue during the year ended December 31, 2020, 2021 and 2022.

Basic loss per share is computed on the basis of the weighted average number of ordinary shares outstanding during the period of the financial statements.

Diluted loss per share of ordinary stock is computed on the basis of the weighted average number of shares of ordinary stock and dilutive securities (such as stock options and convertible securities) outstanding. As of December 31, 2020 the Company had 43,634,049 dilutive shares consisting of 42,820,909 relating to convertible preferred stock and 813,140 relating to options. As of December 31, 2021 the Company had 62,967,406 dilutive shares consisting of 57,543,414 relating to convertible preferred stock and 5,423,992 relating to options. As of December 31, 2022 the Company had 64,300,522 dilutive shares consisting of 57,543,414 relating to convertible preferred stock and 6,757,108 relating to options. Dilutive securities that have an anti-dilutive effect on diluted loss per share are excluded from the calculation.

No adjustment has been made to the basic loss per share amounts presented for the years ended December 31, 2020, 2021 and 2022 in respect of a dilution as the impact of the outstanding share options, restricted stock units and warrant liability had an anti-dilutive effect on the basic loss per share amounts presented.

9. PROPERTY, PLANT AND EQUIPMENT

	Leasehold improvements	Plant and machinery	Office equipment	Motor vehicles	Electronic equipment	Total
	$'000	$'000	$'000	$'000	$'000	$'000
At January 1, 2020, net of accumulated depreciation	85	1,945	117	22	152	2,321
Additions	1,758	70	17	—	87	1,932
Depreciation provided during the year	(86)	(376)	(34)	(5)	(42)	(543)
Disposals	—	(38)	(7)	—	(22)	(67)
Exchange realignment	1	75	5	1	5	87
At December 31, 2020, net of accumulated depreciation	1,758	1,676	98	18	180	3,730
At December 31, 2020:						
Cost	1,758	2,741	167	235	277	5,178
Accumulated depreciation	—	(1,065)	(69)	(217)	(97)	(1,448)
Net carrying amount	1,758	1,676	98	18	180	3,730

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

9. PROPERTY, PLANT AND EQUIPMENT (continued)

	Leasehold improvements	Plant and machinery	Office equipment	Motor vehicles	Electronic equipment	Total
	$'000	$'000	$'000	$'000	$'000	$'000
At January 1, 2021, net of accumulated depreciation	1,758	1,676	98	18	180	3,730
Additions	192	509	2	—	23	726
Depreciation provided during the year	(385)	(364)	(34)	(6)	(72)	(861)
Disposals	—	(3)	—	—	(1)	(4)
Exchange realignment	36	24	2	—	2	64
At December 31, 2021, net of accumulated depreciation	1,601	1,842	68	12	132	3,655
As of December 31, 2021:						
Cost	1,991	3,217	163	240	287	5,898
Accumulated depreciation	(390)	(1,375)	(95)	(228)	(155)	(2,243)
Net carrying amount	1,601	1,842	68	12	132	3,655

	Lease hold improvements	Plant and machinery	Office equipment	Motor vehicles	Electronic equipment	Total
	$'000	$'000	$'000	$'000	$'000	$'000
At January 1, 2022, net of accumulated depreciation	1,601	1,842	68	12	132	3,655
Additions	710	360	—	168	11	1,249
Depreciation provided during the year	(416)	(412)	(31)	(19)	(53)	(931)
Disposals	—	—	—	(10)	—	(10)
Exchange realignment	(121)	(117)	(4)	—	(8)	(250)
At Dec 31, 2022, net of accumulated depreciation	1,774	1,673	33	151	82	3,713
As of December 31, 2022						
Cost	2,532	3,386	150	199	276	6,543
Accumulated depreciation	(758)	(1,713)	(117)	(48)	(194)	(2,830)
Net carrying amount	1,774	1,673	33	151	82	3,713

During the Relevant Periods, none of the Group's property, plant and equipment were pledged.

There was no impairment for the Group's property, plant and equipment during the Relevant Periods.

10. LEASES

The Group has lease contracts of properties and used in its operation with lease terms between 2 and 5 years.

(a) Right-of-use assets

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

10. LEASES (continued)

The carrying amounts of the Group's right-of-use assets and the movements during the Relevant Periods are as follows:

	Offices	Office equipment	Total
	$'000	$'000	$'000
As of January 1, 2020	1,116	—	1,116
Additions	3,946	357	4,303
Depreciation provided during the year	(962)	(19)	(981)
Termination	(593)	—	(593)
Exchange realignment	(10)	(1)	(11)
As of December 31, 2020	3,497	337	3,834

	Offices	Office equipment	Total
	$'000	$'000	$'000
As of January 1, 2021	3,497	337	3,834
Depreciation provided during the year	(821)	(130)	(951)
Exchange realignment	49	2	51
As of December 31, 2021	2,725	209	2,934

	Offices	Office equipment	Total
	$'000	$'000	$'000
As of January 1, 2022	**2,725**	**209**	**2,934**
Additions	463	—	463
Depreciation provided during the year	(961)	(129)	(1,090)
Exchange realignment	(141)	(4)	(145)
As of December 31, 2022	**2,086**	**76**	**2,162**

(b) Lease liabilities

The carrying amount of lease liabilities and the movements during the Relevant Periods are as follows:

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

10. LEASES (continued)

	Lease liabilities
	$'000
As of January 1, 2020	(1,400)
Additions	(4,028)
Accretion of interest recognized during the year	(133)
Payments	1,297
Termination	651
Exchange realignment	(22)
As of December 31, 2020	(3,635)
As of January 1, 2021	(3,635)
Accretion of interest recognized during the year	(160)
Payments	966
Exchange realignment	(59)
As of December 31, 2021	(2,888)
As of January 1, 2022	(2,888)
Additions	(463)
Accretion of interest recognized during the year	(133)
Payments	1,070
Exchange realignment	177
As of December 31, 2022	(2,237)

	2020	2021	2022
	$'000	$'000	$'000
Analyzed into:			
Current portion	794	834	1,001
Non-current portion	2,841	2,054	1,236
Total	3,635	2,888	2,237

(c) The amounts recognized in profit or loss in relation to leases are as follows:

	Year ended December 31,		
	2020	2021	2022
	$'000	$'000	$'000
Interest on lease liabilities	128	158	133
Depreciation charge of right-of-use assets	981	951	1,090
Gain on termination of leases	58	—	—
Total amount recognized in profit or loss	1,167	1,109	1,223

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

11. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	As of December 31,		
	2020	2021	2022
	$'000	$'000	$'000
Current:			
Prepayments (Note i)	4,065	4,673	1,912
VAT deductible tax	1,196	1,586	100
Deposits and other receivables	241	345	246
	5,502	6,604	2,258
Non-current:			
Deposits and other receivables	152	208	—
Prepaid expenses	146	247	327
	298	455	327
Total	5,800	7,059	2,585

Note i:
The amount represents prepayments for Contract Research Organizations ("CROs") and deposit of property, plant and equipment not yet placed in use.

Other receivables had no historical default. The financial assets included in the above balances relate to receivables which were categorized in stage 1 at the end of each of the Relevant Periods. In calculating the expected credit loss rate, the Group considers the historical loss rate and adjusts for forward-looking factors and information. During the Relevant Periods, the Group estimated that the expected credit loss rate for other receivables and deposits was minimal.

The Group seeks to maintain strict control over its outstanding receivables to minimize credit risk. Long ageing balances are reviewed regularly by senior management. In view of the fact that the Group's deposits and other receivables relate to a large number of diversified counterparties, there is no significant concentration of credit risk. The Group does not hold any collateral or other credit enhancements over its deposits and other receivable balances.

12. FINANCIAL ASSETS AT FVTPL

	As of December 31,		
	2020	2021	2022
	$'000	$'000	$'000
Current:			
Wealth management product	—	46,269	21,287
Dual currency structured deposit	—	7,540	—
Total	—	53,809	21,287

During the Relevant Periods, the Group used surplus capital to purchase dual currency structured deposit and wealth management product from domestic commercial banks, which preserved capital and liquidity. The dual currency structured deposits held as of December 31, 2021 were compound financial instruments which combined traditional bank deposits with foreign currency derivatives with investment periods from 1 to 3 months. The wealth management product held as of December 31, 2021 was an investment into a mutual fund whose portfolio included a mixture of fixed income assets and asset-backed securities, which were redeemable

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

12. FINANCIAL ASSETS AT FVTPL (continued)

on any work day. The wealth management product held as of December 31, 2022 was an investment into a mutual fund whose portfolio included a mixture of fixed income assets, preferred shares and repos, which were redeemable every 3 months. The returns on all of these financial products were not guaranteed, hence their contractual cash flows did not qualify solely as payments of principal and interest. Therefore, those products were accounted at fair value through profit or loss. Further details are included in note 20(c) to the Consolidated Financial Statements.

13. OTHER PAYABLES AND ACCRUALS

	As of December 31,		
	2020	2021	2022
	$'000	$'000	$'000
Other payables and accruals (Note i)	521	738	255
Payroll and bonus payables	1,943	2,486	3,622
Total	2,464	3,224	3,877

Note i:
Other payables and accruals are unsecured, non-interest-bearing and repayable on demand. The fair values of other payables and accruals at the end of each of the Relevant Periods approximated to their corresponding carrying amounts.

14. INTEREST-BEARING BANK AND OTHER BORROWINGS

	As of December 31,		
	2020	2021	2022
	$'000	$'000	$'000
Revolving Facility, 4.35% interest, due January 27, 2021, unsecured (Note i)	766	—	—
Non-Revolving Facility, 4.35% interest, due May 20, 2021, guaranteed (Note ii)	3,065	—	—
Non-Revolving Facility, 5.22% interest, due March 19, 2021, secured (Note iii)	2,299	—	—
Non-Revolving Facility, 5.22% interest, due March 18, 2021, secured (Note iii)	1,533	—	—
Non-Revolving Facility, 8% interest, due March 31, 2022 (Note iv)	633	—	—
Revolving Facility, 5.3% interest, due March 8, 2022, unsecured (Note i)	—	784	—
Non-Revolving Facility, 4.35% interest, due March 22, 2022, guaranteed (Note ii)	—	3,137	—
Non-Revolving Facility, 4.35% interest, due May 1, 2022, guaranteed (Note ii)	—	3,137	—
Non-Revolving Facility, LPR+1.73% interest, due March 25, 2022, guaranteed (Note iii)	—	1,569	—
Non-Revolving Facility, 4.2% interest, due March 31, 2022 (Note iv)	—	1,830	—
Non-Revolving Facility, 5.22% interest, due March 22,2023, guaranteed (Note iii)	—	—	1,436
Non-Revolving Facility, 4.8% interest, due April 24,2023, guaranteed (Note v)	—	—	2,871
Total	8,296	10,457	4,307

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

14. INTEREST-BEARING BANK AND OTHER BORROWINGS (continued)

	Bank borrowings	Other borrowings	Total
	$'000	$'000 (Note vi)	$'000
As of January 1, 2020	7,408	3,047	10,455
Additions	9,195	3,700	12,895
Repayments	(8,673)	(6,826)	(15,499)
Effect of foreign exchange rate changes	366	79	445
As of December 31, 2020	8,296	—	8,296
Additions	12,411	—	12,411
Repayments	(10,430)	—	(10,430)
Effect of foreign exchange rate changes	180	—	180
As of December 31, 2021	10,457	—	10,457
Additions	7,897	—	7,897
Repayments	(13,316)	—	(13,316)
Effect of foreign exchange rate changes	(731)	—	(731)
As of December 31, 2022	4,307	—	4,307

All of the Group's bank borrowings were obtained from third party financial institutions. As of December 31, 2020, 2021 and 2022, the Group's credit facilities were $8,296, $10,457 and $4,307, respectively, of which nil, nil and nil was unused by the Group.

Notes:

(i) In January 2020, Adlai Hangzhou entered into a revolving facility agreement for a facility amount of RMB 5,000 and at an interest rate of 4.35% per annum. The revolving facility agreement was repaid at the maturity date of July 21, 2020.

In June 2020, Adlai Hangzhou entered into a revolving facility agreement for a facility amount of RMB 5,000 and at an interest rate of 4.35% per annum. The revolving facility agreement was repaid at the maturity date of December 23, 2020.

In July 2020, Adlai Hangzhou entered into a revolving facility agreement for a facility amount of RMB 5,000 and at an interest rate of 4.35% per annum. The revolving facility agreement was repaid at the maturity date of January 27, 2021.

In March 2021, Adlai Hangzhou entered into a revolving facility agreement for a facility amount of RMB 5,000 and at an interest rate of 5.3% per annum. The revolving facility agreement was repaid at the maturity date of September 25, 2021.

In September 2021, Adlai Hangzhou entered into a revolving facility agreement for a facility amount of RMB 5,000 and at an interest rate of 5.3% per annum. The revolving facility agreement was repaid at the maturity date of March 8, 2022.

In March 2022, Adlai Hangzhou entered into a revolving facility agreement for a facility amount of RMB 5,000 and at an interest rate of 5.3% per annum. The revolving facility agreement was repaid at the maturity date of September 3, 2022.

(ii) In June 2020, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 20,000 and at an interest rate of 4.35% per annum, guaranteed by Mr. Yang Lu, the chief executive officer and chairman of our board of directors. The non-revolving facility agreement was repaid at the maturity date of May 20, 2021.

In May 2021, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 20,000 and at an interest rate of 4,35% per annum, guaranteed by Mr. Yang Lu. The non-revolving facility agreement was repaid at the maturity date of May 31, 2022.

In June 2021, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 20,000 and at an interest rate of 4.35% per annum, guaranteed by Mr. Yang Lu. The non-revolving facility agreement was repaid at the maturity date of December 9, 2021.

In December 2021, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 20,000 and at an interest rate of 4.35% per annum, guaranteed by Mr. Yang Lu. The non-revolving facility agreement was repaid at the maturity date of March 22, 2022.

14. INTEREST-BEARING BANK AND OTHER BORROWINGS (continued)

(iii) In March 2020, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 15,000 and at an interest rate of 5.22% per annum, secured by properties owned by Mr. Yang Lu and his immediate relatives. The non-revolving facility agreement was repaid at the maturity date of March 19, 2021.

In March 2020, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 10,000 and at an interest rate of 5.22% per annum, secured by properties owned by Mr. Yang Lu and his immediate relatives. The non-revolving facility agreement was repaid at the maturity date of March 18, 2021.

In March 2021, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 10,000 and at a floating interest rate of LPR plus 1.73% per annum, guaranteed by Mr. Yang Lu. The non-revolving facility agreement was repaid at the maturity date of March 18, 2021.

In March 2022, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 10,000 and at an interest rate of 5.22% per annum, guaranteed by Mr. Yang Lu, the chief executive officer and chairman of our board of directors. The non-revolving facility agreement was repaid at the maturity date of March 22, 2023.

(iv) In May 2019, the Company entered into a non-revolving facility agreement with SPD Silicon Valley Bank Co., Ltd ("SPD") which was conditional on the Company issuing warrant (the "CEHKL Warrant", further details are included in note 15 to the Consolidated Financial Statements) to China Equities HK Limited ("CEHKL"), an affiliate of SPD Bank. The total facility amount is $10,000 at an interest of 8% per annum, with the maturity date on May 31, 2022. The outstanding balance is $633 as of December 31, 2020.

In April 2021, the Company signed an amendment of its previous loan facility agreement. According to the amendment, it changed the interest rate to 4.2% per annum, and changed the facility availability period to December 31, 2021.

In April 2021, the Company borrowed $3,000 from SPD. At the end of 2021, The outstanding balance is $1,830 as of December 31, 2021. The facility agreement was repaid at the maturity date of March 31, 2022.

(v) In April 2022, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 10,000 and at an interest rate of 4.80% per annum, guaranteed by Mr. Yang Lu, the chief executive officer and chairman of our board of directors. The non-revolving facility agreement was repaid at the maturity date of October 24, 2022.

In October 2022, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 20,000 and at an interest rate of 4.80% per annum, guaranteed by Mr. Yang Lu, the chief executive officer and chairman of our board of directors.

(vi) The outstanding balance of other borrowing from individual third parties at January 1, 2020 was $3,047, the Company repaid all before or at maturity date in 2020. In 2020, the Company borrowed $3,700 from an individual third party at an interest rate of 6% per annum, and repaid it before the maturity date in 2020.

15. FINANCIAL LIABILITIES AT FVTPL

Preferred shares and convertible loans

In late 2015, Adlai Hangzhou raised up to RMB70,000 from the Founders and certain onshore investors ("Series A Investors").

In June 2018, the Company was established in the Cayman Island for seeking overseas listing opportunity, and the Company issued ordinary shares to the Founders and an option to the Series A Investors, which entitled Series A Investors to convert their equity interests in Adlai Hangzhou to up to 14,560,000 series A convertible preferred shares ("Series A Preferred Shares") of the Company, at par value of $ 0.0001 per share, upon completion of the Reorganization. From January 2020 to April 2020, Series A Investors exercised the option and converted their equity interests in Adlai Hangzhou to Series A Preferred Shares of the Company.

In June 2018, to accommodate the Group's Reorganization plan, certain onshore investors ("Series B Onshore Investors") entered into convertible loan subscription agreement (the "Series B Loan Agreement") with Adlai Hangzhou to issue a loan (the "Series B Convertible Loans") to Series B Onshore Investors for a total consideration of RMB165,000. Meanwhile, the Company entered into a forward contract with these Series B Onshore investors to grant them an option ("Series B Preferred Shares Forward") to convert Series B Convertible Loans issued by Adali Hangzhou to 6,600,000 series B convertible redeemable preferred shares ("Series B Preferred Shares") of the Company, at par value of $ 0.0001 per share, upon completion of the Reorganization. Pursuant to the Series B Loan Agreement, these loans bore interest at 15% per annum and

15. FINANCIAL LIABILITIES AT FVTPL (continued)

shall mature upon the exercise of the Series B Preferred Shares Forward. The Series B Onshore Investors agreed Adlai Hangzhou's obligation of repayment the principal and accrued interests of these loans will be automatically relieved with the exercise of Series B Share Purchase Forward upon completion of the Reorganization. From April to May 2020, the Series B Onshore Investors have exercised their Series B Share Purchase Forward and converted their Series B Convertible Loans to an aggregate of 6,600,000 Series B Preferred Shares.

Concurrently, certain offshore investors ("Series B Offshore Investors") subscribed 6,907,896 Series B Preferred Shares ("Series B Preferred Shares") for a total consideration of $27,000. The Series B Onshore Investors and Series B Offshore Investors are collectively referred to as "Series B Investors".

In December 2019, the Company issued 14,653,013 series C convertible redeemable preferred shares ("Series C Preferred Shares") of the Company for a total consideration of $63,700 to certain investors ("Series C Investors").

In April 2021, the Company entered into a Series D share purchase agreement with certain investors ("Series D Investors") to issue an aggregate of 14,722,505 series D convertible redeemable preferred shares ("Series D Preferred Shares") for a total consideration of $97,370 and paid in full as of December 31, 2021.

According to the original and amended Memorandum and Articles of Association ("MOA") upon the issuance of each series of convertible redeemable preferred shares, the Group designated Series B, C and D Preferred Shares and Series B Convertible Loans as financial liabilities measured at FVTPL and recognized Series A Preferred Shares as equity in accordance with the relevant IFRS. There is no significant change in the major terms of MOA among of each series except mentioned otherwise in the notes to the Consolidated Financial Statements.

According to the MOA of the Company in May 2021, the key terms of the Series A, B, C and D Preferred Shares (collectively "Preferred Shares") are as follows:

Conversion Rights (applicable to all Preferred Shares)

Each holder of Preferred Shares may, at the option of the holder thereof, be converted at any time into fully-paid and nonassessable ordinary shares of the Company based on the then-effective applicable conversion price ("Applicable Conversion Price"). Each holder of Preferred Shares shall automatically be converted, based on the Applicable Conversion Price, into ordinary shares of the Company upon the closing of a Qualified IPO (as defined below).

The Applicable Conversion Price is initially equal to the original issue price for each class of Preferred Shares and shall be subject to adjustment from time to time, including but not limited to share splits, share subdivision, share combination and the like, being no less than par value.

If the Company issues any additional ordinary shares at a subscription price less than the corresponding original subscription price of the Series B, C and D Preferred Shares, the Company shall issue new corresponding Series B, C and D Preferred Shares to the holders of Series B, C and D Preferred Shares at the nominal price or the minimum price allowed by applicable laws until the Applicable Conversion Price for each holders of Series B, C and D Preferred Shares is reduced to such issue price.

If the Group fails to meet any of the below two committed business objectives ("Business Objectives") within the timelines, the holders of Series C Preferred Shares are entitled to request the Founders, affiliates of the Founders and the Group (collectively referred to as "Warrantors") to jointly make up the share compensation necessary to make the pre-money valuation of the Company immediately before the investment

15. FINANCIAL LIABILITIES AT FVTPL (continued)

by the holders of Preferred Shares be adjusted to 70% thereof. The share compensation arrangement shall be made on the basis of a nominal transfer price. The Business Objectives are:

a) promote at least three products (self-developed or by introduction) to the next clinical stage within eighteen months from the Series C Preferred Shares closing date, on the basis of existing clinical pipelines; and;

b) obtain the approval of one new drug application from the competent authority for drug administration in the US or PRC by the 3rd anniversary of Series C Preferred Shares closing date.

Qualified IPO means an underwritter initial public offering of the Company completed no later than the earlier of (i) September 7, 2023 and (ii) two years after the date of Closing of the Series D Preferred Shares and which occurs on the New York Stock Exchange, NASDAQ, Hong Kong Exchanges and Clearing Market or such other reputable stock exchange approved by the a majority of all of the investor directors with (i) the pre-public offering market capitalization of no less than $650,000, unless otherwise agreed by the investor directors; and (ii) shares held by the investors can be listed for trading or otherwise disposed of without transfer restrictions after any applicable statutory lock-up period.

Voting Rights (applicable to all Preferred Shares)

Except as otherwise required by law or as set forth herein, the holder of each ordinary share issued and outstanding shall have one vote for each ordinary share held by such holder, and the holder of Preferred Shares shall be entitled to the number of votes equal to the number of ordinary shares into which such Preferred Shares could be converted.

Liquidation Preference (applicable to all Preferred Shares)

Upon any liquidation, closure, dissolution, merger or acquisition of any Group company; or the transfer of a controlling interest (i.e., more than 50% of the equity) by the shareholders of any Group company (excluding the holders of Series A, B, C and D Preferred Shares); or the sale of the majority of any Group's assets to third parties; or the transfer of the majority of any Group's intellectual property to third parties; or any event that can be defined as a transfer of control of any Group company; or any transfer of the Shares of any Group company (excluding the shares of the Company held by the holders of Series A, B, C and D Preferred Shares) or shares held by the Founders or their affiliates without the prior written consent of the Investor Director Majority, Series C Investors and Series D Investors; or any breach of the Warrantors under the Series D Share Purchase Agreements, the Series C Share Purchase Agreements, the Series B Share Purchase Agreement, the Shareholders' Agreement and these Articles, as applicable ("Transaction Documents") which would cause the Series C Investors and Series D Investors to claim for termination of any of the Transaction Documents (each a "Liquidation Event"), whether voluntary or involuntary, all assets and funds of the Company legally available for distribution to the shareholders is distributed to the shareholders of the Company in the sequence as follows:

a) Series D Preferred Shares

b) Series C Preferred Shares

c) Series B Preferred Shares

d) Series A Preferred Shares

If there are any assets or funds remaining after the aggregate Series A, B, C and D Preferred Shares have been distributed or paid fully, the remaining assets and funds of the Company available for distribution is distributed on a pro rata basis among all holders of outstanding ordinary shares and Preferred Shares.

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

15. FINANCIAL LIABILITIES AT FVTPL (continued)

Dividends (applicable to all Preferred Shares)

Each holder of the ordinary shares (on as-converted basis) shall be entitled to receive dividends on a pro rata basis on the number of ordinary shares, out of any funds legally available therefor, pro rata based on the number of ordinary shares held by each holder.

Redemption Rights (applicable to Series B, C and D Preferred Shares)

At any time after the earlier of the following, any investors of Preferred Shares shall be entitled to require the Company to redeem all or portion of the outstanding Preferred Shares held by them, and/or require each of the Warrantors to jointly and severally redeem or repurchase all or portion of the outstanding Preferred Shares held by them:

i. the Company fails to complete a Qualified IPO at the earlier of (a) September 7, 2023; and (b) two years after the date of Closing;

ii. (applicable to Series C Investors and Series D Investors only) with respect to any Series C Investor or Series D Investor, such Series C Investor or Series D Investor fails to achieve the investment return which is 100% of its investment amount and plus an amount that would accrue on its investment amount at a simple interest rate of ten percent (10%) per annum (if such period is less than a year, such interest amount shall be calculated proportionally) through transfer, dividends of the Preferred Shares, or disposal in any other way approved by such Series C Investors or Series D Investors plus the value of the Preferred Shares (if any) still held by such Series C Investors or Series D Investors by September 7, 2023 (with respect to Series C Investors) or by three years following its closing of Series D (with respect to Series D Investors);

iii. (applicable to Series C Investors only) the applicable Group company fails to meet any of the Committed Business Objectives within the timelines specified under these Articles;

iv. (applicable to Series C Investors only) the applicable Group company fails to obtain approval of a new medicine application from the competent authority for drug administration of its first medicine in the U.S. or the PRC by December 30, 2022;

v. (applicable to Series C Investors and Series D Investors only) the first disapproval or rejection by any competent governmental authority (including, without limitation, the National Medical Products Administration of the PRC or the U.S. Food and Drug Administration) of the application made by any Group company with respect to any of its new drugs;

vi. in case that the Group companies meet the requirements for a Qualified IPO, any of the Group companies or the management shareholders refuses the Qualified IPO or declines to make necessary cooperation for such Qualified IPO, or the Group companies fail to complete the Qualified IPO due to any reasons attributable to any management shareholder;

vii. without the written consent of the majority of investor directors, Series C Investors and Series D Investors, Mr. Yang Lu and Mr. Donghui Yang terminate their employment contracts with the applicable Group company or fail to comply their commitment to work full time as per the agreement with certain Series C Investors or Series D Investors prior to the latest to occur of the following events: (a) such Series C Investors or Series D Investors' exit; (b) the occurrence of a Qualified IPO; (c) the expiry of the two years period after the closing of Series D; and (d) September 7, 2023;

viii. material change of principal business or, business scope of the Group companies without the written consent of the majority of investor directors, Series C Investors and Series D Investors;

15. FINANCIAL LIABILITIES AT FVTPL (continued)

ix. any significant intellectual property of any Group company becomes invalid, frozen, or is transferred, authorized, pledged, encumbered, hypothecated to any third party without prior written consent of the majority of investor directors;

x. the occurrence of a material breach by any Group company or any management shareholders of any of their respective representations, warranties, covenants or undertakings under the Transaction Documents and failure by applicable Group companies or management shareholders to make remedy within thirty days after so required;

xi. the occurrence of a material breach by any Group company or any management shareholder of any of mandatory laws or regulations in the applicable jurisdiction; and

xii. the occurrence of any material dishonesty problem by any Group company or any management shareholder.

Next Equity Financing Warrant

In June 2018, in connection with the issuance of the Series B Preferred shares, the Company irrevocably issued to certain Series B Investors a warrant ("Next Equity Financing Warrant"), by which each of these Series B Investors shall be entitled but not obligated to purchase a certain number of the Company's Preferred Shares with a par value of $0.0001 per share prior to the closing date of the Company's next round equity or equity-linked financing (the "Next Equity Financing"), at an exercise price per share of ninety-five percent (95%) of the subscription price per share for the investors in such Next Equity Financing.

The Next Equity Financing Warrant expired upon the closing date of the Company's Series C financing in August 2019 as none of these Series B Investors subscribed the Company's Series C Preferred Shares.

CEHKL Warrant

On May 20, 2019, the Company entered into a warrant agreement with China Equities HK Limited ("CEHKL"), under which the Company agreed to issue certain Series B Preferred Shares to CEHKL with agreed price ("CEHKL Warrant") and the CEHKL Warrant will expire on May 20, 2024. In July 2021, CEHKL elected to exercise the CEHKL Warrant and the Company issued 100,000 Series B Preferred Shares to CEHKL.

Presentation and classification

The Group and the Company have designated the Series B, C and D Preferred Shares and Series B Convertible Loans as financial liabilities measured at FVTPL upon initial recognition. The Next Equity Financing Warrant and CEHKL Warrant are initially recognized at fair value on the date on which the contract is entered into and are subsequently remeasured at fair value.

The change in fair value of financial liabilities at FVTPL is charged to profit or loss except for the portion attributable to credit risk change that shall be charged to other comprehensive income. The net gain or loss recognized in profit or loss includes any interest paid on the financial liabilities and is included in the loss on changes in fair value of financial liabilities at FVTPL line item. Management concluded that there is no credit risk of the financial liability that drives the change of the fair value of the financial liability.

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

15. FINANCIAL LIABILITIES AT FVTPL (continued)

The movements of the Group's financial liabilities at FVTPL are set out as follows:

	Series B Preferred Shares	Series B Convertible Loans	Series C Preferred Shares	Series D Preferred Shares	CEHKL Warrant	Total
	$'000	$'000 (Note i)	$'000	$'000	$'000 (Note ii)	$'000
At January 1, 2020	**27,323**	**26,106**	**5,004**	**—**	**311**	**58,744**
Issuance of Preferred Shares	—	—	58,700	—	—	58,700
Reclassification of Series B Convertible Loans (Note i)	26,106	(26,106)	—	—	—	—
Change in fair value	24,854	—	10,993	—	(8)	35,839
At December 31, 2020	**78,283**	**—**	**74,697**	**—**	**303**	**153,283**
Issuance of Preferred Shares	303	—	—	97,370	(303)	97,370
Change in fair value	13,601	—	23,029	10,280	—	46,910
At December 31, 2021	**92,187**	**—**	**97,726**	**107,650**	**—**	**297,563**
Change in fair value	(1,803)	—	(594)	(4,798)	—	(7,195)
At December 31, 2022	**90,384**	**—**	**97,132**	**102,852**	**—**	**290,368**

	As of December 31,		
	2020	2021	2022
	$'000	$'000	$'000
Analyzed into:			
Current portion (Note iii)	74,697	—	290,368
Non-current portion (Note iii)	78,586	297,563	—
Total	153,283	297,563	290,368

Notes:

(i) The Group has designated the Series B Convertible Loans as whole as financial liabilities at FVPTL as of December 31, 2020.

The Company has recognized the Series B Preferred Shares Forward as financial liabilities at FVPTL as of December 31, 2020.

With the completion of Reorganization, the exercise of Series B Preferred Shares Forward by Series B Onshore Investors from April 2021 to June 2021 resulted in the reclassification of Series B Convertible Loans to Series B Preferred Shares.

(ii) In July 2021, CEHKL elected to exercise CEHKL Warrant and the Company issued 100,000 Series B Preferred Shares to CEHKL.

(iii) Pursuant to the Company's amended and restated MOA upon the Series C Preferred Shares financing in August 2019:

— the holders of the Series C Preferred Shares were entitled to an option to require the Company to early redeem the whole preferred shares when the Company or any other group company fails to consummate a Qualified IPO at any time on or before 30 September 2021; and

— the holders of the Series B Preferred Shares were entitled to an option to require the Company to early redeem the whole preferred shares when the Company or any other group company fails to consummate a Qualified IPO at any time on or before 1 June 2023.

With the Company entering into a series of Series D share purchase agreements from April 2021 to July 2021, the Company adopted an amended and restated MOA on May 28, 2021, pursuant to which the required latest completion date of a Qualified IPO by the Company under the Series C share purchase agreements was modified from September 30, 2021 to June 1, 2023.

As such, the Series C Preferred Shares were presented as a current liability as of December 31, 2020 and further reclassified as a non-current liability as of December 31, 2021. Other financial liabilities measured at FVTPL were presented as a non-current liability as of December 31,2020 and 2021.

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

15. FINANCIAL LIABILITIES AT FVTPL (continued)

Series B, C and D Preferred Shares were reclassified as a current liability as of December 31, 2022 according to the MOA signed on May 28, 2021.

The Company has used the discounted cash flow method and back-solve method to determine the underlying share value of the Company and adopted equity allocation model to determine the fair value of each financial liability as of the dates of issuance and at the end of each of the Relevant Periods.

Set out below is a summary of significant unobservable inputs to the valuation of financial instruments together with a quantitative sensitivity analysis as of December 31, 2020, 2021 and 2022:

	As of December 31		
	2020	2021	2022
Fair value of ordinary shares of the Company	$1.82	$5.25	$6.15
Risk-free interest rate (Note i)	0.07%	0.47%	4.68%
Expected term	0.75 years	1.29 years	0.44 years
Volatility (Note ii)	47.37%	49.38%	52.86%

Notes:

(i) 1% increase/decrease in the risk-free interest rate with all other variables held constant would decrease/increase the fair value of convertible redeemable preferred shares by $267/$328, $267/$(698) and $83/84 as of December 31, 2020, 2021 and 2022, respectively.

(ii) 1% increase/decrease in volatility with all other variables held constant would decrease/increase the fair value of convertible redeemable preferred shares by $121/$1,080, $119/$50 and $(49)/$924 as of December 31, 2020, 2021 and 2022, respectively.

The Group estimated the risk-free interest rate based on the yield of the United States Government Bond with maturity close to the expected exit timing as of the valuation date. Under the option-pricing method, the cost of a put option, which can hedge the price change before the privately held shares can be sold, was considered as a basis to determine the lack of marketability discount. Volatility was estimated based on the annualized standard deviation of the daily stock price return of comparable companies for a period from the valuation date and with a similar time span to expiration.

16. WARRANTS

In connection with issuance of Series B Preferred shares in August 2019, the Company irrevocably issued to CEHKL 171,559 Private Warrants (“CEHKL Warrants”) at a fair value of $486. Please refer to note 15 for details of the CEHKL Warrant.

156,653 CEHKL Warrants were outstanding as of December 31, 2020 and none were outstanding as of December 31, 2021 and 2022.

17. ORDINARY SHARES

Issued and fully paid:

	As of December 31,		
	2020	2021	2022
	$’000	$’000	$’000
25,440,000 shares of $0.0001 each	3	3	3

The authorized share capital of the Company as of December 31, 2022 is $50 divided into 500,000,000 Shares of par value of $0.0001 each, including 442,456,586 ordinary shares.

17. ORDINARY SHARES (continued)

There was no movement in the Company's ordinary shares in 2020 and 2022. In 2021, the Company issued 9,000,000 ordinary shares to Nortye Talent Limited and 6,000,000 ordinary shares to Nortye International Limited respectively to manage the Share Incentive Plan. All these ordinary shares in 2021 were unpaid shares as of December 31, 2021 and 2022.

18. DEFICITS

The amounts of the Group's deficits and the movement therein for the Relevant Periods are presented in the consolidated statements of changes in equity.

(i) Additional paid-in capital

The additional paid-in capital represents the difference between the par value of the shares issued and the consideration received.

(ii) Share option reserve

The share option reverse of the Group represents the equity-settled share-based payments granted by the Group. Please refer to note 19 for details.

(iii) Exchange fluctuation reserve

The exchange fluctuation reserve represents exchange differences arising from the translation of the financial statements of Group companies whose functional currencies are different from the Group's presentation currency.

19. SHARE INCENTIVE PLAN

Adlai Hangzhou Scheme

Adlai Hangzhou, a subsidiary of the Company, was once listed on the National Equities Exchange and Quotations ("NEEQ") (stock code 870946) and adopted a share incentive scheme (the "Adlai Hangzhou Scheme") for the primary purpose of providing incentives to eligible management and employees who render services to Adlai Hangzhou. On June 15, 2017, awards up to 1,220,000 shares were granted to management and employees at the exercise price of RMB7 per share. Awards granted under the Adlai Hangzhou Scheme shall have a contractual term of five years and generally vest over a four year period, with 25% of total awards vesting on the anniversary date one year after the vesting commencement date and the remaining 75% vesting subsequently in three equal annual instalments.

The fair value of the awards granted to management and employees were $ 0.083 per share and $ 0.0765 per share, respectively, using the binomial option-pricing model on the grant date. The variables and assumptions used in computing the fair value of the awards are based on the directors' best estimate. Changes in variables and assumptions may result in changes in the fair value of the awards.

The Group recognized $74 of share-based payment expenses prior to 2020, and $7, nil and nil share-based payment expenses for the years ended December 31, 2020, 2021 and 2022, respectively, in relation to the awards granted under the Adlai Hangzhou Scheme.

Adlai Share Incentive Plan

On June 8, 2020, the Company's Board of Directors approved a share incentive scheme (the "Share Incentive Plan") in order to provide additional incentives to employees and to promote the success of the

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

19. SHARE INCENTIVE PLAN (continued)

Group's business. Unless otherwise cancelled or amended, the Share Incentive Plan will remain in force for 10 years. Under the Share Incentive Plan, the maximum aggregate number of shares shall not exceed 4,000,000 ordinary shares, as appropriately adjusted for subsequent stock splits, stock dividends and the like. On May 28, 2021, the Company's Board of Directors approved to further reserve 11,000,000 ordinary shares of the Company for the Share Incentive Plan for a total of 15,000,000 ordinary shares approved for the Share Incentive Plan. The exercise price of share options is determinable by the directors, but shall not be less than 100% of the fair market value on the grant date. Share options do not confer rights on the holders to dividends or to vote at shareholders' meetings. The awards may be granted but not be exercised prior to the last day of the six-month period following the listing date of the Company.

On July 5, 2021, the Company issued 6,000,000 and 9,000,000 ordinary shares reserved under the Share Inventive Plan to Nortye International Limited and Nortye Talent Limited, respectively, which are holding vehicles of two trusts established by the Company in order to facilitate the administration of the Share Incentive Plan. The sole purpose of the two trusts is to facilitate the issuance of ordinary shares under the Share Incentive Plan, and as such the 15,000,000 ordinary shares are not included in the Company's calculation of weighted average shares outstanding.

On September 8, 2020 and November 1, 2020, awards for 1,435,000 and 2,560,730 shares, respectively, were granted by the Company to its executives, employees and consultants.

On May 31, 2021, 3,348,483 awarded shares were granted by the Company to its executives, employees and consultants.

On October 1, 2021, 412,000 awarded shares were granted by the Company to its executives, employees and consultants.

On January 1, 2022, 83,500 options were granted to certain new employees; 376,172 options were granted to certain employees and managers for outstanding performance.

On April 1, 2022, 1,077,800 options were granted to certain new employees, promoted employees and senior managers; 33,336 options were granted to three consultants.

On July 1, 2022, 207,200 options were granted to five new employees.

On October 1, 2022, 179,200 options were granted to five new employees.

Accordingly, the Group measured the fair value of the awards as of the grant date and recognizes the amount as a compensation expense over the vesting period for each separately vesting portion of the awards.

	Number of awards	Weighted Average Exercise Price $ per share	Weighted Average Grant Fair Value $ per share	Weighted Average Remaining Contractual Life (in years)	Aggregate intrinsic value $
Balances, January 1, 2020	—	—	—	—	
Options granted	3,995,730	1.45	0.76	9.78	
Options forfeited/cancelled	—	—	—	—	
Options exercised	—	—	—	—	
Balances, December 31, 2020	3,995,730	1.45	0.76	9.78	1,464
Options granted	3,760,483	2.01	1.97	9.45	
Options forfeited/cancelled	(120,769)	1.67	0.69	8.83	
Options exercised	—	—	—	—	

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

19. SHARE INCENTIVE PLAN (continued)

	Number of awards	Weighted Average Exercise Price $ per share	Weighted Average Grant Fair Value $ per share	Weighted Average Remaining Contractual Life (in years)	Aggregate intrinsic value $
Balances, December 31, 2021	7,635,444	1.72	1.36	9.11	26,950
Options granted	1,957,208	2.20	3.56	9.26	
Options forfeited/cancelled	(82,550)	2.11	2.68	8.79	
Options exercised	—	—	—	—	
Balances, December 31, 2022	9,510,102	1.82	1.79	8.34	41,218
Vested but not exercisable as of December 31, 2020	2,710,750	1.43	0.76	9.78	
Vested but not exercisable as of December 31, 2021	3,350,480	1.36	0.74	8.46	
Vested but not exercisable as of December 31, 2022	4,980,069	1.59	1.15	8.00	

As of December 31, 2020, 2021 and 2022, there were 4,000,000, 15,000,000 and 15,000,000 shares reserved for the option plan and there were 4,270, 7,364,556 and 5,489,898 shares available for issuance, respectively.

The fair value of the award granted during the years ended December 31, 2020, 2021 and 2022 were $3,031, $ 7,410 and $6,913. The Group recognized share-based payment expenses of $ 2,261, $3,386 and $6,082, respectively, during the years ended December 31, 2020, 2021 and 2022.

The fair value of awards granted during the Relevant Periods was estimated as of the grant date using a binomial option-pricing model, taking into account the terms and conditions upon which the awards were granted. The following table lists the inputs to the model used:

	September 8, 2020	November 1, 2020	May 31, 2021	October 1, 2021	January 1, 2022	April 1, 2022	July 1, 2022	October 1, 2022
Dividend yield (%)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Expected volatility (%)	46.81	46.81	46.13	49.00	48.73	48.78	48.88	48.82
Risk-free interest rate (%)	0.85	1.05	1.67	1.7	1.66	2.52	3.03	3.98
Expected life of options (year)	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00

As of December 31, 2020, 2021 and 2022, the Company had 3,995,730, 7,635,444 and 9,510,102 awards outstanding under the Share Incentive Plan, respectively. The exercise in full of the outstanding awards would, under the present capital structure of the Company, result in the issue of 3,995,730, 7,635,444 and 9,510,102, respectively, additional ordinary shares of the Company and additional share capital of $0.4, $0.8 and $1.0 (before issue expenses), respectively.

20. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

During the year ended December 31, 2020, 2021 and 2022, the Group had non-cash additions to right-of-use assets and lease liabilities of $ 4,028, nil and nil, respectively, in respect of lease arrangements for offices and equipment.

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

20. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

(b) Changes in liabilities arising from financing activities

	Financial instrument measured at FVTPL	New bank loans and other borrowings	Lease liabilities	Payable for issue costs	Total
	$'000	$'000	$'000	$'000	$'000
At January 1, 2020	58,744	10,507	1,400	—	70,651
Interest expense	—	591	133	—	724
Transaction costs for the issuance of convertible redeemable preferred shares	—	—	—	1,076	1,076
Additions	58,700	12,895	4,028	—	75,623
Disposal	—	—	(650)	—	(650)
Payment					
– financing cash flows	—	(15,499)	(1,297)	(1,076)	(17,872)
– operating cash flows	—	—	—	—	—
Interest paid	—	(652)	—	—	(652)
Change in fair value	35,839	—	—	—	35,839
Exchange adjustment	—	467	21	—	488
At December 31, 2020	**153,283**	**8,309**	**3,635**	**—**	**165,227**
Interest expense	—	422	160	—	582
Transaction costs for the issuance of convertible redeemable preferred shares	—	—	—	758	758
Additions	97,370	12,410	—	—	109,780
Disposal	—	—	—	—	—
Payment					
– financing cash flows	—	(10,430)	(966)	(758)	(12,154)
– operating cash flows	—	—	—	—	—
Interest paid	—	(427)	—	—	(427)
Change in fair value	46,910	—	—	—	46,910
Exchange adjustment	—	184	59	—	243
At December 31, 2021	**297,563**	**10,468**	**2,888**	**—**	**310,919**
Interest expense	—	295	138	—	433
Transaction costs for the issuance of convertible redeemable preferred shares	—	—	—	—	—
Additions	—	7,897	463	—	8,360
Disposal	—	—	—	—	—
Payment					
– financing cash flows	—	(13,316)	(936)	—	(14,252)
– operating cash flows	—				
Interest paid	—	(290)	(134)	—	(424)
Change in fair value	(7195)	—	—	—	(7,195)
Exchange adjustment	—	(741)	(176)		(917)
At December 31, 2022	**290,368**	**4,313**	**2,243**	**—**	**296,924**

(All amounts in thousands, except share and per share data, or as otherwise noted)

20. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

(c) Investment activities

	Dual currency structured deposit	Swap deposit	Wealth management product	Total
	$'000	$'000	$'000	$'000
Year ended December 31, 2020				
purchase	—	(26,942)	(2,299)	(29,241)
disposal	—	26,942	2,299	29,241
interest received	—	7	11	18
Year ended December 31, 2021				
purchase	(17,000)	(17,965)	(46,269)	(81,234)
disposal	9,500	17,965	—	27,465
interest received	28	4	—	32
Year ended December 31, 2022				
purchase	(14,900)	—	(44,080)	(58,980)
disposal	22,439	—	65,618	88,057
interest received	19	—	531	550

21. COMMITMENTS

The Group did not have capital commitments at the end of each of the Relevant Periods.

22. RELATED PARTY TRANSACTIONS

(a) Related parties

Parties are considered to be related if one party has the ability, directly or indirectly, to control or exercise significant influence over the other party.

Parties are also considered to be related if they are subject to common control. Members of key management of the Group and their close family members are also considered as related parties.

Name of related parties	Nature of relationship
Mr. Yang Lu	The chief executive officer and chairman of our board of directors and ultimate significant shareholder of the Company

As disclosed in note 14 (ii) and note 14 (iii) to the consolidated financial statements, the RMB45,000, RMB70,000 and RMB40,000 non-revolving facility agreements provided by three third party banks were guaranteed by the ultimate significant shareholder, Mr. Yang Lu for the years ended December 31, 2020, 2021 and 2022, respectively. As disclosed in note 14 (v) to the consolidated financial statements, $3,700 loan agreement provided by an individual third party was guaranteed by the ultimate significant shareholder, Mr. Yang Lu for the year ended December 31, 2020

23. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments of the Group as of the end of each of the Relevant Periods are as follows:

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

23. FINANCIAL INSTRUMENTS BY CATEGORY (continued)

	As of December 31,		
	2020	2021	2022
	$'000	$'000	$'000
Financial assets:			
Financial assets at FVTPL:			
Dual currency structured deposit	—	7,540	—
Wealth management product	—	46,269	21,287
Total	—	53,809	21,287
Other financial assets:			
Financial assets included in prepayments, other receivables and other assets	5,502	6,604	2,258
Cash and cash equivalents	24,261	64,131	42,758
Total	29,763	70,735	45,016
Financial liabilities:			
Trade payables	2,000	2,981	13,098
Financial liabilities included in other payables and accruals	2,464	3,224	3,877
Interest-bearing bank and other borrowings	8,296	10,457	4,307
Total	12,760	16,662	21,282
Financial liabilities at FVTPL:			
Financial instruments measured at FVTPL	153,283	297,563	290,368
Total	153,283	297,563	290,368

24. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

The carrying amounts and fair values of the Group's financial instruments, other than those with carrying amounts that reasonably approximate to fair values, are as follows:

	As of December 31, 2020		As of December 31, 2021		As of December 31, 2022	
	Carrying amount	Fair value	Carrying amount	Fair value	Carrying amount	Fair value
	$'000	$'000	$'000	$'000	$'000	$'000
Financial assets						
Dual currency structured deposit	—	—	7,540	7,540	—	—
Wealth management product	—	—	46,269	46,269	21,287	21,287
Total	—	—	53,809	53,809	21,287	21,287
Financial liabilities						
Financial liabilities at FVTPL	153,283	153,283	297,563	297,563	290,368	290,368
Total	153,283	153,283	297,563	297,563	290,368	290,368

Management has assessed that the fair values of cash and cash equivalents, interest-bearing bank and other borrowings, trade payables, financial assets included in prepayments, other receivables and other assets, and financial liabilities included in other payables and accruals approximate to their carrying amounts largely due to the short term maturities of these instruments.

The Group's finance department headed by the finance manager is responsible for determining the policies and procedures for the fair value measurement of financial instruments. The finance manager reports directly to the chief financial officer and the audit committee. At the end of each of the Relevant Periods, the

(All amounts in thousands, except share and per share data, or as otherwise noted)

24. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS (continued)

finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The valuation is reviewed and approved by the chief financial officer. The valuation process and results are discussed with the audit committee twice a year for interim and annual financial reporting.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. The methods and assumptions used to estimate the fair value, including a summary of significant unobservable inputs together with a quantitative sensitivity analysis, are set out in note 15 to the Consolidated Financial Statements.

The fair values of the non-current portion of interest-bearing bank and other borrowings have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities. The changes in fair value as a result of the Group's own non-performance risk for interest-bearing bank and other borrowings as of the end of each of the Relevant Periods were assessed to be insignificant.

Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group's financial instruments:

As of December 31, 2020

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
	$'000	$'000	$'000	$'000
Financial liabilities				
Financial liabilities at FVTPL	—	—	153,283	153,283

As of December 31, 2021

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
	$'000	$'000	$'000	$'000
Financial assets				
Dual currency structured deposit	—	—	7,540	7,540
Wealth management product	—	—	46,269	46,269
Total	—	—	53,809	53,809
Financial liabilities				
Financial liabilities at FVTPL	—	—	297,563	297,563

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

24. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS (continued)

As of December 31, 2022

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Financial assets				
Dual currency structured deposit	—	—	—	—
Wealth management product	21,287	—	—	21,287
Total	21,287	—	—	21,287
Financial liabilities			290,368	290,368
Financial liabilities at FVTPL	—	—	290,368	290,368

Changes in Level 3 instruments for the years ended December 31, 2020, 2021 and 2022 are as follows:

	2020	2021	2022
	$'000	$'000	$'000
Financial assets			
Balance as of January 1	—	—	53,809
Acquisitions	29,241	81,234	14,900
Disposals	(29,241)	(27,465)	(68,709)
Amount recognized in profit or loss	—	40	—
Balance as of December 31	—	53,809	—

	2020	2021	2022
	$'000	$'000	$'000
Financial liabilities			
Balance as of January 1	58,744	153,283	297,563
Acquisitions	58,700	97,370	—
Amount recognized in profit or loss	35,839	46,910	(7,195)
Balance as of December 31	153,283	297,563	290,368

During the Relevant Periods, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

Information about Level 3 fair value measurements:

	As of December 31, 2021	
	Valuation techniques	Significant unobservable inputs
Dual currency structured deposit	Discounted cash flow method	Forward exchange rate of USD/CNY Expected return rate
Wealth management product	Discounted cash flow method	

The fair value of dual currency structured deposit has been estimated using a discounted cash flow valuation model based on assumptions that are not supported by observable market prices or rates. The un-observable inputs are the forward exchange rates of USD/CNY. The expected rate of return is between

(All amounts in thousands, except share and per share data, or as otherwise noted)

24. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS (continued)

1.5% – 2% and is not guaranteed, it depends on the forward exchange rate of USD/CNY. The valuation requires the managers to make estimates about the expected forward exchange rate of USD/CNY on maturity of the dual currency structured deposit. The term of the structured deposit is from one to three months. The managers believe that the estimated fair values resulting from the valuation technique are reasonable, and that they were the most appropriate values at the end of reporting periods. The actual return rate of dual currency structured deposits held as at December 31, 2021 was 1.93%.

The fair value of wealth management product has been estimated using a discounted cash flow valuation model based on an assumption that is not supported by observable market prices or rates. The un-observable input is expected annual return rate. The expected rate of return is not guaranteed and depends on the market price of underlying financial instruments, including bank deposits, debentures, monetary funds, central bank bills with good liquidity. The wealth management product is open-ended and can be redeemed at any time. The valuation requires the managers to make estimates about the expected future cash flows including expected future return. The managers believe that the estimated fair values resulting from the valuation technique are reasonable, and that they were the most appropriate values at the end of reporting periods. The actual return rate of wealth management products held as at December 31, 2021 was 2.67%.

25. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group's principal financial instruments comprise interest-bearing bank and other borrowings, convertible redeemable preferred shares and cash and cash equivalents. The main purpose of these financial instruments is to raise finance for the Group's operations. The Group has various other financial assets and liabilities such as trade payables, other payables and accruals, which arise directly from its operations.

The main risks arising from the Group's financial instruments are foreign currency risk and liquidity risk. The board of directors reviews and agrees policies for managing each of these risks and they are summarized below.

Foreign currency risk

The Group has transactional currency exposures. Such exposures arise from purchases by operating units in currencies other than the units' functional currencies.

The following table demonstrates the sensitivity at the end of each of the Relevant Periods to a reasonably possible change in the $ and RMB exchange rate, with all other variables held constant, of the Group's profit before tax (due to changes in the fair values of monetary assets and liabilities).

	Increase/ (decrease) in $/RMB rate%	Increase/ (decrease) in profit before tax	Increase/ (decrease) in equity
		$'000	$'000
As of December 31, 2020			
If the $ strengthens against the RMB	5	—	(5)
If the $ weakens against the RMB	(5)	—	5

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

25. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (continued)

	Increase/ (decrease) in $/RMB rate%	Increase/ (decrease) in profit before tax	Increase/ (decrease) in equity
		$'000	$'000
At December 31, 2021			
If the $ strengthens against the RMB	5	—	2,398
If the $ weakens against the RMB	(5)	—	(2,651)

	Increase/ (decrease) in $/RMB rate%	Increase/ (decrease) in profit before tax	Increase/ (decrease) in equity
		$'000	$'000
As of December 31, 2022			
If the $ strengthens against the RMB	5	—	1,939
If the $ weakens against the RMB	(5)	—	(4,081)

Liquidity risk

The Group monitors and maintains a level of cash and cash equivalents deemed adequate by the management of the Group to finance the operations and mitigate the effects of fluctuations in cash flows.

The maturity profile of the Group's financial liabilities as of the end of each Relevant Periods, based on the contractual undiscounted payments, is as follows:

	As of December 31, 2020				
	On demand	Less than 1 year	1 to 5 years	Over 5 years	Total
	$'000	$'000	$'000	$'000	$'000
Financial liabilities at FVTPL	—	74,697	78,586	—	153,283
Trade and bills payables	2,000	—	—	—	2,000
Financial liabilities included in other payables and accruals	2,464	—	—	—	2,464
Interest-bearing bank borrowings	—	8,296	—	—	8,296
Total	4,464	82,993	78,586	—	166,043

	As of December 31, 2021				
	On demand	Less than 1 year	1 to 5 years	Over 5 years	Total
	$'000	$'000	$'000	$'000	$'000
Financial liabilities at FVTPL	—	—	297,563	—	297,563
Trade and bills payables	2,981	—	—	—	2,981
Financial liabilities included in other payables and accruals	3,224	—	—	—	3,224
Interest-bearing bank borrowings	—	10,457	—	—	10,457
Total	6,205	10,457	297,563	—	314,225

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

25. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (continued)

	As of December 31, 2022				
	On demand	Less than 1 year	1 to 5 years	Over 5 years	Total
	$'000	$'000	$'000	$'000	$'000
Financial liabilities at FVTPL	—	290,368	—	—	290,368
Trade and bills payables	13,098	—	—	—	13,098
Financial liabilities included in other payables and accruals	3,877	—	—	—	3,877
Interest-bearing bank borrowings		4,307			4,307
Total	16,975	294,675	—	—	311,650

Capital management

The primary objectives of the Group's capital management are to safeguard the Group's ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximize shareholders' value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the Relevant Periods.

The asset-liability ratios as of the end of each of the Relevant Periods are as follows:

	As of December 31,		
	2020	2021	2022
	$'000	$'000	$'000
Total assets	37,636	131,685	72,594
Total liabilities	169,678	317,113	313,887
Asset-liability ratio (Note i)	0.22	0.42	0.23

Note i:
The asset-liability ratio is calculated by dividing total assets by total liabilities.

26. SUBSEQUENT EVENTS

(a) Cash deposit

On March 12, 2023, the Federal Deposit Insurance Corporation, or the FDIC, took control and was appointed receiver of Silicon Valley Bank. As of April 7, 2023, the Company had four accounts with Silicon Valley Bank with a total balance of $4 which is below the FDIC limit. The Company does not expect any additional exposure or impact to our operations.

(b) Bank loan

In March 2023, Adlai Hangzhou repaid a non-revolving facility amount of RMB10,000 at the maturity date.

26. SUBSEQUENT EVENTS (continued)

In March 2023, Adlai Hangzhou entered into a non-revolving facility agreement with a third party financial institution for a facility amount of RMB30,000 at an interest rate of 4.0% per annum, guaranteed by Mr. Yang Lu and Adlai Shanghai. The maturity date is August 31, 2023.

In March 2023, Adlai Hangzhou entered into a non-revolving facility agreement with a third party financial institution for a facility amount of RMB20,000 at an interest rate of 4.2% per annum, guaranteed by Mr. Yang Lu. The maturity date is March 27, 2024.

27. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY

The business transactions and assets of Adlai Hangzhou and Shanghai Adlai Nortye Biopharma Co., Ltd ("PRC Subsidiaries") are primarily denominated in RMB, which is not freely convertible into foreign currencies. All foreign exchange transactions take place either through the People's Bank of China or other banks authorized to buy and sell foreign currencies at the exchange rates quoted by the People's Bank of China. Approval of foreign currency payments by the People's Bank of China or other regulatory institutions requires submitting a payment application form together with suppliers' invoices, shipping documents and signed contracts. These currency exchange control measures imposed by the PRC government may restrict the ability of PRC Subsidiaries to transfer their net assets to the Company through loans, advances or cash dividends.

The net assets of PRC Subsidiaries in aggregate exceeded 25% of the Company's consolidated net assets. Accordingly, condensed parent company financial statements have been prepared in accordance with Rule 5.04 and Rule 12-04 of SEC Regulation S-X.

The subsidiaries did not pay any dividends to the Company for the periods presented. For the purpose of presenting parent-only financial information, the Company records its investment in its subsidiaries under the cost method of accounting. Such investment is presented on the separate condensed balance sheets of the Company as "Investment in subsidiaries". Certain information and footnote disclosures generally included in financial statements prepared in accordance with IFRSs are not required.

As of December 31, 2020, 2021 and 2022, there were no material contingencies, significant provisions for long-term obligations, or guarantees of the Company, except for those which have been separately disclosed in the consolidated financial statements, if any.

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

27. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY (continued)

PARENT COMPANY BALANCE SHEETS

	December 31,		
	2020	2021	2022
	$'000	$'000	$'000
ASSETS			
Current assets			
Cash and cash equivalents	19,343	48,363	12,194
Prepayments, other receivables and other assets	26	1	36
Total current assets	**19,369**	**48,364**	**12,230**
Non-current assets			
Due from related parties	57,579	104,714	115,743
Investment in subsidiaries	42,175	64,216	94,300
Total non-current assets	**99,754**	**168,930**	**210,043**
Total assets	**119,123**	**217,294**	**222,273**
LIABILITIES			
Current liabilities			
Accounts payable	204	761	888
Interest payables	1	—	—
Non-current liabilities due within one year	542	—	4
Financial liabilities at FVTPL	74,697	—	290,368
Total current liabilities	**75,444**	**761**	**291,260**
Non-current liabilities			
Long-term loans	—	—	—
Financial liabilities at FVTPL	78,586	297,563	—
Total non-current liabilities	**78,586**	**297,563**	**—**
Total liabilities	**154,030**	**298,324**	**291,260**
Ordinary shares (par value of $0.0001 per share; 442,456,586 shares authorized and 25,440,000 shares issued and outstanding as of December 31, 2020; 442,456,586 shares authorized and 40,440,000 shares issued and outstanding as of December 31, 2021 and 2022)	3	4	4
Series A convertible preferred shares (par value of US$0.0001 per share; 14,560,000, 14,560,000 and 14,560,000 shares authorized, issued and outstanding as of December 31, 2020, 2021 and 2022, respectively)	10,980	10,980	10,980
Additional paid-in capital	6,416	6,415	6,415
Share option reserve	2,261	5,647	11,730
Accumulated deficit	(54,567)	(104,076)	(98,116)
Total shareholders' deficit	**(34,907)**	**(81,030)**	**(68,987)**
Total liabilities and shareholders' equity	**119,123**	**217,294**	**222,273**

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022, 2021 AND 2020 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

27. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY (continued)

PARENT COMPANY STATEMENTS OF INCOME AND COMPREHENSIVE INCOME

	For the Years Ended December 31,		
	2020	2021	2022
	$'000	$'000	$'000
REVENUE	—	—	—
Other operating income, net	—	—	156
Administrative expenses	(993)	(2,376)	(1,390)
Research and development expenses	(4,000)	—	
Total operating loss	**(4,993)**	**(2,376)**	**(1,234)**
Other income and gains	34	173	—
Investment income	7	3	—
Fair value loss on financial liabilities at FVTPL	(38,145)	(46,910)	7,194
Finance costs	(139)	(399)	—
LOSS BEFORE TAX	**(43,236)**	**(49,509)**	**5,960**
Income tax expense	—	—	—
LOSS FOR THE YEAR	**(43,236)**	**(49,509)**	**5,960**
TOTAL COMPREHENSIVE (LOSS)/INCOME FOR THE YEAR	**(43,236)**	**(49,509)**	**5,960**

PARENT COMPANY STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2020	2021	2022
	$'000	$'000	$'000
Net cash flows used in operating activities	(4,856)	(1,610)	(1,134)
Net cash flows used in investing activities	(59,536)	(65,798)	(35,035)
Net cash flows from financing activities	79,217	96,428	—
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	**14,825**	**29,020**	**(36,169)**
Cash and cash equivalents at beginning of year	4,518	19,343	48,363
CASH AND CASH EQUIVALENTS AT END OF YEAR	**19,343**	**48,363**	**12,194**

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 6. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Cayman Islands law does not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime.

The post-offering memorandum and articles of association that we expect to adopt and to become effective immediately prior to the completion of this offering provide that we shall indemnify our directors and officers (each an indemnified person) against all actions, proceedings, costs, charges, expenses, losses, damages, or liabilities incurred or sustained by such indemnified person, other than by reason of such person's own dishonesty, willful default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities, or discretions, including, without prejudice to the generality of the foregoing, any costs, expenses, losses, or liabilities incurred by such indemnified person in defending (whether successfully or otherwise) any civil proceedings concerning our company or its affairs in any court whether in the Cayman Islands or elsewhere.

Pursuant to the indemnification agreements, the form of which is filed as Exhibit 10.2 to this registration statement, we agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being such a director or officer.

The underwriting agreement, the form of which is filed as Exhibit 1.1 to this registration statement, also provides indemnification by the underwriters for us and our officers and directors for certain liabilities, including liabilities arising under the Securities Act, but only to the extent that such liabilities are caused by information relating to the underwriters furnished to us in writing expressly for use in this registration statement and certain other disclosure documents.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

ITEM 7. RECENT SALES OF UNREGISTERED SECURITIES.

In the past three years, we have issued the following securities (including options to acquire our ordinary shares) that were not registered under the Securities Act. We believe that each of the following issuances was exempt from registration under the Securities Act pursuant to Section 4(a)(2) of the Securities Act regarding transactions not involving a public offering or in reliance on Regulation S under the Securities Act regarding sales by an issuer in offshore transactions. No underwriters were involved in these issuances of securities.

Securities/Purchaser	Date of Issuance	Number of Shares	Consideration
Ordinary shares			
Lucy Zhang	May 28, 2021	900,000	USD2,833,574
Nortye Talent Limited	July 5, 2021	9,000,000	Nil
Nortye International Limited	July 5, 2021	6,000,000	Nil
PECO International Limited	July 5, 2021	5,000,000	Nil
Archer Future Limited	July 5, 2021	16,990,000	Nil
DH Future Limited	July 5, 2021	2,550,000	Nil
Series A Preferred Shares			
JIN YIN (BVI) LIMITED	January 20, 2020	6,060,000	USD606

Securities/Purchaser	Date of Issuance	Number of Shares	Consideration
Yingzhi International Limited	February 5, 2020	1,570,000	USD157
LV YI (BVI) LIMITED	March 30, 2020	3,430,000	USD343
LAI NUO (BVI) LIMITED	April 16, 2020	3,500,000	USD350
Series B Preferred Shares			
BJKR Management Ltd.	April 8, 2020	1,000,000	RMB25,000,000
Ningbo Meishan Bonded Port Area Yahui Xinrun Investment Management Center (Limited Partnership)	April 14, 2020	960,000	RMB24,000,000
Beijing Yahui Qianfeng Equity Investment Partnership (Limited Partnership)	April 14, 2020	640,000	RMB16,000,000
QHYM Investment Ltd.	May 6, 2020	2,000,000	RMB50,000,000
Dexuan (Shanghai) Enterprise Management Center (Limited Partnership)	May 15, 2020	2,000,000	RMB50,000,000
China Equities HK Limited	July 13, 2021	100,000	Nil
Series C Preferred Shares			
Hongkong Tigermed Co., Limited	December 23, 2019	1,150,158	USD5,000,000
ATCG Holdings Limited	January 22, 2020	4,600,632	USD20,000,000
Pingtan Hongtu No. 5 Venture Capital Partnership (Limited Partnership)	June 8, 2020	230,032	USD1,000,000
Pingtan Yingke Shengxin Chuangye Partnership (Limited Partnership)	June 15, 2020	2,300,316	USD10,000,000
Pingtan Puxin Yingke Ruiyuan Venture Capital Partnership (Limited Partnership)	June 16, 2020	621,085	USD2,700,000
UNIQUE MARK VENTURES LIMITED	August 24, 2020	5,750,790	USD25,000,000
Series D Preferred Shares			
ATCG Holdings Limited	May 28, 2021	2,268,025	USD15,000,000
Hangzhou Tigermed Equity Investment Partnership (Limited Partnership)	May 28, 2021	756,008	USD5,000,000
Triwise Kangnuo Investment Limited	May 28, 2021	2,066,927	USD13,670,000
Qingdao Mukui Equity Investment Partnership (Limited Partnership)	May 28, 2021	1,239,854	USD8,200,000
Wuxi Guolian Guokang Health Industry Investment Centre (Limited Partnership)	May 28, 2021	680,407	USD4,500,000
Week8 Holdings (HK) Limited	May 28, 2021	453,605	USD3,000,000
Ningbo Menovo Ruihe Equity Investment Partnership (Limited Partnership)	May 28, 2021	302,403	USD2,000,000
Xianjin Zhizao Industry Investment Fund II (Limited Partnership)	June 23, 2021	4,536,050	USD30,000,000
Adlai Nortye Investment Limited	June 23, 2021	226,802	USD1,500,000
Legendstar Fund IV, L.P.	June 23, 2021	453,605	USD3,000,000
Phantom Capital Fund L.P.	July 14, 2021	1,512,017	USD10,000,000
WuXi Biologics Healthcare Venture	July 14, 2021	226,802	USD1,500,000

ITEM 8. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Exhibits

See Exhibit Index beginning on page II-4 of this registration statement.

The agreements included as exhibits to this registration statement contain representations and warranties by each of the parties to the applicable agreement. These representations and warranties were made solely for the benefit of the other parties to the applicable agreement and (i) were not intended to be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate; (ii) may have been qualified in such agreement by disclosure that was made to the other party in connection with the negotiation of the applicable agreement; (iii) may apply contract standards of "materiality" that are different from "materiality" under the applicable securities laws; and (iv) were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement.

We acknowledge that, notwithstanding the inclusion of the foregoing cautionary statements, we are responsible for considering whether additional specific disclosure of material information regarding material contractual provisions is required to make the statements in this registration statement not misleading.

(b) Financial statement schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the Consolidated Financial Statements or the Notes thereto.

ITEM 9. UNDERTAKINGS.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the registrant pursuant to the provisions described in Item 6, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

ADLAI NORTYE LTD.

EXHIBIT INDEX

Exhibit Number	Description of Document
1.1*	Form of Underwriting Agreement
3.1*	[Sixth] Amended and Restated Memorandum and Articles of Association of the Registrant, as currently in effect
3.2*	Form of [Seventh] Amended and Restated Memorandum and Articles of Association of the Registrant (effective immediately upon the completion of this offering)
4.1*	Specimen American Depositary Receipt (included in Exhibit 4.3)
4.2*	Registrant's Specimen Certificate for Ordinary Shares
4.3*	Form of Deposit Agreement, among the Registrant, the depositary and the owners and holders of American Depositary Shares issued thereunder
5.1*	Opinion of Maples and Calder (Hong Kong) LLP regarding the validity of the ordinary shares being registered and certain Cayman Islands tax matters
8.1*	Opinion of Maples and Calder (Hong Kong) LLP regarding certain Cayman Islands tax matters (included in Exhibit 5.1)
8.2*	Opinion of Han Kun Law Offices regarding certain PRC tax matters (included in Exhibit 99.2)
10.1*	Form of Employment Agreement between the Registrant and its executive officers
10.2*	Form of Indemnification Agreement between the Registrant and its directors and executive officers
10.3**	License Agreement, dated as of December 22, 2017, between the Registrant and Novartis
10.4	License Agreement, dated as of January 19, 2018, between the Registrant and Eisai
10.5	Right and Interest Transfer Agreement dated as November 15, between the Registrant and Biotime
21.1*	List of Subsidiaries
23.1*	Consent of Mazars USA LLP
23.2*	Consent of Maples and Calder (Hong Kong) LLP (included in Exhibit 5.1)
23.3*	Consent of Han Kun Law Offices (included in Exhibit 99.2)
24.1*	Powers of Attorney (included on signature page)
99.1*	Code of Business Conduct and Ethics (effective immediately prior to the completion of this offering)
99.2*	Opinion of Han Kun Law Offices regarding certain PRC law matters
107*	Filing Fee Table

* To be filed by amendment.

** Previously Filed.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, on , 2023.

Adlai Nortye Ltd.

By: _____

Name:
Title:

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of and as attorneys-in-fact with full power of substitution for him or her in any and all capacities to do any and all acts and all things and to execute any and all instruments which said attorney and agent may deem necessary or desirable to enable the registrant to comply with the Securities Act of 1933, as amended, the Securities Act, and any rules, regulations and requirements of the Securities and Exchange Commission thereunder, in connection with the registration under the Securities Act of ordinary shares of the registrant, or the Shares, including, without limitation, the power and authority to sign the name of each of the undersigned in the capacities indicated below to the Registration Statement on Form F-1, or the Registration Statement to be filed with the Securities and Exchange Commission with respect to such Shares, to any and all amendments or supplements to such Registration Statement, whether such amendments or supplements are filed before or after the effective date of such Registration Statement, to any related Registration Statement filed pursuant to Rule 462(b) under the Securities Act, and to any and all instruments or documents filed as part of or in connection with such Registration Statement or any and all amendments thereto, whether such amendments are filed before or after the effective date of such Registration Statement; and each of the undersigned hereby ratifies and confirms all that such attorney and agent shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on , 2023.

Signature	Title
Yang Lu	Chief Executive Officer, Chairman of Board of Directors
Hui Shao	Director
Yuan Sun	Director
Yuan Tian	Director
Shuqing Wu	Director
Lars Erik Birgerson	President, Chief Medical Officer, Chief Executive Officer of U.S. Subsidiary
Kaiyang Tang	Senior Vice President, Global Head of Clinical Operations

Signature	Title
Wei (Vicky) Zhang	Chief Financial Officer
Victoria Elizabeth Demby	Senior Vice President, Global Head of Regulatory Affairs

SIGNATURE OF AUTHORIZED REPRESENTATIVE IN THE UNITED STATES

Pursuant to the Securities Act of 1933, the undersigned, the duly authorized representative in the United States of Adlai Nortye Ltd. has signed this registration statement or amendment thereto in on , 2023.

Authorized U.S. Representative

By: _____

Name:
Title:

Exhibit 10.4

Certain confidential information contained in this document, marked by brackets as [***], has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed. In addition, certain personally identifiable information contained in this document, marked by brackets as [***], has been omitted from this exhibit pursuant to Item 601(a)(6) under Regulation S-K.

EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement (this **"Agreement"**) is entered into as of January 19, 2018 (the **"Effective Date"**), between Adlai Nortye Biopharma Co., Ltd., a company organized and existing under the laws of People's Republic of China, whose principal place of business is located at No. 452, 6th Street, Hangzhou Eco. & Tech. Development Zone, Zhejiang, P. R. China (**"Adlai Nortye"**)

and

Eisai Co., Ltd., a Japanese corporation having a principal place of business at 4-6-10 Koishikawa, Bunkyo-ku, Tokyo 112-8088, Japan ("**Eisai**").

RECITALS

A. Eisai is engaged in research, clinical development and commercialization of oncology compounds, which is currently developing the Compound (as defined below).

B. Adlai Nortye evaluated the Compound utilizing data contributed by Eisai.

C. Adlai Nortye and its Affiliates desire to obtain an exclusive license under the Eisai Intellectual Property (defined below) to exclusively develop the Compound in the Field pursuant to this Agreement.

D. Eisai is willing to grant to Adlai Nortye an exclusive license under the Eisai Intellectual Property to develop the Compound in the Field subject to the conditions set forth in, and pursuant to, this Agreement.

AGREEMENT

In consideration of the mutual covenants set forth in this Agreement, Adlai Nortye and Eisai hereby agree as follows.

ARTICLE 1
Definitions and Rules of Construction

The definitions and rules of constructions set forth below shall apply throughout this Agreement.

Section 1.1 Definitions.

"Adverse Event" has the meaning set forth in the Applicable Law for such term (or comparable term), and will generally mean any untoward medical occurrence in a subject in any Clinical Trial who has received a Product, medical device or placebo, and that does not necessarily have a causal relationship with such Product, medical device or placebo, including any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of the applicable Product, whether or not related to such Product.

"Affiliate" means, with respect to a Person, any Person that is controlled by, controls, or is under common control with such first Person, as the case may be. For purposes of this definition, the term "control" means (a) direct or indirect ownership of fifty percent (50%) or more of the voting interest in the entity in question, or fifty percent (50%) or more interest in the income of the entity in question; *provided*, *however*, that if local Law requires a minimum percentage of local ownership of less than fifty percent (50%), control will be established by direct or indirect beneficial ownership of one hundred percent (100%) of the maximum ownership percentage that may, under such local Law, be owned by foreign interests, or (b) possession, directly or indirectly, of the power to direct or cause the direction of management or policies of the entity in question (whether through ownership of securities or other ownership interests, by contract or otherwise), or (c) member of the group constructed under a VIE (variable interest entities) structure for the purposes of US public listing as commonly adopted by Chinese companies when going public in the US.

"**Annual Net Sales**" means, on a Product-by-Product basis, total Net Sales by the Selling Parties in the Territory of such Product in a particular Calendar Year.

"Applicable Laws" means all applicable common law, statutes, ordinances, rules, regulations, guidances and orders of any Governmental Authority, including Regulatory Laws.

"Business Day" means a day on which banking institutions in both Tokyo, Japan and Hangzhou, P. R. China are open for business, excluding any Saturday or Sunday.

"Calendar Quarter" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 or December 31, during the Term, or the applicable part thereof during the first or last calendar quarter of the Term.

"Calendar Year" means any calendar year ending on December 31, or the applicable part thereof during the first or last year of the Term.

"Change of Control" means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party which results in the stockholders or equity holders of such Party or any Parent Corporation not owning at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, or (b) except in the case of a bona fide equity or debt financings, whether private or public, in which a Party issues new shares of its capital stock or securities convertible into shares of such Party, a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Party or Parent Corporation or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's business to which the subject matter of this Agreement relates.

"Clinical Trials" means a human clinical study conducted on sufficient numbers of human subjects that is designed to (a) establish that a pharmaceutical product is reasonably safe for continued testing; (b) investigate the safety and efficacy of the pharmaceutical product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with the pharmaceutical product in the dosage range to be prescribed; or (c) support Regulatory Approval of such pharmaceutical product or label expansion of such pharmaceutical product.

"Clinical Trial Application/Clinical Trial Notification" or "CTA/CTN" means an application filed or to be filed with a Regulatory Authority for purposes of requesting the ability to start or continue a clinical trial.

"Combination Product" means a Product that contains one or more additional active ingredients (whether co-formulated or co-packaged) that are neither the Compound nor generic or other non-proprietary compositions of matter equivalents.

"Commercialization" means any and all activities of marketing, promoting, distributing, offering for sale or selling the Product in the Field in the Territory, including, for example, marketing, branding, pricing, distribution, sales, obtaining health insurance reimbursement and formulary coverage, market research, business analytics, pharmacovigilance and medical affairs activities, pre-commercial launch market development activities conducted in anticipation of Regulatory Approval to sell or market the Product, seeking pricing and reimbursement approvals for the Product (if applicable), preparing advertising and promotional materials, sales force training, and all interactions and correspondence with a Regulatory Authority regarding Clinical Trials commenced following Regulatory Approval. When used as a verb, "Commercialize" means to engage in Commercialization.

"Commercially Reasonable Efforts" means the use of reasonable, diligent, good faith efforts and resources, as normally used by such Party for a product discovered or identified internally by such Party, which product is at a similar stage in its development or product life and is of similar market potential, taking into account efficacy, safety, patent and regulatory exclusivity, anticipated or approved labelling, present and future market potential, competitive market conditions, the profitability of the product in light of pricing and reimbursement issues, and other relevant factors.

"Competitive Product" means, other than the Product, any pharmaceutical product having a primary mechanism of action (or in the case of a combination product, any component of such combination product having as its primary mechanism of action) through acting as an antagonist of EP4, whether currently marketed or in development, that is labeled, advertised, marketed, promoted or intended for similar use in the Field except for pharmaceutical products, whether currently marketed or in development, that is labeled, advertised, marketed, promoted or intended for central nervous system CNS indication other than brain cancer.

"Compound" means the compound commonly referred to as E7046, a small molecule antagonist of EP4, as more specifically described on **Schedule 3**, and including therapeutically-active variants.

"Control" or **"Controlled"** means, with respect to any intellectual property right, information, documents or materials of a Party (or, as described below, a Future Acquirer), that such Party or its Affiliates, or a Future Acquirer, (a) owns or has a license to such intellectual property right, information, documents or materials (other than pursuant to this Agreement); and (b) has the ability to grant access, a license or a sublicense to such intellectual property right, information, documents or materials to the other Party as provided in this Agreement without violating an agreement with or other rights of any Third Party, provided that any intellectual property Controlled by a Future Acquirer of a Party shall not be treated as "Controlled" by such Party for purposes of this Agreement, except to the extent that, and only to the extent that, such intellectual property (i) is actually used by such Party or its Affiliates, or the Future Acquirer, to Develop, Manufacture or Commercialize the Product after the Future Acquirer qualifies as such; or (ii) comes under the Control of such Future Acquirer due to reference or access by such Future Acquirer to, or use by such Future Acquirer of, intellectual property of such Party. Notwithstanding the foregoing, with respect to any intellectual property acquired after the Effective Date for which a Party will be required to make payments to any Third Party in connection with the access, licenses and sublicenses granted to the other Party under this Agreement, such intellectual property shall not be treated as "Controlled" by the licensing Party except to the extent that, and only to the extent that and for so long as, the other Party agrees and does promptly pay to the licensing Party all such payments arising out of the grant of the license to the other Party (as mutually agreed between the Parties in good faith).

"Cover", **"Covering"** or **"Covered"** means, with respect to a claim of a Patent and a Product, that the manufacture, use, offer for sale, sale or importation of the Product would infringe a Valid Claim of such Patent in the country in which such activity occurred, but for the licenses granted in this Agreement (or ownership thereof).

"Damages" means all claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney's fees), or judgments, whether for money or equitable relief, of any kind and is not limited to matters asserted by Third Parties against a Party, but includes claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney's fees) or judgments incurred or sustained by a Party in the absence of Third Party claims; provided that no Party shall be liable to hold harmless or indemnify the applicable indemnified party, as applicable, for any claims, threatened claims, damages, losses, suits, proceedings, liabilities, costs or judgments for punitive or exemplary damages, except to the extent the Party seeking indemnification is actually liable to a Third Party for such punitive or exemplary damages in connection with a claim by such Third Party.

"Data" shall mean all data and information generated, collected or filed, in relation to research and development activities relating to the Product in the Field in the Territory, including toxicology data, pharmacological data, biomarker data, bioanalytical data, non-clinical reports, clinical reports, single patient clinical report forms, data points and the databases, and stability data, chemical data, quality control data (excluding the closed portion of any drug master file), adverse event and pharmacovigilance data, marketing data, pharmaco-economic data, branding and naming research reports, and all CMC data (including CMC (chemistry, manufacturing and control) development reports).

"Development" means all activities related to research, preclinical testing, clinical development efforts, test method development and stability testing, assay development, toxicology, formulation, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical pharmacology, clinical studies (including Clinical Trials) and clinical study regulatory activities, seeking Regulatory Approval and otherwise handling regulatory affairs, statistical analysis and report writing with respect to the Product. Development shall not include Manufacturing or Commercialization. When used as a verb, "Develop" means to engage in Development.

"Development Plan" means the development plan governing the series of Clinical Trials and other Development activities (if needed) to be conducted by Adlai Nortye with respect to the Compound, the initial draft of which is attached to this Agreement as **Exhibit A**, as may be amended from time to time by the JDC pursuant to Section 3.1.

"Eisai Intellectual Property" means Eisai Patents and Eisai Know-How.

"Eisai Know-How" means Know-How owned or Controlled by Eisai or its Affiliates as of the Effective Date or during the Term of this Agreement that is necessary or useful to Develop, Manufacture, or Commercialize the Product in the Field in the Territory.

"Eisai Patents" means the Product-Specific Patents.

"EMA" means the European Medicines Agency, and any successor entity thereto.

"FDA" means the United States Food and Drug Administration (or any successor agency having the administrative authority to grant Regulatory Approval in the United States).

"Field" shall mean as of the Effective Date, any and all preventative, therapeutic and/or diagnostic uses in humans.

"Field Action" means any action by a Party that meets the criteria of "recall," "correction," or "removal" or similar field or customer action as defined by applicable Regulatory Law, including where any event, incident or circumstance has occurred that may result in the need for a recall from the market, market suspension or market withdrawal of the Product by a Party in the Territory.

"First Commercial Sale" means, with respect to a Product and any country in the Territory, the first sale of such Product under this Agreement by a Selling Party or a sub-licensee for use in the Field to a Third Party in such country, after such Product has been granted Regulatory Approval for distribution, marketing and sale (in each case to the extent required by Applicable Laws) in the Field by the competent Regulatory Authorities in such country. For avoidance of doubt, First Commercial Sales exclude transfers or dispositions of a Product for charitable, promotional (including samples), pre-clinical, clinical or regulatory purposes.

"Force Majeure" means any war, revolution, civil commotion, act of terrorism, blockade, epidemic, embargo, labor strike or lock-out, scarcity of raw materials, flood, fire, earthquake, tsunami, nuclear disaster, unforeseen change in Applicable Law or similar event that is beyond the reasonable control of the Party affected.

"Future Acquirer" means the Third Party to any Change of Control transaction and any of such Third Party's Affiliates.

"Generic Product" means, other than the Product, any pharmaceutical product (i) that contains the Compound as an active ingredient(s) (including an active moiety) as such approved Product; (ii) is approved for use in such country pursuant to (a) Article 10.1 of Directive 2001/83/EC of the European Parliament and Council of 6 November 2001, or any enabling legislation thereof, or any amended or successor abbreviated route of approval, or (b) any Laws or abbreviated routes of approval in any other countries worldwide that are comparable to those described above; and (iii) is sold in the same country as such Product by any Third Party that is not a sublicensee of Adlai Nortye or its Affiliates and did not purchase such product in a chain of distribution that included any of Adlai Nortye or any of its Affiliates or its sublicensees. A pharmaceutical product that is AB-rated or comparably rated in any jurisdiction outside the United States to the applicable Product shall be a Competitive Product with respect to such Product in such country.

"Good Clinical Practices" or **"GCP"** means the then-current ethical and scientific quality standards for designing, conducting, recording, and reporting trials that involve the participation of human subjects as are required by applicable Regulatory Authorities or Law in the relevant jurisdiction. In the United States, GCP shall be based on Good Clinical Practices established through FDA guidances (including Guideline for Good Clinical Practice – ICH Harmonized Tripartite Guideline (ICH E6)), and, outside the United States, GCP shall be based on Guideline for Good Clinical Practice – ICH Harmonized Tripartite Guideline (ICH E6), as each may be amended and/or updated from time to time.

"Good Laboratory Practices" or **"GLP"** means the then-current good laboratory practice standards promulgated or endorsed by the FDA, as defined in U.S. 21 C.F.R. Part 58 (or such other comparable regulatory standards in jurisdictions outside the United States, as they may be amended and/or updated from time to time).

"Good Manufacturing Practices" or **"GMP"** means all applicable then-current standards relating to manufacturing practices for fine chemicals, intermediates, bulk products and/or finished pharmaceutical products, including (a) all applicable requirements detailed in the FDA's current Good Manufacturing Practices regulations, U.S. 21 C.F.R. Parts 210 and 211 and "The Rules Governing Medicinal Products in the European Community, Volume IV, Good Manufacturing Practice for Medicinal Products", as each may be amended and/or updated from time to time, and (b) all Applicable Laws promulgated by any Governmental Authority having jurisdiction over the manufacture of any Product, as applicable.

"Governmental Authority" means in any country the government entity having authority over the manufacturing, marketing, selling, pricing, reimbursement, testing, investigating or regulating of the Product, and all states or other political subdivisions thereof and supranational bodies applicable thereto, including the European Union, and all agencies, commissions, officials, courts or other instrumentalities of the foregoing.

"IFRS" means the International Financial Reporting Standards developed by the International Accounting Standards Board (IASB).

"IND" means an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct Clinical Trials filed with or submitted to a Regulatory Authority in the applicable jurisdiction in conformance with the requirements of such Regulatory Authority.

"Indication" means any human disease or condition, or sign or symptom of a human disease or condition in a particular target patient population that makes a particular treatment or procedure advisable; which needs to be specifically approved to be a part of the product label by a Regulatory Authority.

"Insolvency Event" means that the Party has (a) commenced a voluntary proceeding under any insolvency law, or (b) had an involuntary proceeding commenced against it under any insolvency law which has continued undismissed or unstayed for [***] days, or (c) had a receiver, trustee or similar official appointed for it or for any substantial part of its property, or (d) made a general assignment for the benefit of creditors, or (e) had an order for relief entered with respect to it by a court of competent jurisdiction under any insolvency law. For purposes hereof, the term "insolvency law" means any applicable bankruptcy, insolvency or other similar law now or hereafter in effect.

"Inventions" means any process, method, composition of matter, article of manufacture, discovery, improvement or finding that is discovered, generated or invented (whether patentable or not) in the course of activities performed under this Agreement.

"Joint Intellectual Property" means the Joint Know-How and the Joint Patents, and all intellectual property rights therein.

"Joint Know-How" means any Know-How that is conceived or developed or, in the case of Patentable Know-How, including any Inventions, jointly by one or more employees of Eisai or its Affiliates (or a Third Party acting on any of their behalf) and one or more employees of Adlai Nortye or its Affiliates (or a Third Party acting on any of their behalf) in the course of such Person's performance of activities in connection with this Agreement.

"Joint Patent" means any Patent that Covers Joint Know-How.

"Know-How" means (a) any research information (including trade secrets, inventions (whether patentable or not), methods, knowledge, skill, experience, data, results (including pharmacological, toxicological and clinical test data and results, chemical structures, sequences, processes, formulae, techniques, research data, reports, standard operating procedures and batch records), analytical and quality control data, analytical methods (including applicable reference standards), full batch documentation, packaging records, release, stability, storage and shelf-life data, and manufacturing process information, results or descriptions, software and algorithm and (b) tangible manifestations thereof. As used in this Agreement, "clinical test data" shall include all information related to clinical or non-clinical testing, including patient report forms, investigators' reports, biostatistical, pharmaco-economic and other related analyses, regulatory filings and communications, and the like.

"Knowledge" means knowledge after reasonable due inquiry with respect to the applicable facts and information of the employees of each of the Parties and their Affiliates.

"Major Country" means the countries listed hereto on **Schedule 1**.

"Manufacture" or **"Manufacturing"** means all operations necessary or appropriate to make, test, release, package, store, label, supply and ship a Product, in accordance with applicable packaging, controls industry standards, GMPs, Applicable Laws, and the Product's specifications.

"Marketing Authorization Application" or **"MAA"** shall mean an application for Regulatory Approval to market a product in any country, except the USA.

"NDA" means a **"**New Drug Application**"**, as defined in the United States Federal Food, Drug, and Cosmetic Act, as amended, and applicable regulations promulgated thereunder by the FDA and all amendments and supplements thereto filed with the FDA, or the equivalent application filed with any Regulatory Authority, including all documents, data, and other information concerning Product, which are necessary for gaining Regulatory Approval to market and sell Product in the relevant jurisdiction.

"Net Sales" means, on a country-by-country and Product-by-Product basis in the Field in the Territory, with respect to any period for each country, the gross amounts invoiced by Adlai Nortye, its Affiliates (each, a **"Selling Party"**), as applicable, to unrelated Third Parties for sales of a Product in the Field in such country, less the following deductions to the extent included in the gross invoiced sales price for such Product or otherwise directly paid, incurred, allowed, accrued or specifically allocated by the Selling Parties with respect to the sale of such Product in such country: (a) discounts, including trade, quantity or cash discounts, credits, adjustments or allowances, including those granted on account of price adjustments, billing errors, rejected goods, or damaged goods, which discounts are applied on a basis consistent with the selling Person's practices with respect to the selling Person's other pharmaceutical products; (b) rebates and chargebacks allowed, given or accrued (including cash, governmental and managed care rebates, hospital or other buying group chargebacks, cash and non-cash coupons, retroactive price reductions, and governmental taxes in the nature of a rebate based on usage levels or sales of such Product); (c) sales, excise, turnover, inventory, value-added, import, export, excise (including annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48) and other comparable laws) and other taxes levied on, absorbed, determined or imposed with respect to the sale of such Product (excluding income or net profit taxes or franchise taxes of any kind); (d) freight and insurance charges, customs charges, postage, shipping, handling, REMS compliance costs and other transportation costs incurred in shipping such Product; (e) amounts paid or credited to customers for inventory management services; (f) the portion of any management fees paid during the relevant time period to group purchasing organizations, wholesalers and managed care organizations to the extent determined by sales or utilization of such Product; (g) other reductions or specifically identifiable amounts deducted for reasons similar to these listed above in accordance with the Accounting Standards; (h) any amounts recorded in gross revenue associated with goods provided to customers for free; (i) delayed ship order credits, discounts or payments related to the impact of price increases between purchase and shipping dates or retroactive price reductions; (j) any payment in respect of sales to a Governmental Authority in the PRC, any province government or any foreign government, or to any other Governmental Authority, or with respect to any government-subsidized program or managed care organization to the extent treated as a revenue deduction to arrive at Net Sales as reported externally under the Accounting Standards. Net Sales will be determined in accordance with IFRS or US GAAP. Without limiting the generality of the foregoing, transfers or dispositions of a Product for charitable, promotional (including samples), pre-clinical, clinical, or regulatory purposes will be excluded from Net Sales, as will sales or transfers of a Product among the Selling Parties.

Subject to the above deductions, Net Sales shall be deemed to occur on, and only on, the first sale by a Selling Party or sub-licensee to a non-sublicensee Third Party. If non-monetary consideration is received by a Selling Party or sub-licensee for the Product in the relevant country, Net Sales will be calculated based on the average price charged for such Product, as applicable, during the preceding period, or in the absence of such sales, the fair market value of the Product, as applicable, as determined by the Parties in good faith.

If a Product is sold as part of a Combination Product, Net Sales will be the product of (i) Net Sales of the Combination Product calculated as above (i.e., calculated as for a non-Combination Product) and (ii) the fraction (A/(A+B)), where:

"A" is the gross invoice price in such country of the Product comprising the Compound as the sole therapeutically active ingredient; and

"B" is the gross invoice price in such country of the other therapeutically active ingredients contained in the Combination Product.

If "A" or "B" cannot be determined by reference to non-Combination Product sales as described above, then Net Sales will be calculated as above, but the gross invoice price in the above equation shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining the same that takes into account, in the applicable country, variation in dosage units and the relative fair market value of each therapeutically active ingredient in the Combination Product.

"Order" means any award, injunction, judgment, decree, order, ruling, verdict or other decision issued, promulgated or entered by or with any Governmental Authority of competent jurisdiction.

"Out-of-Pocket Costs" means, with respect to certain activities hereunder, direct expenses paid or payable by either Party or its Affiliates to Third Parties (other than employees of such Party or its Affiliates) that are specifically identifiable and incurred to conduct such activities for the Product hereunder and have been recorded in accordance with either U.S. generally accepted accounting principles or International Financial Reporting Standards, as designated and used by the applicable Party in preparing its financial statements from time to time.

"Parent Corporation" means any Person which owns, directly or indirectly, at least fifty percent (50%) of the outstanding voting securities of any Party.

"Party" means Eisai and/or Adlai Nortye, as the context requires.

"Patent" means any and all (a) patent applications filed under Applicable Laws in any jurisdiction, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon; (b) all patents, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates or the equivalent thereof; and (c) any other form of government-issued right substantially similar to any of the foregoing.

"Person" means any individual or entity (including partnerships, corporations, limited liability companies, trusts and Governmental Authorities).

"Phase 1 Clinical Trial" means (a) both a Phase 1a Clinical Trial and a Phase 1b Clinical Trial, or (b) a single trial that may contain elements of both a Phase 1a Clinical Trial and a Phase 1b Clinical Trial.

"Phase 1a Clinical Trial" means a human clinical trial of a compound, the principal purpose of which is a preliminary determination of safety, pharmacokinetics, and pharmacodynamic parameters in healthy individuals or patients, as described in 21 C.F.R. 312.21(a), or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.

"Phase 1b Clinical Trial" means a human clinical trial of a compound, the principal purpose of which is a further determination of safety and pharmacokinetics (including exploration of trends of a biomarker-based or clinical endpoint-based efficacy relationship to dose which are not designed to be statistically significant) of the compound whether or not in combination with concomitant treatment after an initial Phase 1a Clinical Trial, prior to commencement of Phase 2 Clinical Trials or Phase 3 Clinical Trials, and which provides (itself or together with other available data) sufficient evidence of safety to be included in filings for a Phase 2 Clinical Trial or a Phase 3 Clinical Trial with Regulatory Authorities, or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.

"Phase 2 Clinical Trial" means a human clinical trial of a product in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(b) and is intended to explore a variety of doses, dose response, and duration of effect, and to generate evidence of clinical safety and effectiveness for a particular Indication or Indications in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

"Phase 3 Clinical Trial" means a human clinical trial of a product in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(c) and is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

"Pivotal Clinical Trial" means a human clinical trial of a product on a sufficient number of subjects that, prior to commencement of the trial or during its course, satisfies both of the following ((a) and (b)):

(a) such trial is designed to establish that such product has an acceptable safety and efficacy profile for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such product in the dosage range to be prescribed, which trial is intended to support Regulatory Approval of such product, or a similar clinical study prescribed by the U.S. or EMA; and

(b) such trial is a registration trial sufficient for filing an application for a Regulatory Approval for such product in the U.S. or the EMA, as evidenced by (i) an agreement with or statement from the FDA or the EMA on a Special Protocol Assessment or equivalent, or (ii) other guidance or minutes issued by the FDA or EMA, for such registration trial.

"Product" means all preparations, compositions and formulations of the Compound, together with all current and future formulations, versions, compositions and presentations of product, together with any improvements or modifications, that use the Compound as its active pharmaceutical ingredient alone or in combination with other therapeutically or prophylactically active pharmaceutical ingredients as part of a Combination Product.

"Product-Specific Patents" means those Patents listed on **Schedule 2** attached hereto under the heading "Product-Specific Patents" as well as any Patent, , owned or Controlled by Eisai or its Affiliates as of the Effective Date and during the Term that: (a)(i) claims or Covers any Eisai Know-How and/or (ii) is otherwise necessary or useful to Develop, Manufacture or Commercialize the Product in the Field in the Territory, and (b) specifically describes or references a Product or exploitation of a Product in the Field.

"Product Complaint" means any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, delivery, effectiveness or performance of the Product after it is released by Adlai Nortye for distribution.

"Proprietary Information" means a Party's trade secrets, know-how, business plans, manufacturing processes, clinical strategies, product specifications, scientific data, market analyses, formulae, designs, training manuals and other non-public information (whether business, financial, commercial, scientific, clinical, regulatory or otherwise) that the Party treats as proprietary and uses Commercially Reasonable Efforts to protect.

"Prosecute" or **"Prosecution"** means, with respect to Patents, the preparation of, filing for, prosecuting, responding to oppositions, nullity actions, re-examinations, revocation actions and similar proceedings (including conducting or participating in interference, oppositions, reissue proceedings, reexaminations, post-grant proceedings and any other similar proceeding relating thereto) filed by Third Parties against, and maintaining, Patents.

"Regulatory Approval" means the approval and authorization of a Regulatory Authority in a country or regulatory jurisdiction necessary to develop, manufacture, distribute, sell or market a pharmaceutical product in that country or regulatory jurisdiction. Regulatory Approval shall include pricing and reimbursement approval in any country or regulatory jurisdiction in the Territory.

"Regulatory Authority" means, with respect to any country or jurisdiction, any Governmental Authority involved in granting Regulatory Approval or in administering Regulatory Laws in that country or jurisdiction.

"Regulatory Documentation" shall mean all applications, registrations, licenses, authorizations, approvals (including all Regulatory Approvals), and correspondence (registration and licenses, pricing and reimbursement correspondence, regulatory drug lists, advertising and promotion documents) submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents in connection therewith, and all non-clinical, preclinical trials and Clinical Trials, tests and biostudies, relating to the use of the Product in the Field, or as required for regulatory purposes (including all Regulatory Approvals) and all Data contained in any of the foregoing, including all INDs, NDAs and Regulatory Approvals, regulatory drug lists, advertising and promotion documents, manufacturing data and records, drug master files, inspection reports, Data from Clinical Trials, adverse event files and complaint files, in each case related to the Product in the Field, or as required for regulatory purposes.

"Regulatory Laws" means all Applicable Laws governing the import, export, testing, investigation, manufacture, marketing or sale of a product, or establishing recordkeeping or reporting obligations for Product Complaints or Adverse Events, or relating to Field Actions or similar regulatory matters.

"Right of Reference or Use" means a "Right of Reference or Use" as that term is defined in 21 C.F.R. §314.3(b), and any non-United States equivalents.

"Royalty Term" means, on a Product-by-Product and country-by-country basis, the period of time commencing on the First Commercial Sale of any Product in such country and continuing for so long as such Product is sold in such country during the Term. expiring on the latest of (a) expiration of the last Valid Claim of any and all Eisai Patents, Adlai Nortye Patents and Joint Patents Covering such Product in such country, (b) the tenth (10^{th}) anniversary of the date of First Commercial Sale of such Product in such country and (c) expiration of the regulatory exclusivity of such Product in such country; provided that, with respect to a Product being Commercialized in the US and the Major Countries, the Royalty Term shall continue in both the US and the Major Countries until expiration of the last Valid Claim of any and all Eisai Patents, Adlai Nortye Patents and Joint Patents Covering such Product in the US and each of the countries in the Major Countries.

"Territory" means [***]

"Third Party" means any Person other than the Parties and their Affiliates.

"US" or **"United States"** means the United States of America.

"US GAAP" means the generally accepted accounting principles as adopted by the AICPA (American Institute of Public Accountants).

"Valid Claim" means, with respect to a particular country, (a) a claim of a pending Patent claiming priority from any Patent that has been pending for no more than five (5) years following the earliest priority filing date for such Patent and that has not been abandoned, finally rejected or expired without the possibility of appeal or refiling or (b) a claim of an issued and unexpired Patent and that has not been held permanently revoked, held unenforceable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, which decision is unappealed or unappealable within the time allowed for appeal and has not been cancelled, withdrawn, abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, in the case of (a) and (b) above, which claims the composition of matter or method of use of a Product in the Field. For clarity, a claim of a Patent that ceased to be a Valid Claim before it issued because it had been pending too long, but subsequently issued and is otherwise described by clause (a) of the foregoing sentence shall again be considered to be a Valid Claim once it issues. A Product is "Covered" by a Valid Claim if its registration, manufacture, use, sale, offer for sale, marketing, Commercialization, distribution, importation or exportation by Adlai Nortye in a given country in the Territory would, but for the rights granted by Eisai to Adlai Nortye under this Agreement, infringe such Valid Claim.

Section 1.2 Terms Defined Elsewhere in this Agreement.

Capitalized terms defined in other provisions of this Agreement shall have the meanings specified therein. Those terms include the following:

Term	Section
Adlai Nortye	Preamble
Adlai Nortye Indemnified Parties	Section 10.1(a)
Adlai Nortye Know-How	Section 9.1(b)
Adlai Nortye Patents	Section 9.1(b)
Adlai Nortye Technology	Section 9.1(b)
Agreement	Preamble
Auditee	Section 13.2(e)
Audit Rights Holder	Section 13.2(e)
Audit Team	Section 13.2(a)
Challenge	Section 14.2(d)
Clinical Quality Agreement	Section 3.6(c)
Confidential Information	Section 12.1(a)
Development Milestone Events	Section 7.3(b)
Dispute	Section 15.3
Effective Date	Preamble
Eisai	Preamble
Eisai Indemnified Parties	Section 10.2(a)
Eisai Option	Section 6.1
Eisai Option Notice	Section 6.1
ICC	Section 15.3
Inventory	Section 3.6(d)
JDC	Section 3.1(a)
Option Exclusivity Period	Section 6.1
Option Period	Section 6.1
Recovery	Section 9.4
Rules	Section 15.3
Sales Milestone Events	Section 7.3(a)
Term	Section 14.1
Third Party Claim	Section 10.1(a)

Section 1.3 Rules of Construction.

(a) **Elements of this Agreement**. When a reference is made in this Agreement to a Recital, an Article, a Section, a Schedule, an Attachment or an Exhibit, such reference is to a Recital, Article or Section of, or a Schedule, Attachment or Exhibit to, this Agreement, unless otherwise indicated.

(b) **Meaning of "Include" and Variations Thereof**. Whenever the words "include," "includes" or "including" are used in this Agreement, they shall be understood to be followed by the words "without limitation."

(c) **Use of Pronouns**. Pronouns, including "he," "she" and "it," when used in reference to any person, shall be deemed applicable to entities or individuals, male or female, as appropriate in any given case.

(d) **Headings**. Article, Section and other headings contained in this Agreement are for reference purposes only and are not intended to describe, interpret, define or limit the scope, extent or intent of any provision of this Agreement.

(e) **Variations on Terms.** Standard variations on defined terms (such as the plural form of a term defined in the singular form, and the past tense of a term defined in the present tense) shall be deemed to have meanings that correlate to the meanings of the defined terms.

(f) **Currency References.** All references to "dollars" or "$" shall be deemed to be references to the lawful currency of the United States.

ARTICLE 2
Grant of Rights; Diligence

Section 2.1 Grant of Eisai Intellectual Property and Retention of Rights.

(a) During the Term, subject to the terms and conditions of this Agreement, Eisai, on behalf of itself and its Affiliates, hereby grants to Adlai Nortye and Adlai Nortye's Affiliates an exclusive (even as to Eisai), royalty-bearing right and license under the Eisai Intellectual Property to Develop, make, have made, store, use, sell, have sold, import, export and otherwise Commercialize Products in the Field in the Territory. For clarity, in the foregoing sentence, "exclusive" means that neither Eisai nor its Affiliates shall, for its or their own account, and shall not grant to any Third Party the right and license under the Eisai Intellectual Property to, Develop, make, have made, store, use, sell, have sold, import, export and otherwise Commercialize Products in the Field in the Territory but allows that Eisai or its Affiliates shall subcontract with Third Parties in the Territory on the Manufacture for supply outside the Territory.

(b) Eisai, on behalf of itself and its Affiliates, hereby grants Adlai Nortye and Adlai Nortye's Affiliates a Right of Reference or Use to all Data and Regulatory Documentation (including all Regulatory Approvals) related to the Product owned or Controlled by Eisai or its Affiliates as of the Effective Date and during the Term for all uses in connection with the Product for Development, Manufacturing and Commercialization in the Field in the Territory.

Section 2.2 Grant of Adlai Nortye Technology and Retention of Rights.

(a) During the Term, subject to the terms and conditions of this Agreement, Adlai Nortye, on behalf of itself and its Affiliates, hereby grants to Eisai and Eisai's Affiliates an exclusive (even as to Adlai Nortye), right and license under the Adlai Nortye Technology to Develop, make, have made, store, use, sell, have sold, import, export and otherwise Commercialize Products outside the Territory. For clarity, in the foregoing sentence, "exclusive" means that neither Adlai Nortye nor its Affiliates shall, for its or their own account, and shall not grant to any Third Party the right and license under the Adlai Nortye Technology to, Develop, make, have made, store, outside the Territory.

(b) Adlai Nortye, on behalf of itself and its Affiliates, hereby grants Eisai and Eisai's Affiliates a Right of Reference or Use to all Data and Regulatory Documentation (including all Regulatory Approvals) related to the Product owned or Controlled by Adlai Nortye or its Affiliates during the Term for all uses in connection with the Product for Development, Manufacturing and Commercialization, in each case, solely for use outside the Territory.

Section 2.3 Sublicenses.

(a) Adlai Nortye shall have the right to grant sublicenses with respect to Adlai Nortye's rights and obligations under this Agreement to (i) any Affiliates of Adlai Nortye. Before the consideration of sub-license to any party which is not an Affiliate of Adlai Nortye, Adlai Nortye shall grant to Eisai the first right of refusal to sub-license Adlai Nortye's rights and obligations in the Product on terms which shall have been offered by any Third Party. Adlai Nortye shall give notice to Eisai of their intent to engage in a sub-license transaction and Eisai shall have [***] days to meet the terms of the agreement and enter into a sub-license agreement with Adlai Nortye. If Eisai provides written confirmation that it is not interested in such a sub-license, then Adlai Nortye shall have the right to grant sublicenses with respect to Adlai Nortye's rights and obligations under this Agreement to Third Parties pursuant to Article 6; *provided* that, with respect to sublicenses granted to Third Parties, subject to Article 6, (x) Adlai Nortye provides Eisai with written notice of such sublicense promptly after the grant of such sublicense, which notice shall not be required for rights granted to distributors, wholesalers or marketing agents, (y) such sublicense shall be in writing and shall be consistent with the applicable terms and conditions of this Agreement, and (z) Adlai Nortye shall remain responsible for performance of this Agreement.

(b) Should this Agreement terminate for any reason, Eisai shall have the right but not the obligation to grant such sublicensee under Section 2.3(a) a direct license to the Eisai Intellectual Property in the Territory and the Field.

(c) Eisai shall have the right to grant sublicenses with respect to the license and rights granted pursuant to Section 2.2 under this Agreement to (i) any Affiliates of Eisai and (ii) Third Parties, in each of (i) and (ii), solely in connection with carrying out the activities set forth in Section 2.2; *provided* that, with respect to sublicenses granted to Third Parties hereunder (x) Eisai provides Adlai Nortye with written notice of such sublicense promptly after the grant of such sublicense, which notice shall not be required for rights granted to distributors, wholesalers or marketing agents, (y) such sublicense shall be in writing and shall be consistent with the applicable terms and conditions of this Agreement, and (z) Eisai shall remain responsible for its obligations under this Agreement.

(d) Should this Agreement terminate for any reason, Adlai Nortye shall have the right but not the obligation to grant such sublicensee under Section 2.3(c) a direct license to the Adlai Nortye Technology in the Territory and outside the Field.

Section 2.4 Rights to Inventions. Adlai Nortye, its Affiliates and permitted sublicensees shall have the right to make Inventions involving the Eisai Intellectual Property, and to utilize such Inventions to develop, make, have made, store, use, sell, have sold, import, export and otherwise commercialize Products in the Field in the Territory. Eisai, its Affiliates and permitted sublicensees shall have the right to make Inventions involving the Adlai Nortye Technology, and to utilize such Inventions to develop, make, have made, store, use, sell, have sold, import, export and otherwise commercialize Products, in each case, solely for use of the Product in the Field outside the Territory; provided, that any such Inventions shall be deemed included in the Eisai Intellectual Property licensed to Adlai Nortye hereunder.

ARTICLE 3
Product Development.

Section 3.1 Governance.

(a) Within thirty (30) days after the Effective Date, Eisai and Adlai Nortye will establish a joint development committee (the **"JDC"**) to implement and oversee Development activities in the Field in the Territory pursuant to the Development Plan leading to regulatory approval and commercialization of the Product across all intended indications in the Major Countries in the Territory, and will serve as a forum for exchanging data, information and Development, regulatory and commercialisation strategy regarding the Product. The JDC will comprise of three (3) representatives (or such other number of representatives as the Parties may agree) from each of Eisai and Adlai Nortye. Each representative of a Party shall have sufficient seniority and expertise in the biotechnology and pharmaceutical industry to participate on the JDC. Each Party may replace any or all of its representatives on the JDC at any time upon written notice to the other in accordance with Section 15.6 of this Agreement. Adlai Nortye shall designate a chairperson (the "Chairperson") to oversee the operation of the JDC.

(b) The JDC shall meet at least once a half year (or more frequently as the Parties deem necessary) in person or by video or telephone conference. Meetings of the JDC that are held in person shall alternate between the offices of Eisai and Adlai Nortye., or at such other place as the Parties may agree. Each Party will bear its own costs for travel, accommodation and the like in relation to attending such meetings. The specific timing and location of the JDC meetings will be determined by the Chairperson (provided, that such meetings shall only be held on dates as such Parties mutually agree). An agenda shall be agreed upon by the JDC members and be distributed to the Parties by Adlai Nortye no less than ten (10) Business Days before any meeting. Adlai Nortye shall be responsible for creating the meeting minutes. Each Party shall use reasonable efforts to cause its representatives to attend the meetings of the JDC, provided that Adlai Nortye's representative must be present at each meeting. Each JDC representative shall have one (1) vote on the JDC.

(c) The JDC will be responsible for (i) implementing, overseeing and amending the Development Plan and regulatory strategy for the Product in the Field in the Territory, including determining whether to amend the Development Plan (ii) attempting to resolve disputes arising under this Agreement with respect to Development and Commercialization activities, (and (iii) performing such other Development and Commercialization functions set forth in this Agreement.

(d) Except as otherwise set forth in this Agreement, all decisions of the JDC shall be made by a simple majority vote (consisting of more than fifty percent (50%) of the votes cast), with each representative having one (1) vote. If the JDC cannot, after good faith efforts, agree on a matter for which the JDC has decision-making authority within fifteen (15) Business Days after it has met and attempted to reach such decision, then such matter must be elevated to the Chief Clinical Officer, Oncology Business Group for Eisai and the Chief Executive Officer for Adlai Nortye for attempted resolution through good faith efforts (which shall include at least one discussion in person, by video or telephone conference) during a period of five (5) Business Days (or longer period upon mutual agreement of such senior officers in writing), and if after such five (5) Business Day period (or such mutually agreed to longer period) such matter is still unresolved, then, subject to Section 3.1(d), the Chairperson shall have the controlling vote and decision unless such matter involves an amendment of the Development Plan.

Section 3.2 Development. Subject to ARTICLE 3, Adlai Nortye and its Affiliates and/or sublicensees shall be solely responsible for the Development of Products in the Field in the Territory, and shall use Commercially Reasonable Efforts to complete the Development Plan and submit for Regulatory Approval in all Major Countries. Subject to the terms and conditions of this Agreement, Adlai Nortye shall bear one hundred percent (100%) of all costs and expenses associated with the Development of Products. Adlai Nortye shall provide a summary report to Eisai, through its representatives on the JDC, on a quarterly basis regarding its Development activities that Adlai Nortye and/or its Affiliates undertake in the preceding Calendar Quarter in accordance with this Section 3.

Section 3.3 Transfer.

(a) Within [***] days after the Effective Date, Eisai shall disclose and provide to Adlai Nortye the data and information set forth in Schedule 4 and which shall include all tangible embodiments of data and information concerning the Eisai Intellectual Property and Regulatory Documentation (including without limitation (a) all safety data for the Product and (b) by providing reasonable assistance with respect to the transfer of ownership, control and sponsorship, as applicable, of any INDs/CTAs relating to the Product), as well as preclinical and clinical data, manufacturing and CMC data, in its Control as of the Effective Date critical to, necessary or useful for developing, making, using or selling Products in the Territory.

(b) Adlai Nortye shall obligate to take over Clinical Trials, which have not been concluded on the Effective Date, provided Adlai Norte shall have an option to cease any such Clinical Trials in strict accordance with the Regulatory Laws. For the avoidance of the doubt, the expense on or after the Effective Date for such ongoing Clinical Trails shall be borne by Adlai Norte.

Section 3.4 Assistance. During the Term, Eisai will cooperate with Adlai Nortye to provide reasonable assistance requested by Adlai Nortye to facilitate the transfer of Development, Manufacture and Commercialization responsibilities to Adlai Nortye as required under this Agreement, including providing reasonable assistance with respect to regulatory and Manufacturing transition matters related to Product, and continuing the transfer to Adlai Nortye of the data and information concerning the Eisai Intellectual Property (and related Regulatory Documentation) licensed to Adlai Nortye under Section 2.1. Such cooperation will include providing Adlai Nortye with reasonable access by teleconference or in-person to Eisai personnel involved in the research, Development and Manufacture of Product. [***]

Section 3.5 Pharmacovigilance. Adlai Nortye will deploy and administer any safety monitoring activity implemented for the Product in the Territory, and be responsible for all pharmacovigilance activities for the Product in the Territory. In addition:

(a) Eisai shall cooperate with Adlai Nortye and share information concerning the pharmaceutical safety of Product. Eisai shall promptly advise Adlai Nortye of any information that comes to its knowledge that may affect the safety, effectiveness or labelling of such Product and any actions taken in response to such information.

(b) Adlai Nortye shall be solely responsible for reporting all adverse drug experiences associated with Product in the Territory, and for establishing, holding and maintaining the global safety database for Product. Eisai shall provide Adlai Nortye with all Product complaints, adverse event information and safety data from clinical studies that are in its possession and control and that are necessary or desirable for Adlai Nortye to comply with all Applicable Laws with respect to the Product.

Notwithstanding the foregoing, within [***] days following Eisai's written notice to Adlai Nortye that it intends to conduct clinical activities with respect to the Product as permitted under this Agreement, the Parties shall enter into a reasonable and customary written pharmacovigilance agreement (the "PV Agreement") governing each Party's obligations with respect to reporting to the other Party and appropriate Regulatory Authorities adverse events, complaints, and other safety-related matters with respect to the Product.

Section 3.6 Manufacturing and Supply.

(a) Manufacturing. Adlai Nortye shall be solely responsible for sourcing the Manufacturing and supplying of Product in the Territory and shall be entitled to identify and manage Third Party contract manufacturers, as well as lead all supply chain management and quality control activities.

(b) Supply to Adlai Nortye. Notwithstanding this Section 3.6 (a), Eisai shall supply the Product to Adlai Nortye for [***] years from the Effective Date, and Adlai Nortye shall purchase all the Product which Adlai Nortye orders Eisai to supply. Parties shall in good faith negotiate and enter into a clinical supply agreement pursuant to which Eisai would Manufacture and supply to Adlai Nortye such quantity of Product as shall be reasonably requested by Adlai Nortye in writing in order to conduct Development activities. Such clinical supply agreement shall: (i) provide that Eisai shall Manufacture such Product in accordance with cGMP and other Law and the applicable specifications therefor, and shall deliver such Product to Adlai Nortye's, or its designee's, location as specified by Adlai Nortye with DAP (Incoterms 2010); (ii) provide that Adlai Nortye shall pay [***] Eisai's documented cost of goods for the Manufacture of such Product (iii) provide that Eisai shall invoice Adlai Nortye for the applicable purchase price promptly after delivery, and Adlai Nortye shall pay such invoice not later than [***] thereof; and (iv) contain other reasonable and customary clinical supply terms including provisions addressing forecasting and ordering, delivery, payment, acceptance and rejection procedures, regulatory assistance, warranties, indemnification, limitations of liability and quality assurance and control.

(c) *Clinical Quality Agreement*. Within [***] days from the Effective Date, the Parties shall enter into a quality agreement that shall address and govern issues related to the quality of Product to be supplied by the Parties for use in such Clinical Trials ("**Clinical Quality Agreement**"). In the event of any inconsistency between the terms of this Agreement and a given Clinical Quality Agreement, the terms of this Agreement shall control. The Clinical Quality Agreement shall, among other things: (i) detail classification of any Product found to have a non-conformance; (ii) include criteria for Manufacturer's release and related certificates and documentation; (iii) include criteria and timeframes for acceptance of the Product; (iv) include procedures for the resolution of disputes regarding any Product found to have a non-conformance; and (v) include provisions governing the recall of Product.

(d) Inventory. Eisai hereby agrees to sell to Adlai Nortye, at Adlai Nortye's written request as set forth below, such quantities of drug substance for Product hereunder held by Eisai on the Effective Date (including raw materials, intermediates, and finished, unfinished, or partially finished goods) in the Territory (the "**Inventory**"). At any time until [***] months after the Effective Date, Adlai Nortye shall have the right to make requests for deliveries of all or a portion of the Inventory. Eisai shall deliver such Inventory to Adlai Nortye within [***] days of Adlai Nortye's request and Adlai Nortye shall, within [***] days of receipt of any such Inventory which it requested from Eisai, pay to Eisai an amount equivalent to [***] set forth in Schedule 3.6 for such requested and delivered Inventory, which U.S. Dollar value Eisai confirms is equal to Eisai's documented cost of goods for the Manufacture of such Product incurred with respect to the Manufacturing of such drug substance (as reflected in the carrying value of this inventory in Eisai's financial statements) and cost of transportation of the Inventory.

Section 3.7 **No Other Rights**. Eisai and Adlai Nortye each acknowledges and agrees that, except as expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party. All rights with respect to technology, Patents or other Intellectual Property Rights that are not specifically granted herein are reserved.

Section 3.8 **Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement, including amendments hereto, are, for all purposes of 11 U.S.C. § 365(n), licenses of rights to intellectual property as defined in the United States Bankruptcy Code, and any comparable Law of a relevant jurisdiction. Each Party may elect to retain and may fully exercise all of its rights and elections under 11 U.S.C. § 365(n). The Parties further agree that, in the event of the commencement a bankruptcy proceeding by or against a Party under the Enterprise Bankruptcy Law of People's Republic of China, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to such other Party and all embodiments of such intellectual property, which, if not already in such other Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon written request therefor, unless the Party subject to bankruptcy proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement by the Party upon written request therefor by Adlai Nortye.

Section 3.9 **No Representation**. Subject to the foregoing obligation to use Commercially Reasonable Efforts, neither Party makes any representation, warranty or guarantee that the Product will be successful, or that any other particular results will be achieved with respect to the Product hereunder.

ARTICLE 4
Commercialization Activities.

Section 4.1 **Commercialization Responsibilities**. Subject to Article 6, Adlai Nortye shall use Commercially Reasonable Efforts to obtain Regulatory Approval for the Product in the Major Countries and to maximize the total amount of net sales in the Major Countries and globally. Subject to the terms and conditions of this Agreement, Adlai Nortye will be responsible, at its own cost, for all Commercialization activities for the Product in the Field in the Territory where Regulatory Approval is expected to be or has been obtained, including all costs and expenses relating thereto. Within [***] days after the end of each Calendar Quarter beginning with the Calendar Year in which the First Commercial Sale is made in a country following receipt of Regulatory Approval in such country, Adlai Nortye shall deliver to Eisai a report setting forth for the previous Calendar Quarter Adlai Nortye's and its Affiliates' gross sales and Net Sales in the Territory on a country-by-country basis. Adlai Nortye shall have sole discretion to establish the pricing and other terms and conditions of sale of the Product to its customers.

ARTICLE 5
Non-Compete.

Section 5.1 **Non-Compete**. Neither Party nor its Affiliates shall, at any time during the Term, either on its own behalf or through any Affiliate or Third Party, directly or indirectly make, market, promote, sell, offer for sale, import, export or otherwise Commercialize any (a) Competitive Product in the Field, or (b) any other formulations of the Compound, or in-license or otherwise acquire any product that is a Competitive Product or other formulation of the Compound, in the Field anywhere in the Territory.

ARTICLE 6
Option to Re-Acquire

Section 6.1 **Eisai Option to Re-Acquire.** For the period of time commencing with enrollment of the first five (5) patients in a Phase 3 Clinical Trial for the Product pursuant to the Development Plan and ending [***] days following the completion of such Phase 3 Clinical Trial (the "**Option Period**"), Eisai shall have the option to notify Adlai Nortye in writing (the "**Eisai Option Notice**") that it is interested in re-acquiring the rights to Develop, Manufacture and Commercialize the Product in the Field in the Territory from Adlai Nortye and its Affiliates (the "**Eisai Option**"). Following receipt by Adlai Nortye of the Eisai Option Notice, the Parties will negotiate in good faith on an exclusive basis, for up to [***] days (unless otherwise agreed by the Parties) the terms of Eisai exercising the Eisai Option at a fair market value, which value shall take into consideration the value of the Development activities performed by Adlai Nortye, its Affiliates and sublicensees pursuant to the Development Plan, any Data, Know-How, Inventions or Patents related to the Product and any applicable drug substance for Product held by Adlai Nortye (including raw materials, intermediates, and finished, unfinished, or partially finished goods, or otherwise) (the "**Option Exclusivity Period**").

ARTICLE 7
Payments

Section 7.1 **Upfront Payment.** In consideration of the rights granted to Adlai Nortye under this Agreement, Adlai Nortye shall pay to Eisai a one-time, non-refundable and non-creditable payment of [***] U.S. Dollars ($[***]) no later than [***] after the Effective Date.

Section 7.2 **Royalties.**

(a) Product Royalties. Adlai Nortye shall pay Eisai royalties on Annual Net Sales equal to the following portions of Annual Net Sales multiplied by the applicable royalty rate for such portion during the applicable Royalty Term for each such Product in accordance with Section 7.2(a):

Annual Net Sales	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Each Royalty Rate set forth in the table above will apply only to that portion of the Annual Net Sales of Product in the Territory during a given Calendar Year that falls within the indicated range.

For example, if Annual Net Sales of Product in the Territory by Adlai Nortye, its Affiliates and sublicensees was [***], then the royalties payable with respect to such Annual Net Sales, subject to adjustment as set forth in this Section 7.2(a), would be:

[***]

(b) Payment of Royalties. Adlai Nortye shall: (a) within [***] days following the end of each Calendar Quarter in which a royalty payment accrues, provide to Eisai a report for each country in the Territory in which sales of Product occurred in the Calendar Quarter covered by such statement, specifying for such Calendar Quarter: the number of Product units sold; the gross sales and Annual Net Sales in each country's currency; the applicable royalty rate under this Agreement; the royalties payable in each country's currency, including an accounting of deductions taken in the calculation of Annual Net Sales in accordance with Adlai Nortye's normal practices used to prepare its audited financial statements for internal and external reporting purposes; the applicable exchange rate to convert from each country's currency to U.S. Dollars under Section 7.5; and the royalty calculation and royalties payable in U.S. Dollars, and (b) make the royalty payments owed to Eisai hereunder in accordance with such royalty report in arrears, within [***] days from the end of each Calendar Quarter in which such payment accrues.

Section 7.3 Milestones; Survival. Adlai Nortye shall pay Eisai the applicable milestones set forth in this Section 7.3. For each of Sections 7.3(a) and (b) of this Agreement, the Parties understand and agree that in no event will more than one (1) milestone payment be paid with respect to any specific event triggering a payment under this Agreement.

(a) Sales Milestones. Adlai Nortye shall make the sales milestone payments to Eisai that are set forth below upon the first achievement of the sales milestone events ("**Sales Milestone Events**") set forth below with respect to the Net Sales of Products in a rolling 12 month achieves such event. For clarity, each milestone set forth below shall be due and payable one time only

Milestone Number	Sales Milestone Event	Milestone Payments (in $ millions)
1	[***]	[***]
2	[***]	[***]
3	[***]	[***]
4	[***]	[***]

(b) Development Milestones. Adlai Nortye shall make the following development milestone payments to Eisai that are set forth below upon the first achievement by or on behalf of Adlai Nortye, its Affiliates or sublicensees of the Development milestone events ("**Development Milestone Events**") set forth below with respect to the first Product in the Field that achieves such event in the Field. For clarity, each milestone set forth below shall be due and payable one time only (regardless of the number of Products or Indications to achieve any such Development Milestone Event). For additional clarity, when certain milestones do not occur as part of the Development Plan, such milestones shall become due and payable once the subsequent milestone is reached.

Milestone Number	Development Milestone Event (For the first Product that achieves such event)	Milestone Payments (in $ millions)
1	[***]	[***]
2	[***]	[***]
3	[***]	[***]
4	[***]	[***]

Milestone Number	Development Milestone Event (For the first Product that achieves such event)	Milestone Payments (in $ millions)
5	[***]	[***]
6	[***]	[***]
7	[***]	[***]
8	[***]	[***]

[***]

Section 7.4 Sublicense Remuneration Payment Terms.

Adlai Nortye shall remunerate Eisai equal to the following portions of any financial compensation which the sublicensee pays to Adlai Nortye under the sublicense agreement pursuant to Section 2.3.

Sublicense conclusion date	Remuneration Rate (of total compensation)
[***]	[***]
[***]	[***]

Section 7.5 Additional Payment Terms.

(a) Accounting. All payments hereunder shall be made in the United States in U.S. Dollars by wire transfer to a bank to be designated in writing by Eisai. Conversion of sales recorded in local currencies to Dollars shall be performed in a manner consistent with Adlai Nortye's normal practices used to prepare its audited financial statements for internal and external reporting purposes.

(b) Late Payments. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at an annual rate equal to the lesser of: (a) [***] above the prime rate as published [***], or any successor thereto, at [***] in which such payments are overdue or (b) the maximum rate permitted by Applicable Law; in each case calculated on the number of days such payment is delinquent, compounded [***].

Section 7.6 Currency Conversion. All amounts payable and calculations under this Agreement will be in U.S. Dollars. As applicable, Net Sales and any Milestone Payments will be translated into U.S. Dollars based on the Oanda foreign currency exchange rate (Oanda.com) for the applicable currencies on the last business Friday of the month (in accordance with IFRS). If, due to restrictions or prohibitions imposed by national or international authority, a given payment cannot be made as provided in this Section 7.6, the Parties will consult with a view to finding a prompt and acceptable solution. If the Parties are unable to identify a mutually acceptable solution regarding such payment, then Adlai Nortye may elect, in its sole discretion, to deliver such payment in the relevant jurisdiction and in the local currency of the relevant jurisdiction.

Section 7.7 Taxes. Adlai Nortye may withhold from payment made to Eisai under this Agreement any income tax required to be withheld by Adlai Nortye under the laws of the country or jurisdiction where Adlai Nortye has commercially sold Products. If any tax is withheld by Adlai Nortye, Adlai Nortye shall provide Eisai receipts or other evidence of such withholding and payment to the appropriate tax authorities on a timely basis following that tax payment. Each Party agrees to cooperate with the other Party in claiming refunds or exemptions from such deductions or withholdings under any relevant agreement or treaty which is in effect. The Parties shall discuss applicable mechanisms for minimizing such taxes to the extent possible in compliance with Applicable Law. In addition, the Parties shall cooperate in accordance with Applicable Law to minimize indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes) in connection with this Agreement.

ARTICLE 8
Regulatory Matters

Section 8.1 Compliance with Laws. Each Party shall comply in all material respects with all Applicable Laws, including all Regulatory Laws, that pertain to its activities under this Agreement and, except as otherwise provided herein, each Party shall bear its own cost and expense of such compliance.

Section 8.2 Regulatory Approval. In seeking any Regulatory Approval in the Territory, Adlai Nortye shall have primary responsibility for all communications, submissions and interactions with Regulatory Authorities, including serving as sponsor of any required investigational new drug or device applications or exemptions and preparing and submitting the application for Regulatory Approval. Adlai Nortye shall bear all costs and expenses of obtaining such Regulatory Approval. Adlai Nortye shall maintain such approval throughout the Term (and bear all associated costs and expenses). Adlai Nortye shall own all and be responsible for preparing, filing and maintaining all regulatory filings and Regulatory Approval that are required for the Development, Manufacture, use, or Commercialization of the Product in the Field in the Territory, provided that: (i) Adlai Nortye shall provide Eisai with copies of material regulatory submissions to, and material communications with, any Governmental Authority in the Territory and Eisai shall have the right to review and comment on such submissions and communications, and (ii) Adlai Nortye shall take such actions and otherwise cooperate with Eisai as may be reasonably requested by Eisai to enable Eisai to perform activities assigned to Eisai under this Agreement or to Develop the Product outside the Territory.

ARTICLE 9
Intellectual Property

Section 9.1 Ownership of Intellectual Property.

(a) Inventorship. Inventorship of Inventions shall be determined by application of U.S. patent law pertaining to inventorship.

(b) Adlai Nortye. As between the Parties, Adlai Nortye will be the sole owner of any Inventions and intellectual property rights therein that are discovered, developed, invented or created solely by Adlai Nortye, its Affiliates or Third Parties acting on its or its Affiliates' behalf while conducting activities under this Agreement (such Inventions and intellectual property rights, "**Adlai Nortye Know-How**") and any Patents that claim such Adlai Nortye Know-How ("**Adlai Nortye Patents**" and, together with the Adlai Nortye Know-How, the "**Adlai Nortye Technology**"), and will retain all of its rights, title and interest thereto.

(c) Joint Intellectual Property. Any Joint Intellectual Property will be owned jointly by Adlai Nortye and Eisai on an equal and undivided basis, including all rights, title and interest thereto, subject to any assignment, rights or licenses expressly granted by one Party to the other Party under this Agreement. Except as expressly provided in this Agreement, neither Party will have any obligation to account to the other for profits with respect to, or to obtain any consent of the other Party to license or exploit, Joint Intellectual Property by reason of joint ownership thereof, and each Party hereby waives any right it may have under the laws of any jurisdiction to require any such consent or accounting. At the reasonable written request of a Party, the other Party will in writing confirm that no such accounting is required to effect the foregoing regarding Joint Intellectual Property. To the extent necessary in any jurisdiction to effect the foregoing, each Party hereby grants to the other Party a non-exclusive, royalty-free, fully-paid, worldwide license, with the right to grant sublicenses, to practice such Joint Intellectual Property for any and all purposes, subject to any licenses granted by one Party to the other under this Agreement.

(d) Cooperation. The determination of whether Know-How and inventions claimed in Patents that are conceived, discovered, developed or otherwise made or reduced to practice by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, will, for purposes of this Agreement, be made in accordance with Applicable Law in the United States. In the event that United States law does not apply to the conception, discovery, development, making or reduction to practice of any Know-How or Patents hereunder, each Party will, and does hereby, assign, and will cause its Affiliates to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Know-How and Patents as well as any intellectual property rights with respect thereto, as is necessary to fully effect ownership as would have been determined under U.S. law unless otherwise provided in this Article 9.

Section 9.2 Patent Filings, Prosecution and Maintenance of Eisai Intellectual Property and any Joint Intellectual Property.

(a) The Parties agree to cooperate in the Prosecution of all Patents under this Section 9.2, including obtaining and executing necessary powers of attorney and assignments by the named inventors, providing relevant technical reports to the filing Party concerning the invention disclosed in such Patents and Patent applications, obtaining execution of such other documents which are needed in the Prosecution of such Patents and Patent applications, and shall cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to obtain or maintain such Patents and Patent applications.

(b) On a country-by-country basis, the Parties understand and agree that Eisai shall have the right (but not the obligation) to Prosecute any Eisai Patents in such country, at Eisai's expense, and shall control any interferences, oppositions, reissue proceedings, reexaminations, post-grant proceedings and any other similar proceeding relating thereto, in each such country in the Territory. Eisai shall inform and consult with Adlai Nortye regarding the Prosecution of all such Eisai Patents sufficiently in advance of any deadline for taking any substantive action in connection therewith to permit meaningful consultation, and shall give due consideration to any of Adlai Nortye's suggestions, recommendations or requests with respect to such filing or strategies. Each Party shall pay for its own costs with respect to any consultation hereunder.

(c) Adlai Nortye shall have the first right (but not the obligation) to Prosecute any Patents for any Joint Intellectual Property, in both Parties' names, and to control any interferences, oppositions, reissue proceedings, reexaminations, post-grant proceedings and any other similar proceeding relating thereto, in the Territory; provided that the costs of such Prosecution shall be borne equally by the Parties. Adlai Nortye shall inform and consult with Eisai regarding the Prosecution of all such Joint Intellectual Property sufficiently in advance of any deadline for taking any substantive action in connection therewith to permit meaningful consultation, and shall give due consideration to any of Eisai's suggestions or recommendations (including reasonable requests in connection with Eisai's strategy for the Product outside the Field). Each Party shall pay for its own costs with respect to this consultation.

(d) If Adlai Nortye elects in any country not to Prosecute, or elects to abandon any Joint Intellectual Property or declines to control any related interference, opposition, reissue proceeding, reexamination, post-grant proceeding and similar proceeding, Adlai Nortye shall give Eisai reasonable written notice to this effect sufficiently in advance (but in any event no later than at least sixty (60) days prior to the date upon which the subject matter of such Joint Patent shall become unpatentable or such Joint Patent shall lapse or become abandoned) to permit Eisai, in its sole discretion and expense, to undertake such Prosecution, or to control such interferences, oppositions, reissue proceedings, reexaminations, post-grant proceedings and similar proceeding, without a loss of rights. If Eisai does so elect, then Adlai Nortye shall provide such cooperation to Eisai, including the execution and filing of appropriate instruments, as may reasonably be requested to facilitate the transition of such Joint Patent activities, and shall assign all of its right, title and interest to such Joint Patents, other than its rights thereto provided by this Agreement, to Eisai electing to pursue such Joint Patent activities. For clarity, Eisai shall have the right, in its sole discretion, to abandon such Patent at any time after it takes control pursuant to this Section 9.2(d).

(e) Each Party agrees to cooperate with the other with respect to the Prosecution of Joint Intellectual Property and related interferences, oppositions, reissue proceedings, reexaminations, post-grant proceedings and similar proceeding thereof. If required under Applicable Law in order for the prosecuting Party to control such interferences, oppositions, reissue proceedings, reexaminations, post-grant proceedings and similar proceeding relating to the Joint Intellectual Property, the other Party shall join as a party to such interferences, oppositions, reissue proceedings, reexaminations, post-grant proceedings and similar proceeding.

Section 9.3 Extensions of Patent Term for Products.

Eisai shall have the sole right, but not the obligation, to seek patent term extensions, adjustments, restorations, or supplementary protection certificates under Applicable Law with respect to Eisai Patents for the Product in the Territory; it being understood and agreed that, if Eisai seeks a patent term extension, then Adlai Nortye agrees to cooperate with respect to any measures required by Applicable Law for Eisai to obtain such extension. Eisai, its agents and attorneys will give due consideration to all suggestions and comments of Adlai Nortye regarding any such activities, including the choice of which Patent to apply term extensions to, but in the event or a disagreement between the Parties, Eisai shall have the final decision making authority. For clarity, (a) any such extended Patent will remain included in the definition of Valid Claim for purposes of extending the Term and (b) Eisai shall have the right, in its sole discretion, to abandon such Patent at any time.

Section 9.4 Enforcement of Eisai Intellectual Property and Joint Intellectual Property.

(a) If either Party learns of any infringement or violation by a Third Party of any Eisai Intellectual Property or Joint Intellectual Property in the Territory, whether or not within the Field, it shall notify the other Party as soon as practicable. Thereafter, (a) Adlai Nortye shall have the sole right (but not the obligation), at its own cost to take the appropriate steps to enforce or defend any Joint Intellectual Property, as applicable, against Third Parties and (b) Eisai shall have the sole right (but not the obligation) at its own cost to take the appropriate steps to enforce or defend any Eisai Patents in the Field against Third Parties. Any settlements, damages or other monetary awards relating to such infringement or violation by a Third Party of any Eisai Intellectual Property and/or Joint Intellectual Property (a **"Recovery"**) recovered by either Party will be forwarded to Adlai Nortye (if not then previously paid to Adlai Nortye) and any such Recovery pursuant to a suit, action or proceeding brought pursuant to this Section 9.4(a) will be allocated first to the costs and expenses of the enforcing or defending Party, and second, all remaining Recoveries shall be deemed to be Net Sales.

(b) If either Party brings any suit, action or proceeding under this Section 9.4, the other Party agrees to be joined as party plaintiff if necessary to prosecute the suit, action or proceeding and to give the prosecuting Party reasonable authority to file and prosecute the suit, action or proceeding; provided, however, that neither will be required to transfer any right, title or interest in or to any property to the other in order to confer standing on the prosecuting Party hereunder. The non-prosecuting Party will provide reasonable assistance to the prosecuting Party including by providing access to relevant documents and other evidence and making its employees available, subject to the prosecuting Party's reimbursement of any reasonable Out-of-Pocket Costs incurred by the non-prosecuting Party in providing such assistance.

Section 9.5 Enforcement of Adlai Nortye Technology. If either Party learns of any infringement or violation by a Third Party of any Adlai Nortye Technology in the Territory, it shall notify the other Party as soon as practicable. Thereafter, Adlai Nortye shall have the sole right to (a) enforce all Adlai Nortye Technology against Third Parties and (b) any settlements, damages or other monetary awards recovered pursuant to a suit, action or proceeding brought pursuant to this Section 9.5.

Section 9.6 Defense of Infringement Claims of Eisai Intellectual Property and Joint Intellectual Property. If any Third Party asserts a claim, demand, action, suit or proceeding against a Party (or any of its Affiliates), alleging that any Product, the use or practice of the Eisai Intellectual Property or the Joint Intellectual Property infringes, misappropriates or violates the intellectual property rights of any Person (any such claim, demand, action, suit or proceeding being referred to as an "Infringement Claim"), the Party first having notice of the Infringement Claim shall promptly notify the other Party thereof in writing specifying the facts, to the extent known, in reasonable detail. With respect to any Infringement Claim in the Field in the Territory, the Parties shall negotiate in good faith a resolution with respect thereto. If settlement is deemed an appropriate resolution and the Parties cannot settle such Infringement Claim with the Third Party within thirty (30) days after receipt of the notice pursuant to the notice pursuant to this Section 9.6, then subject to indemnification requirements of ARTICLE 10, the following shall apply:

(a) In the case of any such Infringement Claim against either Party individually or against both Adlai Nortye and Eisai, in each case, with respect to the Product in the Field in the Territory, then Adlai Nortye shall assume control of the defense of such Infringement Claim. Eisai, upon request of Adlai Nortye and if required by Applicable Law, agrees to join in any such litigation at Adlai Nortye's expense, and in any event to reasonably cooperate with Adlai Nortye at Adlai Nortye's expense. Eisai will have the right to consult with Adlai Nortye concerning such Infringement Claim and to participate in and be represented by independent counsel in any litigation in which Eisai is a party, at its own expense. Adlai Nortye shall have the exclusive right to settle any Infringement Claim against Adlai Nortye alone or both Parties without the consent of Eisai, unless such settlement shall have a material adverse impact on Eisai (in which case the consent of Eisai shall be required). Adlai Nortye shall fully consider and use reasonable efforts to accommodate Eisai's global intellectual property litigation positions in all such decisions with respect to any such defense or settlement that may impact such global positions. If (a) Adlai Nortye elects (in a written communication submitted to Eisai within a reasonable amount of time after notice of the alleged patent infringement) not to defend or control the defense of, or otherwise fails to initiate and maintain the defense of, any such claim, suit or proceeding, within such time periods so that Eisai is not prejudiced by any delays, Eisai shall have the right (but not the obligation) to control the defense of such Infringement Claim, and Adlai Nortye upon request of Eisai and if required by Applicable Law, agrees to join in any such litigation at Eisai's expense.

(b) If either Party individually shall control of the defense of any such Infringement Claim described in this Section 9.6, the other Party shall cooperate, and shall cause its and its Affiliates' employees to cooperate, with the controlling Party in all reasonable respects in connection therewith, including giving testimony and producing documents lawfully requested, and using its reasonable efforts to make available to the controlling Party, at the controlling Party's cost, such employees who may be helpful with respect to such suit, investigation, claim or other proceeding.

(c) Neither Party, nor its Affiliates, nor its or their employees, agents or independent contractors, shall be liable to the other Party or any of its Affiliates in respect of any good faith act, omission, default, or neglect of such Party, any of its Affiliates, or its or their employees, agents or independent contractors in connection with the Prosecution of Eisai Intellectual Property, Adlai Nortye Technology or Joint Intellectual Property.

ARTICLE 10 Indemnification

ARTICLE 10 shall survive the expiration or termination of this Agreement.

Section 10.1 Indemnification by Eisai.

(a) **Scope**. Eisai shall indemnify and hold harmless Adlai Nortye and its Affiliates and their respective, directors, officers, employees and agents (collectively, the **"Adlai Nortye Indemnified Parties"**) from and against any and all Damages, arising out of or resulting from any claim, demand, action, suit or proceeding by a Third Party (collectively, a **"Third Party Claim"**) based upon or arising from: (i) any breach by Eisai of any of its representations, warranties or obligations under this Agreement; (ii) any actual violation by Eisai or any of its Affiliates or licensees or sublicensees (other than Adlai Nortye) of Applicable Laws or any Development of the Product outside of the Field in the Territory or Commercialization of the Product in or outside the Field in the Territory by Eisai or any of its Affiliates or licensees or sublicensees (other than Adlai Nortye) on, prior to or after the Effective Date; or (iii) any willful act or omission of Eisai or its Affiliates or subcontractors or any of their respective employees or agents relating to the activities in connection with this Agreement.

(b) **Defense.** Adlai Nortye shall give Eisai prompt written notice of any Third Party Claim with respect to which Eisai's indemnification obligations apply, but any delay or failure of such notice shall not excuse Eisai's indemnification obligations except to the extent that Eisai's legal position is actually and materially prejudiced thereby. Eisai shall have the right to assume and control the defense and settlement of any Third Party Claim; provided, however, that following conditions must be satisfied: (i) Eisai must provide to Adlai Nortye written acknowledgement to Adlai Nortye of Eisai's obligation to indemnify Adlai Nortye hereunder against Damages that may result from the Third Party Claim, and (ii) Adlai Nortye shall not have given Eisai written notice that it has determined, in the exercise of its reasonable discretion based on the advice of counsel, that a conflict of interest makes separate representation by Adlai Nortye's own counsel advisable, (iii) the Third Party Claim does not include damages other than monetary damages for which indemnity hereunder is available, (iv) the Third Party Claim does not relate to or arise in connection with any criminal proceeding, action, indictment, criminal allegation or investigation, and (v) if requested by Adlai Nortye, Eisai has reasonably demonstrated Eisai's financial ability to pay for the defense of such Third Party Claim and to satisfy the full amount of any Damages that may result from such Third Party Claim. Adlai Nortye shall have the right to participate in the defense of the Third Party Claim at its own expense, but in any event shall cooperate with Eisai in the investigation and defense of the Third Party Claim.

(c) **Settlement.** If Eisai is entitled to, and does, assume and control the defense and settlement of any Third Party Claim with respect to which its indemnification obligations apply, then Eisai shall not settle such Claim without Adlai Nortye's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed), unless (i) the sole relief provided in such settlement is monetary in nature and shall be paid in full by Eisai and (ii) such settlement does not include any finding or admission of a violation by Adlai Nortye, its Affiliates or sublicensees of any Applicable Laws or Third Party's rights.

Section 10.2 Indemnification by Adlai Nortye.

(a) **Scope.** Adlai Nortye shall indemnify and hold harmless Eisai and its Affiliates and their respective directors, officers, employees and agents (collectively, the "**Eisai Indemnified Parties**") from and against any and all Damages in connection with any Third Party Claim based upon or arising from: (i) any breach by Adlai Nortye or any of its Affiliates of any of Adlai Nortye's representations, warranties or obligations under this Agreement; (ii) any actual violation by Adlai Nortye or any of its Affiliates of Applicable Laws; (iii) any willful act or omission of Adlai Nortye or its Affiliates or any of their respective employees or agents relating to the activities in connection with this Agreement; or (iv) any exploitation by Adlai Nortye and its Affiliates of the Product.

(b) **Defense.** Eisai shall give Adlai Nortye prompt written notice of any Third Party Claim with respect to which Adlai Nortye's indemnification obligations apply, but any delay or failure of such notice shall not excuse Adlai Nortye's indemnification obligations except to the extent that Adlai Nortye's legal position is actually and materially prejudiced thereby. Adlai Nortye shall have the right to assume and control the defense and settlement of any such Third Party Claim; provided, however, that following conditions must be satisfied: (i) Adlai Nortye must provide to Eisai written acknowledgement to Eisai of Adlai Nortye's obligation to indemnify Eisai hereunder against Damages that may result from the Third Party Claim, and (ii) Eisai shall not have given Adlai Nortye written notice that it has determined, in the exercise of its reasonable discretion based on the advice of counsel, that a conflict of interest makes separate representation by Eisai's own counsel advisable, (iii) the Third Party Claim does not include damages other than monetary damages for which indemnity hereunder is available, (iv) the Third Party Claim does not relate to or arise in connection with any criminal proceeding, action, indictment, criminal allegation or investigation, and (v) if requested by Eisai, Adlai Nortye has reasonably demonstrated Adlai Nortye's financial ability to pay for the defense of such Third Party Claim and to satisfy the full amount of any Damages that may result from such Third Party Claim. Eisai shall have the right to participate in the defense of the Third Party Claim at its own expense, but in any event shall cooperate with Adlai Nortye in the investigation and defense of the Third Party Claim.

(c) **Settlement.** If Adlai Nortye is entitled to, and does, assume and control the defense and settlement of any Third Party Claim with respect to which its indemnification obligations apply, then Adlai Nortye shall not settle such Claim without Eisai's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed), unless (i) the sole relief provided in such settlement is monetary in nature and shall be paid in full by Adlai Nortye and (ii) such settlement does not include any finding or admission of a violation by Eisai, its Affiliates or sublicensees of any Applicable Laws or Third Party's rights.

Section 10.3 **Waiver**. Any waiver by an indemnified Party of its rights under this ARTICLE 10 must be set forth expressly and in writing in order to be effective.

Section 10.4 **Insurance**. Each Party shall maintain insurance with creditworthy insurance companies or self insure in accordance with Applicable Laws against such risks and in such amounts as are usually maintained or insured against by such Party.

Section 10.5 **Limitation of Consequential Damages**. Except for (a) Third Party Claims that are subject to indemnification under this ARTICLE 10, (b) claims arising out of a Party's willful misconduct, or (c) a Party's breach of ARTICLE 5 or ARTICLE 12 or any other confidentiality obligations under this Agreement, neither Party nor any of its Affiliates will be liable to the other Party or its Affiliates in connection with this Agreement for any incidental, consequential, special, punitive or other indirect damages or lost or imputed profits or royalties, lost data or cost of procurement of substitute goods or services, whether liability is asserted in contract, tort (including negligence and strict product liability), indemnity or contribution, and irrespective of whether that Party or any representative of that Party has been advised of, or otherwise might have anticipated the possibility of, any such loss or damage.

ARTICLE 11
Representations and Warranties

ARTICLE 11 shall survive the expiration or termination of this Agreement.

Section 11.1 **General Corporate Matters**. Each Party hereby represents and warrants to the other Party that:

(a) **Organization and Power**. It is a corporation or limited liability company duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or organization. It has all requisite power and authority to conduct its business and engage in the transactions provided for in this Agreement.

(b) **Authorization and Validity of Agreements**. The execution, delivery and performance by it of this Agreement, and the consummation by it of the transactions contemplated hereby, have been duly authorized and approved by all necessary corporate or equivalent action on its part. This Agreement has been duly executed and delivered by it and constitutes its legal, valid and binding obligation, enforceable against it in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency or other laws relating to or affecting creditors' rights generally and by general equity principles.

(c) **Absence of Conflicts**. The execution, delivery and performance by it of this Agreement, and the consummation by it of the transactions contemplated hereby, do not and will not: (i) violate any Applicable Laws; (ii) conflict with, or result in the breach of any provision of, its certificate or articles of incorporation, bylaws or equivalent organizational documents; (iii) result in the creation of any lien or encumbrance of any nature upon any property being transferred or licensed by it pursuant to this Agreement; or (iv) violate, conflict with, result in the breach or termination of, or constitute a default under (or event which, with notice, lapse of time or both, would constitute a default under), any permit, contract or agreement to which it is a party or by which any of its properties or businesses are bound.

(d) **Consents**. No authorization, consent or approval of, or notice to or filing with, any Governmental Authority is required for the execution, delivery and performance by it of this Agreement (excluding approvals of Regulatory Authorities as contemplated herein).

(e) **Affiliates**. Where this Agreement refers to an action or obligation to be undertaken by a Party's Affiliates, such Party will cause such Affiliates to undertake such obligations or other actions, and such Party will be responsible and liable for any acts or omissions by its Affiliates.

(f) **FCPA compliance**. In the course of the business, Adlai Nortye (i) shall not, directly or indirectly, make payment or offer or promise to make payment of any bribe ("Corruption") to a governmental official (including a foreign official, a person deemed to be a governmental official under the law, and a healthcare professional), a person related to a political party, or a candidate for public post, (ii) shall not engage in Corruption even in terms of private citizens other than government officials through providing entertainments or gifts deemed inappropriate under business customs, (iii) shall establish and maintain an appropriate compliance procedure to prevent its management or employees from engaging in Corruption, and (iv) shall, per Eisai's request, disclose information relevant to suspected Corruption and any other accounting books and records to Eisai, and allow an audit by Eisai, and if necessary, cooperate with investigative authorities, in the event that it is suspected that Adlai Nortye was involved in Corruption.

Section 11.2 Intellectual Property Matters. Eisai hereby represents and warrants to Adlai Nortye that, as of the Effective Date:

(a) **Ownership**. Eisai has sole and exclusive ownership of the Eisai Intellectual Property. Eisai has not granted to any Person other than Adlai Nortye a license, covenant not to sue or similar right with respect to any component of the Eisai Intellectual Property in the Field in the Territory. The Eisai Intellectual Property in the Field in the Territory are free of any lien, covenant, easement, lien, lease, sublease, option, encumbrance, security interest, mortgage, pledge or claim of any nature, including limitations on transfer or any subordination arrangement in favor of a Third Party.

(b) **Patents.** **Schedule 2** sets forth a complete and correct list of all Eisai Patents owned or otherwise Controlled by Eisai and its Affiliates, and, except as set forth on **Schedule 2**, Eisai, together with its Affiliates, is the sole and exclusive owner of, and has the sole right, title and interest in and to, the Eisai Patents listed on **Schedule 2** (as updated from time to time) and the related Know-How. To its Knowledge, the Eisai Patents are valid and enforceable and none of the Eisai Patents are currently involved in any court, administrative, interference, reissue, re-examination, cancellation or opposition proceedings, and neither Eisai nor any of its Affiliates has received any written notice from any Third Party of such actual or threatened proceedings or challenge.

(c) **No Additional IP.** To Eisai's Knowledge, there is no intellectual property right, in particular no Eisai Patents, owned by or licensed to Eisai or its Affiliates other than the Eisai Intellectual Property, that are necessary for Adlai Nortye or its Affiliates and sublicensees to Develop and Commercialize the Product as set forth herein.

(d) **Third Party Obligations.** Eisai and its Affiliate are not subject to any payment obligations to Third Parties as a result of the execution or performance of this Agreement.

(e) **Data and Information.** Eisai has furnished or made available to Adlai Nortye all material information that is in Eisai's or its Affiliates' possession concerning the Eisai Intellectual Property and Product relevant to the safety, efficacy, or CMC data thereof, and all Regulatory Documentation, Data and other correspondence with Regulatory Authorities relating to the Product, and to Eisai's Knowledge, such information is accurate, complete and true in all material respects.

(f) **Non-Infringement**. As of the Effective Date and to Eisai's Knowledge, the use, manufacture, marketing, sale, promotion, importation, distribution and commercialization of the Product in the Field in the Territory does not infringe, violate or misappropriate the intellectual property rights of any Person.

(g) **IP Claims**. As of the Effective Date, no Person has made, nor has Eisai received, any written, nor to the Knowledge of Eisai has any Person threatened, any written or oral, claim of ownership, inventorship or Patent infringement, or any other claim of intellectual property misappropriation or violation, from any Third Party (including by current or former officers, directors, employees, consultants, or personnel of Eisai or any predecessor) with respect to the Eisai Intellectual Property, or initiated a lawsuit against Eisai, in any case (i) challenging the ownership, validity or enforceability of any of the Eisai Intellectual Property in the Field in the Territory, (ii) alleging that the license, use or practice of them infringes, violates or misappropriates: (A) the intellectual property rights of any Person; or (B) the rights of any Third Party, or (iii) seeking to enjoin or restrain such use or practice. Eisai has no Knowledge that any Person intends to assert such a claim or initiate such a lawsuit, or that any Person has a valid basis to do so.

(h) **Claims.** There are no claims, litigations, suits, actions, disputes, arbitrations, or legal, administrative or other proceedings or governmental investigations pending or, to Eisai's Knowledge, threatened against Eisai, nor is Eisai a party to any judgment or settlement, which would be reasonably expected to adversely affect or restrict the ability of Eisai to consummate the transactions contemplated under this Agreement and to perform its obligations under this Agreement, or which would affect the Eisai Intellectual Property, or Eisai's Control thereof, or the Product.

(i) **Infringement by Others**. As of the Effective Date and to the Knowledge of Eisai, Eisai has no reason to believe that any Person has infringed, violated or misappropriated any of the Eisai Intellectual Property in the Field in the Territory.

Section 11.3 Eisai Covenants.

(a) Except as set forth in Section 15.12, neither Eisai nor its Affiliates will (a) assign, transfer, convey, encumber (including any liens or charges, but excluding any licenses, which are the subject of subsection (b), below) or dispose of, or enter into any agreement with any Third Party to assign, transfer, convey, encumber (including any liens or charges, but excluding any licenses, which are the subject to subsection (b), below) or dispose of, any assets specifically related to the Compound in the Field, including with respect to Products and related diagnostic products developed therefor, or pre-clinical or Clinical Trial results or other data specifically related to the Compound in the Field, or any intellectual property specifically related to any of the foregoing (the "Licensed Assets"), except to the extent such assignment, transfer, conveyance, encumbrance or disposition would not conflict with or adversely affect in any respect any of the rights granted to Adlai Nortye hereunder, (b) license or grant to any Third Party, or agree to license or grant to any Third Party, any rights to any Licensed Assets if such license or grant would conflict with or adversely affect in any respect any of the rights granted to Adlai Nortye hereunder, or (c) disclose any Confidential Information relating to the Licensed Assets to any Third Party if such disclosure would impair or conflict in any respect with any of the rights granted to Adlai Nortye hereunder.

(b) Neither Eisai nor any of its Affiliates will effect any corporate restructuring or enter into any new agreement, transfer ownership of the Eisai Intellectual Property, or Eisai's interest in the Joint Intellectual Property, or obligate itself to any Third Party, or amend an existing agreement with a Third Party, in each case, in a manner that restricts, limits, or encumbers the rights granted to Adlai Nortye under this Agreement.

(c) Eisai will update **Schedule 2** from time to time to include any Patents that are necessary or useful to Develop, Manufacture or Commercialize the Product in the Field in the Territory (including, for the avoidance of doubt, any Patents Covering Eisai's interest in any Joint Intellectual Property); provided that, regardless of Eisai's failure to update such **Schedule 2**, such Patents shall be deemed to be included in the definition of Eisai Patents.

Section 11.4 Adlai Nortye Covenants. Adlai Nortye shall perform all of its obligations under this Agreement, and shall comply in all material respects with all Applicable Laws in the exercise of its rights under this Agreement, including development, marketing, distribution and sale of the Products. Adlai Nortye's specifications for the text (including any trademarks, logos or other graphics) for all marketing material used in connection with Product, and any such marketing material for the Product provided by Adlai Nortye or its designee, shall be true and accurate in all respects, comply in all material respects with all Applicable Laws and not infringe or otherwise violate the intellectual property of any person.

ARTICLE 12
Confidentiality and Publicity

Section 12.1 Confidentiality. In the course of their activities pursuant to this Agreement, the Parties anticipate that they may disclose Confidential Information to one another and that either Party may, from time to time, be a disclosing Party or a recipient of Confidential Information. The Parties wish to protect such Confidential Information in accordance with this Section 12.1. The provisions of this Section 12.1 shall apply to disclosures furnished to or received by a Party and its agents and representatives (which may include agents and representatives of its Affiliates). Each Party shall advise its agents and representatives of the requirements of this Section 12.1 and shall be responsible to ensure their compliance with such provisions.

(a) **Definition of Confidential Information.** For purposes hereof, **"Confidential Information"** with respect to a disclosing Party means all Proprietary Information, in any form or media, concerning the disclosing Party or its Affiliates that the disclosing Party or its Affiliates furnish to the recipient, whether furnished before or after the date hereof, and all notes, analyses, compilations, studies and other materials, whether prepared by the recipient or others, that contain or reflect such Proprietary Information; provided, however, that Confidential Information does not include information that (i) is or hereafter becomes generally available to the public other than as a result of a disclosure by the recipient, (ii) was already known to the recipient prior to receipt from the disclosing Party as evidenced by prior written documents in its possession not subject to an existing confidentiality obligation to the disclosing Party, (iii) is disclosed to the recipient on a non-confidential basis by a person who is not in default of any confidentiality obligation to the disclosing Party, (iv) is independently developed by or on behalf of the recipient without reliance on the Confidential Information received hereunder, or (v) is required to be submitted to a governmental agency for the purpose of obtaining product approval, provided that the recipient will make a good faith attempt to obtain confidential treatment of the information by such agency. The contents of this Agreement shall be deemed to be Confidential Information of each Party. For clarity, Confidential Information shall not include clinical data contained in clinical reports that are not permitted under Applicable Laws to be redacted.

(b) **Treatment of Confidential Information.** The recipient of Confidential Information shall (i) use such Confidential Information solely and exclusively in connection with the discharge of its obligations under this Agreement and (ii) not disclose such Confidential Information without the prior written consent of the disclosing Party to any Person other than those of its and/or its Affiliates' agents and representatives who need to know such Confidential Information in order to accomplish the objectives for which it was disclosed. Notwithstanding the foregoing, if the recipient of Confidential Information becomes legally compelled to disclose any Confidential Information in order to comply with Applicable Laws or with an order issued by a court or regulatory body with competent jurisdiction, the recipient shall (x) provide prompt written notice to the disclosing Party so that the disclosing Party may seek a protective order or other appropriate remedy or waive its rights under this Section 12.1; and (y) disclose only the portion of Confidential Information that is legally required to furnish; provided that, in connection with such disclosure, the recipient shall use Commercially Reasonable Efforts to obtain assurance that confidential treatment will be given with respect to such Confidential Information. If any Party is required to file this Agreement with any Governmental Authority, such Party shall redact the terms of this Agreement to the extent possible in order to keep particularly sensitive provisions confidential.

(c) **Return and Destruction.** Upon the termination or expiration of this Agreement, upon the request of the disclosing Party, the recipient of Confidential Information shall promptly redeliver to the disclosing Party all Confidential Information provided to the recipient in tangible form or destroy the same and certify in writing that such destruction has occurred; provided, however, that nothing in this Agreement shall require the alteration, modification, deletion or destruction of computer backup tapes made in the ordinary course of business. All notes or other work product prepared by the recipient based upon or incorporating Confidential Information of the disclosing Party shall be destroyed, and such destruction shall be certified in writing to the disclosing Party by Adlai Nortye. Notwithstanding the foregoing, legal counsel to the recipient shall be permitted to retain in its files one copy of all Confidential Information to evidence the scope of and to enforce the Party's obligation of confidentiality under this Section 12.1.

(d) **Term of Obligation.** The obligations under this Section 12.1 shall remain in effect from the date hereof through the latter of [***] of the expiration or termination of this Agreement.

(e) **Prior Agreements**. The provisions of this Section 12.1 shall supersede and replace any prior agreements between the Parties relating to Confidential Information covered hereby, including, for the avoidance of doubt, that certain Confidentiality Agreement entered into by and between Eisai and Adlai Nortye prior to the Effective Date.

Section 12.2 Publicity. Upon or following the Effective Date, the Parties may issue the press release attached hereto as Exhibit C. Neither Party shall issue any other press release or otherwise publicize this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that consent shall not be required in connection with disclosures (a) required by Applicable Law, (b) relating to previously disclosed information, and (c) expressly authorized by Section 12.1. In the event of a required press release or other public announcement, the Party making such announcement shall provide the other Party with a copy of the proposed text prior to such announcement.

ARTICLE 13
Record-keeping and Audits

ARTICLE 13 shall survive the expiration or termination of this Agreement.

Section 13.1 Records Retention. Adlai Nortye and its Affiliates shall maintain reasonably detailed records of Net Sales, and any other information reasonably necessary for the calculation of payments to be made to Eisai pursuant to this Agreement. Adlai Nortye shall be fully responsible for its Affiliates retention obligations herein. Each Party shall maintain reasonably detailed records of any information necessary to comply with Applicable Laws or this Agreement. Adlai Nortye and its Affiliates shall maintain its sales records for at least three (3) years following the date of sale.

Section 13.2 Audit Request.

(a) **Audit Team**. Eisai may, upon request and at its expense (except as provided for herein), cause an internationally recognized independent accounting firm selected by it (except one to whom the Auditee has a reasonable objection) (the "**Audit Team**") to audit during ordinary business hours the books and records of Adlai Nortye and its affiliates and the correctness of any payment made or required to be made to or by such Party, and any report underlying such payment (or lack thereof), pursuant to the terms of this Agreement. Prior to commencing its work pursuant to this Agreement, the Audit Team shall enter into an appropriate confidentiality agreement with the Auditee obligating the Audit Team to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations set forth in Article 13.

(b) **Limitations**. In respect of each audit of the Auditee's books and records: (i) the Auditee may be audited only once per year, (ii) no records for any given year for an Auditee may be audited more than once; provided that the Auditee's records shall still be made available if such records impact another financial year which is being audited, and (iii) the Audit Rights Holder shall only be entitled to audit books and records of an Auditee from the three (3) calendar years prior to the Calendar Year in which the audit request is made.

(c) **Audit Notice**. In order to initiate an audit for a particular Calendar Year, the Audit Rights Holder must provide written notice to the Auditee. The Audit Rights Holder exercising its audit rights shall provide the Auditee with notice of one or more proposed dates of the audit not less than sixty (60) days prior to the first proposed date. The Auditee will reasonably accommodate the scheduling of such audit. The Auditee shall provide such Audit Team(s) with full and complete access to the applicable books and records and otherwise reasonably cooperate with such audit.

(d) **Payments**. If the audit shows any under-reporting or underpayment, or overcharging by any Party, that under-reporting, underpayment or overcharging shall be reported to the Audit Rights Holder and the underpaying or overcharging Party shall remit such underpayment or reimburse such overcompensation (together with interest at a rate per annum equal to the lesser of the [***] as reported by The Wall Street Journal) to the underpaid or overcharged Party within [***] days after receiving the audit report. Further, if the audit for an annual period shows an under-reporting or underpayment or an overcharge by any Party for that period in excess of [***] of the amounts properly determined, the underpaying or overcharging Party, as the case may be, shall reimburse the applicable underpaid or overcharged Audit Rights Holder conducting the audit, for its respective audit fees and reasonable Out-of-Pocket Costs in connection with said audit, which reimbursement shall be made within [***] days after receiving appropriate invoices and other support for such audit-related costs.

(e) **Definitions**. For the purposes of the audit rights described herein, an individual Party subject to an audit in any given year will be referred to as the "**Auditee**" and the other Party who has certain and respective rights to audit the books and records of the Auditee will be referred to as the "**Audit Rights Holder**."

(f) Any information received by a Party pursuant to this Section 13.2 shall be deemed to be Confidential Information for purposes of Section 12.1. Such information shall be used solely for the purpose for which the audit was conducted.

ARTICLE 14
Term and Termination

Section 14.1 Term. This Agreement shall become effective as of the Effective Date and shall continue in full force and effect on a Product-by-Product and country-by-country basis until (a) if there has not been a First Commercial Sale of a Product in the Field in such country before [***] of the Effective Date, [***] of the Effective Date, or (b) if there has been a First Commercial Sale of a Product in the Field in such country before [***] of the Effective Date, expiration of the Royalty Term for such Product in such country or group of countries as specified in the definition of "Royalty Term" herein (the "**Term**"). This Agreement may be terminated before expiration of the Term only by mutual agreement of the Parties in writing or in accordance with Section 14.2.

Section 14.2 Rights of Termination.

(a) **Termination for Material Breach**. In the event that a Party commits a material breach of its overall obligations under this Agreement in a manner that fundamentally frustrates the purpose of this Agreement (other than payment obligations), taken as a whole, and such material breach of its overall obligations is not cured within [***] days (or such other time period as mutually agreed by the Parties), or a material breach of its payment obligations under this Agreement that is not cured within [***] days, after such Party receives written notice from the non-breaching Party, which notice shall specify the nature of the breach and demand its cure, the non-breaching Party may terminate this Agreement in its entirety upon written notice to the breaching Party.

(i) Notwithstanding the foregoing, if a material breach is not susceptible to cure within the cure period specified in Section 14.2(a), the non-breaching Party's right of termination shall be suspended only if, and for so long as, (i) the breaching Party has provided to the non-breaching Party a written plan that is reasonably calculated to effect a cure, (ii) such plan is reasonably acceptable to the non-breaching Party and (iii) the breaching Party commits to and does carry out such plan; provided, however, that, unless otherwise mutually agreed by the Parties in such plan, in no event shall such suspension of the non-breaching Party's right to terminate extend beyond [***] days after the original cure period.

(ii) Notwithstanding the foregoing, if either Party is alleged to be in material breach and disputes such termination through the dispute resolution procedures set forth in this Agreement, then the other Party's right to terminate this Agreement shall be tolled for so long as such dispute resolution procedures are being pursued by the allegedly breaching Party in good faith and, if it is finally and conclusively determined that the allegedly breaching Party is in material breach, then the breaching Party shall have the right to cure such material breach after such determination within the cure period provided above in this Section 14.2(a).

(b) **Adlai Nortye Right of Termination for Safety Reasons**. Notwithstanding anything to the contrary in this Agreement, Adlai Nortye shall have the right to terminate this Agreement upon [***] days written notice in the event that:

(i) a competent Regulatory Authority in a Major Country prohibits the further clinical use of the Product in the applicable country or regulatory jurisdiction within the Territory under 21 C.F.R. § 312.44 on grounds of safety (or equivalent grounds with respect to any country or regulatory jurisdiction in the Territory outside of the United States); or

(ii) a clinical hold imposed by a competent Regulatory Authority in a Major Country relating to the Product is definitively converted to "inactive status" by such Regulatory Authority under 21 C.F.R. § 312.45 on grounds of safety (or equivalent grounds with respect to any country or regulatory jurisdiction in the Territory outside of the United States), despite Adlai Nortye's use of Commercially Reasonable Efforts to eliminate such clinical hold.

(c) **Bankruptcy**. This Agreement may be terminated by written notice by a Party at any time during the Term if the other Party shall file in any court or agency, pursuant to any statute or regulation of any state or country, a petition in bankruptcy or other Insolvency Event or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within [***] days after the filing thereof, or if the other Party shall propose or be a Party to any dissolution or liquidation, or if the other Party shall make a general assignment for the benefit of its creditors.

(d) **Termination for Patent Challenge.** Each Party shall have the right to terminate this Agreement upon written notice to the other effective upon receipt, if a Party or any of its wholly-owned Affiliates formally challenges the validity of any Patents that are licensed to it under this Agreement (subject to the exceptions described in this Section 14.2(e), a "**Challenge**") (other than as may be necessary or reasonably required to assert a defense, cross-claim or a counter-claim in an action or proceeding asserted by a Party or any of its wholly-owned Affiliates under this Agreement against the other Party or any of its Affiliates or to respond to a court request or order or administrative law, request or order); it being understood and agreed that a Party's right to terminate this Agreement under this Section 14.2(e) shall not apply to any actions undertaken by an Affiliate of such Party that first becomes such an Affiliate as a result of a Change of Control involving such Party, where such new Affiliate was undertaking any of the activities described in the foregoing clause prior to such Change of Control if such new Affiliate terminates or otherwise ceases participating in such action, proceeding, challenge or opposition within [***] days after the effective date of such Change of Control. If a sublicensee of a Party initiates a Challenge of the intellectual property described in this Section 14.2(e), then such Party shall, upon written notice from the other Party, terminate such sublicense. Neither Party shall, and each Party shall ensure that its Affiliates and sublicensees do not, use or disclose any Confidential Information of the other Party or any nonpublic information regarding the Prosecution or enforcement of any Patents to which a Party or any of its Affiliates or sublicensees are or become privy as a consequence of the rights granted to such Party pursuant to this Agreement, in initiating, requesting, making, filing or maintaining, or in funding or otherwise assisting any other Person with respect to, any Challenge.

(e) **Eisai Right of Termination for Development.**

Where Adlai Nortye does not use Commercially Reasonable Efforts to perform its obligations as per the Development Plan and achieve regulatory and commercial milestones as envisaged in this Agreement, Eisai may ask Adlai Nortye to resolve the issue at JDC, provided the Chairperson shall not have the controlling vote and decision on such issue. If the issue remains unresolved, Eisai may terminate this Agreement in its entirety, in its sole discretion, after at least one hundred and twenty (120) days prior written notice.

Section 14.3 Surviving Rights and Obligations. Any provisions required for the interpretation or enforcement of this Agreement shall survive the expiration or termination of this Agreement. Expiration or termination of this Agreement shall not relieve any Party of any obligations that are expressly indicated to survive expiration or termination. Except as otherwise expressly provided, expiration or termination of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such expiration or termination. If a license to intellectual property rights survives expiration or termination, each Party shall provide to the other (to the extent it has not previously done so) all Proprietary Information reasonably useful or necessary for such other Party to exploit such license, including reasonable technical assistance; provided that such Proprietary Information shall remain subject to Section 12.1 so long as it is possessed by a Party.

Section 14.4 Effect of Expiration or Termination; Remaining Inventory.

(a) Upon expiration or termination of this Agreement, neither Party shall have any further rights or obligations hereunder in the Territory except pursuant to provisions that expressly survive such expiration or termination (including, for the avoidance of doubt, this Section 14.4).

(b) After expiration (but not after early termination) of this Agreement pursuant to Section 14.1, on a Product-by-Product, country-by-country basis, the rights and licenses granted (i) by Eisai to Adlai Nortye under this Agreement to Develop, Manufacture and Commercialize the Products in the Field, including any permitted sublicense, shall immediately cease, and (ii) by Adlai Nortye to Eisai under this Agreement in connection with Eisai's Development, Manufacture or Commercialization of the Product outside the Field shall convert to irrevocable, non-exclusive, royalty-free, fully paid-up, non-terminable rights and licenses, with the right to grant sublicenses (through multiple tiers).

(c) Upon early termination of this Agreement, subject to Section 14.3 and this Section 14.4, Adlai Nortye shall immediately discontinue and cease all use of any trademark(s) registered by Eisai in the Territory. Following any such termination of this Agreement, subject to Section 14.3 and this Section 14.4, Eisai shall have the right and option to purchase any trademark(s) registered by Adlai Nortye or its Affiliates for the Product on a country-by-country basis. The purchase price shall be negotiated by the Parties on a country-by-country basis in good faith on the basis of a third party willing and able to purchase such trademark(s). If the Parties are unable to come to an agreement on the purchase price within [***] days (or such other days as mutually agreed upon by the Parties) of Eisai exercising the right and option to purchase, the Parties will appoint an independent third party valuator to conduct a valuation of such trademark(s) on the basis of how much a willing and able third party will pay for such trademark(s), and the Parties shall share the costs of such third party valuation. The valuation of the third party will be the purchase price to be paid by Eisai to Adlai Nortye.

(d) Upon early termination of this Agreement or expiration of the Agreement, Adlai Nortye shall, on behalf of itself and its Affiliates, grant to Eisai and its Affiliates (i) a perpetual, fully paid-up, exclusive right and license under Adlai Nortye's interest to the Joint Intellectual Property and (ii) a perpetual, fully paid-up, non-exclusive right and license under any Adlai Nortye Technology Developed by Adlai Nortye and/or its Affiliates or sublicensees under this Agreement, in each case of (i) and (ii) as reasonably required to develop, validate or optimize the Product-Specific Biomarker for clinical and commercial use as a biomarker for the Product in the Field in the Territory.

(e) Upon expiration or early termination of this Agreement,

(i) Adlai Nortye shall, and shall cause its Affiliates and take all reasonable steps to cause its licensees and permitted sublicensees to, transfer back to Eisai those items transferred to Adlai Nortye under Section 3.3.

(ii) Adlai Nortye shall, and shall cause its Affiliates and take all reasonable steps to cause its licensees and permitted sublicensees to, transfer to Eisai all safety data and CMC data (including for clarity any documentation solely containing such safety data and CMC data) for the Product; provided that to the extent such a transfer of safety data and CMC data is not permitted under Applicable Laws or such documentation contains clinical data generated by Adlai Nortye (including Affiliates, licensees and permitted sublicensees) other than safety data and CMC data, Adlai Nortye shall, and shall cause its Affiliates and take all reasonable steps to cause its licensees and permitted sublicensees to, provide Eisai an automatic Right of Reference or Use to the safety and CMC data in such documentation for the Product.

(iii) Subject to Eisai's rights to safety data and CMC data set forth above in Section 14.4(e)(ii), with respect to any ongoing Clinical Trials at such time, Eisai shall notify Adlai Nortye whether or not Eisai elects to take over such Clinical Trial(s). In the event that Eisai elects to take over such Clinical Trial(s), subject to Applicable Laws, Adlai Nortye shall transfer, or cause the transfer by an Affiliate and take all reasonable steps to cause its licensees and permitted sublicensees to transfer, all Regulatory Documentation for the Product and Eisai shall have the right to any data generated by such trials and Controlled by Adlai Nortye; provided that, to the extent such a transfer of Regulatory Documentation is not permitted under Applicable Laws, Adlai Nortye and its Affiliates will provide Eisai an automatic Right of Reference or Use to such Regulatory Documentation for the Product. Whether or not Eisai elects to take over any of such Clinical Trials as described in this Section 14.4(e)(iii), Eisai shall pay to Adlai Nortye a reverse royalty rate of [***] on Annual Net Sales of such Product beginning on and after the date of First Commercial Sale of the Product in the US or Major Countries (whichever occurs first) until Adlai Nortye and any licensee and sublicensee has been reimbursed for [***] of its direct and documented (which documentation Eisai shall have a right to review) out-of-pocket expenses incurred with respect to and to the extent allocable to the Development of such Product. If Eisai does not elect to have an ongoing Clinical Trial transferred to Eisai, then the Parties shall work together to conduct an orderly wind-down of such ongoing Clinical Trial(s) in a manner medically necessary to safely transition subjects out of such ongoing Clinical Trial(s), in any event subject to Applicable Laws and the advice and guidance of all applicable Regulatory Authorities and clinical trial monitoring boards.

(f) Upon termination of this Agreement, subject to Section 14.3, the Selling Parties shall be permitted to import, market, promote, distribute, use, offer to sell and sell their remaining inventories of Product for a period of [***] and, for such purpose, the rights and licenses granted hereunder to Adlai Nortye shall continue in effect but shall be non-exclusive in the Territory. Furthermore, upon termination of this Agreement, Eisai shall have to the right to purchase any clinical supply of the Product (including raw materials, intermediates, and finished, unfinished, or partially finished goods) on terms substantially similar to Adlai Nortye's purchase of Inventory set forth in Section 3.6.

ARTICLE 15
Miscellaneous

Section 15.1 Entire Agreement; Amendments. This Agreement, including the Exhibits hereto, constitutes the entire agreement between the Parties concerning its subject matter and supersedes all previous negotiations, agreements and commitments with respect thereto, as of the Effective Date. This Agreement shall not be released, discharged, amended or modified in any manner except by a written instrument signed by duly authorized officers or representatives of each of the Parties. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein.

Section 15.2 Governing Law. Any claim or controversy relating in any way to this Agreement shall be governed by and interpreted exclusively in accordance with the laws of the State of New York, without regard to the conflicts of law principles thereof. This Agreement shall not be governed by the United Nations Convention on Contracts for the International Sale of Goods of April 11, 1980.

Section 15.3 Dispute Resolution. The Parties shall attempt in good faith to resolve any dispute or claim between them arising out of or relating to this Agreement ("**Dispute**") promptly by negotiations between executives or other representatives of the Parties with authority to resolve the Dispute. If a Dispute should arise, such representatives shall confer in person or by telephone at least once and attempt to resolve the matter. Such conference shall take place within [***] days of a written request therefor at a mutually agreed time and location.

If the Dispute is not settled within [***] days of the conference or time to confer described above, either Party may submit the Dispute for arbitration. The Dispute shall be finally settled under the Rules of Arbitration (the "**Rules**") of the International Chamber of Commerce (the "**ICC**"). The place of the arbitration shall be New York. The language of the arbitration shall be English. There shall be three (3) arbitrators, one of whom shall be appointed by each of the Parties in accordance with the Rules, and the third of whom shall be appointed by the ICC. The arbitrator appointed by the ICC shall act as the chairperson of the arbitrating body. The arbitrators shall decide the matters in the Dispute in accordance with the laws of the State of New York, without reference to the conflict of laws rules thereof or the United Nations Convention on Contracts for the International Sale of Goods.

The arbitration shall be commenced and shall proceed according to the Rules, except as otherwise provided herein. Any Confidential Information disclosed in the arbitration shall be subject to the confidentiality provisions of this Agreement. Any time period specified in the Rules shall be extended or accelerated upon the Parties' written agreement. At the request of either Party, all time periods specified in the Rules may, at the discretion of the arbitrators, be accelerated or extended to the extent necessary to comply with the timetables specified in the Rules or for the reasonable management of the arbitration.

The procedures specified in this Section 15.3 shall be the sole and exclusive procedures for the resolution of Disputes; provided, however, that a Party may, in addition or as an alternative to seeking interim relief from the ICC, seek injunctive or other provisional judicial relief in any court of competent jurisdiction if in its reasonable judgment such action is necessary to avoid irreparable harm or to preserve the status quo.

The decision of the arbitrators shall be final and binding on all Parties to the arbitration. Judgment upon any award rendered by the arbitrators may be entered by any court having jurisdiction over the Party against whom enforcement is sought. Each of the Parties hereby consents, for the benefit of the other Party, to the service of process by certified or registered mail or by an express delivery service providing a return receipt at its address set forth for notices herein.

While the procedures set forth above are being followed, the Parties shall continue to perform their respective obligations under this Agreement. Each Party shall bear its own costs and fees, including attorneys' fees and expenses, in connection with the arbitration, except that the arbitrators shall be empowered to assess costs and fees against any Party who the arbitrators find to have acted in bad faith or to have maintained a frivolous position in the arbitration.

Section 15.4 Partial Illegality. If any provision of this Agreement or the application thereof to any Party or circumstances shall be declared void, illegal or unenforceable, the remainder of this Agreement shall be valid and enforceable to the extent permitted by Applicable Laws. In such event, the Parties shall use their best efforts to replace the invalid or unenforceable provision by a provision that, to the extent permitted by the Applicable Laws, achieves the purposes intended under the invalid or unenforceable provision. Any deviation by any Party from the terms and provisions of this Agreement in order to comply with Applicable Laws shall not be considered a breach of this Agreement.

Section 15.5 Waiver of Compliance. No provision of this Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees, except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party, which waiver shall be effective only with respect to the specific obligation and instance described therein.

Section 15.6 Notices. All notices and other communications in connection with this Agreement shall be in writing and shall be sent to the respective Parties at the following addresses, or to such other addresses as may be designated by the Parties in writing from time to time in accordance with this Section 15.6, by registered or certified mail, postage prepaid, or by express courier service, or service fee prepaid, or by email upon confirmed delivery sent by the recipient in return in accordance with this Section 15.6.

To Eisai:	Eisai Co., Ltd. Attention: [***] [***] [***] [***] [***] With a copy to: Eisai Co., Ltd. Attention: [***] [***] [***]
To Adlai Nortye:	Adlai Nortye Nortye Biopharma Co., Ltd Attention: [***] [***] [***] [***] [***] [***] With a copy to: Adlai Nortye Biopharma Co., LTD. Attention: [***] [***] [***] [***] [***]

All notices shall be deemed given and received (a) if delivered by hand, immediately, (b) if sent by mail, [***] Days after posting, (c) if delivered by express courier service, [***] Days in the jurisdiction of the recipient, (d) if sent by fax, at the time shown in the confirmed electronic receipt, or on the first Business Day thereafter if the notice is sent on other than a Business Day, or (e) if sent by email, the date indicated as being sent in the recipient's email browser.

Section 15.7 Limitation on Liability. NOTWITHSTANDING THE FOREGOING, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES UNDER THIS AGREEMENT, EXCEPT TO THE EXTENT THE DAMAGES RESULT FROM A PARTY'S WILLFUL MISCONDUCT OR ARE PAYABLE IN CONNECTION WITH A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 10 FOR LIABILITY OWED TO THIRD PARTIES.

Section 15.8 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument.

Section 15.9 Further Assurances. From time to time, as and when requested by any Party, the other Party shall execute and deliver, or cause to be executed and delivered, all such documents and instruments and shall take, or cause to be taken, all such further actions as such other Party may reasonably deem necessary or desirable to carry out the intentions of the Parties embodied in this Agreement.

Section 15.10 Injunctive Relief. The Parties acknowledge and agree that, in addition to any other remedies available in law or equity, either Party shall be entitled to temporary and permanent injunctive relief in the event of a breach under this Agreement.

Section 15.11 Jointly Prepared. This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.

Section 15.12 Assignment.

(a) Generally. Subject to Section 6.1 and this Section 15.12, a Party shall not have the right to assign, by operation of law or otherwise, any of its rights or obligations under this Agreement without the prior written consent of the other Party. Any assignment not in accordance with this Section 15.12 shall be void.

(b) Adlai Nortye. Notwithstanding the limitations in Section 15.12(a), Adlai Nortye may assign this Agreement, or any rights or obligations hereunder in whole or in part, to (a) one or more Affiliates or (b) its successor in interest in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement, *provided* that in each case Adlai Nortye shall remain liable for all obligations imposed upon Adlai Nortye under this Agreement as if no such assignment had occurred.

(c) Eisai. Notwithstanding the limitations in Section 15.12(a), Eisai may assign this Agreement, or any rights or obligations hereunder in whole or in part, to (a) one or more Affiliates solely as provided in this Section 15.12 or (b) its successor in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement, *provided* that in each case Eisai shall remain liable for all obligations imposed upon Adlai Nortye under this Agreement as if no such assignment had occurred.

Section 15.13 **Relationship of Parties**. Each Party to this Agreement is an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties. Employees and agents of one Party are not employees or agents of the other Party, shall not hold themselves out as such, and shall not have any authority or power to bind the other Party to any contract or other obligation.

Section 15.14 **Force Majeure**. If the performance of any obligation under this Agreement is prevented, restricted or interfered with by reason of any Force Majeure event, then the Party so affected shall be excused, upon giving prior written notice to the other Party, from such performance to the extent of such prevention, restriction or interference, provided that the Party so affected shall use reasonable commercial efforts to avoid or remove such causes of nonperformance and shall continue performance to the extent reasonably possible and, in any event, at such time as the Force Majeure conditions come to an end. If the Force Majeure conditions prevent performance completely and such prevention continues for more than one hundred and eighty days (180) days, then the Parties shall attempt to negotiate a mutually acceptable compromise within the spirit and intent of this Agreement. If they are unable to reach a mutually acceptable compromise within ninety (90) days and if performance is still completely prevented at the end of that time, then the Party who is not affected by the Force Majeure conditions shall have the option, by delivery of written notice of termination to the affected Party, to terminate this Agreement with immediate effect and such termination shall be treated as a termination for material breach by Party affected by the Force Majeure, except that in such event no cure period shall apply and the terminating Party shall have the right to effect such termination upon written notice, in its sole discretion, (a) solely with respect to the country or Product affected by such non-performance or (b) the Agreement in its entirety.

Section 15.15 **Severability**. If any one or more of the terms or provisions of this Agreement is held by a court of competent jurisdiction or arbitrator to be void, invalid or unenforceable in any situation in any jurisdiction, such holding shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the invalid, void or unenforceable term or provision in any other situation or in any other jurisdiction and the term or provision shall be considered severed from this Agreement, unless the invalid or unenforceable term or provision is of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid or unenforceable term or provision. If the final judgment of such court or arbitrator declares that any term or provision hereof is invalid, void or unenforceable, the Parties agree to (a) reduce the scope, duration, area or applicability of the term or provision or to delete specific words or phrases to the minimum extent necessary to cause such term or provision as so reduced or amended to be enforceable, and (b) make a good faith effort to replace any invalid or unenforceable term or provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

Section 15.16 **Third-Party Beneficiaries**. Nothing in this Agreement, whether express or implied, is intended to confer any rights or remedies under or by reason of this Agreement on any Persons other than the Parties hereto and their respective successors, assigns, and Affiliates.

Section 15.17 **Expenses**. Except as expressly provided herein (including with respect to the allocation of Out-of-Pocket Costs), each of Adlai Nortye and Eisai agrees to pay, without right of reimbursement from the other, all costs and expenses incurred by it and its Affiliates incident to the preparation, execution and delivery by it of this Agreement and the performance of its obligations hereunder, including the fees and disbursements of counsel, accountants, financial advisors, experts, consultants and employees employed by such party in connection with the preparation, execution and delivery by it of this Agreement and with the performance of its obligations contemplated hereby.

[REMAINDER OF PAGE INTENTIONALLY BLANK;
SIGNATURE PAGE FOLLOWS]

The Parties have executed this Agreement as of the Effective Date to evidence their agreement to the terms and provisions set forth herein.

Adlai Nortye Biopharma Co., Ltd

By: _____

Name: _____

Title:

[Signature Page to Exclusive License Agreement]

The Parties have executed this Agreement as of the Effective Date to evidence their agreement to the terms and provisions set forth herein.

Eisai Co., Ltd.

By: _____

[***]

Title: [***]

[Signature Page to Exclusive License Agreement]

EXHIBIT A

Development Plan

[***]

Schedule 1

Major Countries

[***]

Schedule 2

Product-Specific Patents

[***]

Schedule 3

Compound

[***]

Schedule 4

Data and Information

[***]

[***]

[***]

[***]

[***]

[***]

Exhibit 10.5

Right and Interest Transfer Agreement (Confidential)

Certain confidential information contained in this document, marked by brackets as [***], has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed. In addition, certain personally identifiable information contained in this document, marked by brackets as [***], has been omitted from this exhibit pursuant to Item 601(a)(6) under Regulation S-K.

Right and Interest Transfer Agreement

This Rights and Interests Transfer Agreement (hereinafter referred to as this "Agreement") is entered into by and between the parties below on ___ (Date) of 2021:
Party A/ Transferor: Hangzhou Adlai Nortye Biopharma Co., Ltd. (hereinafter referred to as "Adlai Nortye")
Unified social credit code: 9133010176547745XB
Legal representative: Lu Yang
Legal address: Building 8, No. 1008, Xiangwang Street, Yuhang District, Hangzhou City, Zhejiang Province
Zip code: 311100
Contact number: [***]

Party B/Transferee: Xiamen Biotime Biotechnology Co., Ltd. (hereinafter referred to as "Biotime Biotechnology")
Unified social credit code: 91350205671268681J
Legal representative: Zhang Guofeng
Legal address: No. 188, Pingcheng South Road, Haicang Street, Haicang District, Xiamen City
Zip code: 361026
Contact number: [***]

WHEREAS,

A. Adlai Nortye is a limited company incorporated and duly existing under the laws of China. Biotime Biotechnology is a limited company incorporated and duly existing under the laws of China.

B. After long-term biomedical research and development, Adlai Nortye has independently developed five compounds: "AN4005", "AN3025", "AN0015", "AN9015" and "AN6015" (these five compounds are hereinafter respectively or collectively referred to as "New Drugs under Investigation" or "Cooperative Compounds").

C. [***]

D. Adlai Nortye agrees to exclusively transfer to Biotime Biotechnology the rights and interests of R&D, production and commercialization of “AN4005” and “AN3025” (two new drugs under investigation) in the Mainland of China, Hong Kong Special Administrative Region, Macau Special Administrative Region and the Taiwan Region of China (hereinafter collectively referred to as “**Greater China Right and Interest Region**”), and the patent rights and know-how of “AN4005” and “AN3025” obtained or to be obtained under application in the Greater China Right and Interest Region. In addition, Adlai Nortye agrees to exclusively transfer to Biotime Biotechnology the rights and interests of R&D, production and commercialization of “AN0015”, “AN9015” and “AN6015” (three cooperative compounds) in the global region (hereinafter collectively referred to as “**Global Right and Interest Region**”), and the patent rights and know-how of “AN0015”, “AN9015” and “AN6015” obtained or to be obtained under application in the Global Right and Interest Region. Biotime Biotechnology agrees to accept the transfer of such transaction objects and agrees to pay the corresponding transaction price (as defined below) (the foregoing transfer transactions are hereinafter collectively referred to as this “**Transaction**”).

NOW, THEREFORE, both parties agree to establish a long-term and stable cooperative relationship in the process of R&D, production and commercialization of the five Cooperative Compounds “AN4005”, “AN3025”, “AN0015”, “AN9015” and “AN6015” in the principle of equality, voluntariness and good faith and on the basis of unlocking their respective advantages. Through amicable negotiation and on the basis of truthful and full expression of their respective wishes, both parties covenant and agree as follows for mutual observance:

1. Definition of Contract Terms

Unless otherwise expressly set forth in this Agreement, the following terms used in this Agreement are defined as follows:

“**Applicable Law**” refers to all national, supranational, federal, state, local, foreign or provincial laws, regulations and rules, including case law, and any guidance, principles and requirements of any regulatory authority, as well as any industry norms in force at that time and applicable to the activities carried out under this Agreement.

“**Associated Entity**” refers to any entity that directly or indirectly controls, is controlled by, or is under common control with a party. “Control”, “controlled by”, “under common control with” refers to the power, at present or thereafter, directly or indirectly, to determine the management and policy direction of the controlled party through voting rights, contracts or other means ; in addition to the foregoing provisions, any entity that holds or controls fifty percent (50%) or more of the outstanding voting securities and/or proxy voting securities or other forms of owner’s equity shall be deemed to have such power of control over the controlled party.

“**Clinical Trial Approval**”, in mainland China, refers to the approval issued by the State Food and Drug Administration for conducting human clinical trials of drugs in China; or according to the *Announcement on Adjusting the Review and Approval Procedures of for Drug Clinical Trials* (No. 50, 2018) of State Food and Drug Administration and its alternative regulations, the applicant who applies for drug clinical trials in China, has not received negative or questioning comments from the Center for Drug Evaluation of State Food and Drug Administration within 60 days from the date of acceptance of the application and payment, and has carried out drug clinical trials in accordance with the submitted protocols shall be deemed to have obtained “Clinical Trial Approval”; in regions outside mainland China, “Clinical Trial Approval” refers to the approval or license issued by the drug administration departments in regions outside mainland China for conducting human clinical trials of drugs in mainland China.

“**Commercialization**” shall have the meaning conferred to it in Article 2.2.

“**Cooperative Compound**” shall have the meaning conferred to it in light of Clause B.

“Cooperative Product” refers to the pharmaceutical preparation in any form that contains, in part or in whole, any cooperative compound.

"**Encumbrance**" refers to any claim, easement, encumbrance, lease, security interest, lien, option, pledge, third party rights or restrictions (on voting rights, sale, transfer, disposition or otherwise).

"**Financial Year**" refers to the period of 12 consecutive months from 1 January each year.

"**Force Majeure**" refers to the event that is beyond the reasonable control of both parties, unforeseeable, (even foreseeable) unavoidable, and prevents, affects or delays the performance by either party of all or part of its obligations under this Agreement. Such events include but are not limited to earthquakes, typhoons, floods, fires or other acts of God, wars, riots, strikes, severe epidemics or any other similar events.

"**Global Right and Interest Region**" shall have the meaning conferred to it in light of Clause D.

"**Governmental Authority**" refers to any federal, national, transnational, state, provincial, local or similar government, governmental, taxation, regulatory or administrative department, agency or commission, or any court, tribunal, judicial or arbitral body in or outside China.

"**Greater China Right and Interest Region**" shall have the meaning conferred to it in light of Clause D.

"**Intellectual Property Right**", on a global scale, refers to (i) all registered and unregistered trademarks (including but not limited to service marks, brand names, certification marks and collective marks), Internet domain names, Internet and wireless network keywords, registered and unregistered designs, copyright, trade dress, registered and unregistered company names and trade names, registered and unregistered tentative names and other indications of origin, applications and registrations of the foregoing, and all goodwill related to and represented by them; (ii) proprietary inventions and discoveries (whether patentable or not), and all patents, registrations, disclosure of inventions and applications for the foregoing, including divisional application, continuation application, continuation-in-part application and renewal application, as well as including renewal, extension and regrant; (iii) confidential information, business secrets, trade secrets and know-how, including processes, systematic combinations, business methods, formulas, drawings, prototypes, models, designs, lists of customers and lists of suppliers; (iv) published and unpublished works, whether copyrightable or not (including but not limited to source code, databases and other combinations of information), copyright in the foregoing, registrations and applications of the foregoing, and all renewals, extensions, recoveries and adaptations thereof; and (v) any other intellectual property or proprietary rights.

"**Losses**", to the extent enforceable under applicable laws, refer to all liabilities, losses, claims, damages (including direct, indirect, consequential, incidental and/or special damages), impairment of value, loss of profits, punitive damages, cause of action, litigation, arbitration, administrative proceedings (including informal proceedings), investigations, audits, requirements, assessments, adjustments, judgments, settlement costs, defects, taxes, penalties, fines, interest (including interest accrued from the date on which such compensation is payable), costs and expenses (including settlement costs, interest, litigation costs, arbitration costs, investigation costs, fees and expenses of attorneys, accountants, financial advisers or other experts, and other expenses related to the litigation).

"**Mainland China**" or "**Domestic**" refers to the People's Republic of China, but for the purpose of this Agreement, Hong Kong, Macau and Taiwan are not included.

"**Net Sales**" refers to the sales of cooperative product in a certain right and interest region minus: (1) customary discounts and rebates given during the sales process; (2) taxes arising from the sales of cooperative product by the seller.

"**New Drugs under Investigation**" shall have the meaning conferred to it in light of Clause B.

"**Patent**" refers to an invention patent, application for an invention patent and all substitute applications thereof, divisional patent, continuation patent and continuation-in-part patent, licensed patents related to the patent application, any re-authorized and re-examined licensed patents, utility model patent or design patent and its renewal or continuation (including any supplementary certificate of protection), and any confirmed or registered patent or additional patent based on any such patent and its corresponding patent or application in any country.

"**Phase I Clinical Trial**" refers to preliminary clinical pharmacology and human safety evaluation trial, which are used to observe the tolerance and the pharmacokinetics of human body to a new drug so as to provide a basis for formulating dosage regimens.

"**Phase II Clinical Trial**" refers to the preliminary evaluation phase of therapeutic effect, which aims to preliminarily evaluate the therapeutic effect and safety of a drug in patients with target indications and also provide basis for the determination of research design and dosage regimen of Phase III Clinical Trial.

"**Phase III Clinical Trial**" refers to the confirmation phase of therapeutic effect, which aims to further verify the therapeutic effect and safety of the drug in patients with target indications, evaluate the overall benefit and risk relationship, and ultimately provide sufficient basis for the review of drug registration application.

"**Production License**" refers to a certificate issued by the relevant government authority that permits the production of a product within its jurisdiction.

"**Research and Development**" shall have the meaning conferred to it in Article 2.2.

"**Technical secret**" refers to all undisclosed technical information, including but not limited to data, results, technologies, inventions, discoveries, concepts, methods, templates, research, development and test procedures, sources and supplies, production processes, techniques and specifications, quality control data, analyses and reports, regulatory filings and packaging.

"**Transaction Objects**" shall have the meaning conferred to it in Article 2.

2. Transaction Objects

The transaction object under this Agreement refers to the rights and interests of R&D, production and commercialization of "AN4005" and "AN3025" in the Greater China Right and Interest Region, and the rights and interests of R&D, production and commercialization of "AN0015", "AN9015" and "AN6015" in the Global Right and Interest Region.

The rights and interests of R&D, production and commercialization of the foregoing five Cooperative Compounds include: (1) exclusive rights of preclinical research, clinical development, registration, production and marketing of the foregoing five Cooperative Compounds in their corresponding right and interest regions; (2) as of the signing date of this Agreement, all research data, technical secrets and technical results that have been completed in the research and owned by Adlai Nortye in the research process of the foregoing five Cooperative Compounds; (3) all patent rights, patent application rights of "AN4005" and "AN3025" obtained by Adlai Nortye in the Greater China Right and Interest Region and of "AN0015", "AN9015" and "AN6015" obtained by Adlai Nortye in the Global Right and Interest Region, and all patent rights, R&D and commercialization rights obtained in the corresponding right and interest regions based on such application; (4) the right to obtain other intellectual property rights in the corresponding right and interest regions based on the above information or based on the technical secrets, technical results and intellectual property rights related to the foregoing five Cooperative Compounds (hereinafter collectively referred to as the "**Transaction Objects**". [***])

2.1 "R&D" in the Transaction Objects under this Agreement refers to analysis, test, non-clinical research, clinical research and all other regulatory trials of compounds or drugs, including all post-marketing clinical trials, drug registration application and all relevant regulatory activities (including the activities required by regulatory authorities or activities required by regulatory authorities as a condition or support for obtaining or maintaining regulatory approval of a product), as well as any and all activities relating to new indications, pharmacokinetic studies and all related activities, including work on new formulations, new therapeutic method and new manufacturing methods, etc.

2.2 "Commercialization" in the Transaction Objects under this Agreement refers to all marketing, sales and distribution (including import, export, transportation and commercial sales, customs clearance, warehousing, invoicing, processing and delivery of products) activities prior to and after receipt of the relevant regulatory approvals, including but not limited to: (1) work of sales personnel, advertising, medical education, planning, marketing, training for sales personnel, sales and distribution; and (2) science and medical affairs. For the avoidance of doubt, commercialization does not include any R&D activities, whether conducted before or after regulatory approval.

3. Handover of R&D Data and Results

3.1 Adlai Nortye will, within [***] days from the effective date of this Agreement, hand over all data and R&D results related to the Transaction Objects listed in Appendix I to Biotime Biotechnology, including but not limited to all preclinical research data and other technical materials related to the New Drugs under Investigation; data related to PCT international patents that have been applied for New Drugs under Investigation; priority patents and global patents, and evidence of related application rights/ patent right -related data obtained based on such applications; existing data used for registration application; and clinical trial approvals (if any) actually obtained in the Greater China Right and Interest Region/ overseas, etc. At the request of Biotime Biotechnology, Adlai Nortye is obliged to guide Biotime Biotechnology to repeatedly verify the experimental data and results of related research data and technical data.

3.2 Regarding the change of the patentee involved in the Transaction Objects, for the domestic patent or PCT international patent that has been submitted for application or granted the patent right and listed in Appendix II, Adlai Nortye and Biotime Biotechnology will cooperate to submit the change application within [***] days from the effective date of this Agreement and the actual completion time of the change is subject to relevant laws and regulations as well as relevant policies of the administrative departments; for the subsequent unapplied compound patents based on PCT patents in the patent list of Appendix II and other patents that Biotime Biotechnology entrusts Adlai Nortye to apply for, Adlai Nortye and Biotime Biotechnology will cooperate to submit the application for change of patentee or patent applicant from Adlai Nortye to Biotime Biotechnology within [***] days after the application is accepted by relevant intellectual property authorities. Where the actual completion time of such change is delayed resulting from relevant laws and regulations or the policies of the administrative department, Adlai Nortye will not assume the corresponding legal liability.

[***]

3.3 Regarding the change (if any) of the applicant of clinical trial approval involved in the Transaction Objects, Adlai Nortye shall, within [***] days from the date of actually obtaining the relevant clinical trial approval, cooperate with Biotime Biotechnology to apply to the relevant administrative department for such change and the actual completion time of the change is subject to relevant laws and regulations as well as relevant policies of the administrative department. Where the actual completion time of such change is delayed resulting from relevant laws and regulations or the policies of the administrative department, Adlai Nortye will not assume the corresponding legal liability.

3.4 Adlai Nortye shall attach the list (i.e., Appendix I and Appendix II) when handing over all data and R&D results and deliver such materials to Party B by email, in person or by post.

Data delivery address: [***], designated recipient of Party B: [***], telephone: [***], E-mail: [***]

4. Transaction Price

4.1 Transaction pricing

Both parties agree through negotiation that this transaction is composed of the [***] transfer price, product milestone fees and sales commission fees (collectively referred to as the “transaction price”).

4.2 Payment arrangement

Both parties agree that the transaction price and payment arrangement shall be as follows:

(1) The transaction price and payment arrangement for AN4005 and AN3025 are as follows:

a. [***] transfer price: The [***] transfer price of "AN4005" and "AN3025" is RMB [***] and RMB [***] respectively. Biotime Biotechnology shall pay 100% of the [***] transfer price corresponding to the said New Drugs under Investigation to Adlai Nortye within forty-five (45) days from the effective date of this Agreement as the [***] transfer price. [***]

b. Product milestone fees and sales commission fees: Both parties acknowledge that Adlai Nortye shall, upon the effectiveness of this Agreement, have the right to obtain the corresponding payments for the development, production or commercialization of "AN4005" and "AN3025" under this Agreement according to the development progress of New Drugs under Investigation and the sales results of the cooperative products after commercialization:

Milestone fees for AN4005		
Development milestones for AN4005	**1. [***]**	[***]
	2. [***]	[***]
	3. [***]	[***]
	[***]	**[***]**
	[***]	[***]
Sales milestones for AN4005	**1. [***]**	[***]
	2. [***]	[***]
	3. [***]	[***]
	[***]	**[***]**
Sales commission fees for AN4005		
1. [***]		
2. [***]		
3. [***]		

Milestone fees for AN3025		
Development milestones for AN3025	**1. [***]**	[***]
	2. [***]	[***]
	3. [***]	[***]
	[***]	**[***]**
	[***]	[***]
Sales milestones for AN3025	**1. [***]**	[***]
	2. [***]	[***]
	[***]	**[***]**
Sales commission fees for AN3025		
1. [***]		
2. [***]		
3. [***]		

(2) The transaction price and payment arrangement for “AN0015”, “AN9015” and “AN6015” are as follows:

a. [***] transfer price: The [***] transfer price of “AN0015”, “AN9015” and “AN6015” is RMB [***], RMB [***] and RMB [***] respectively. Biotime Biotechnology shall pay 100% of the [***] transfer price corresponding to the said New Drugs under Investigation to Adlai Nortye within forty-five (45) days from the effective date of this Agreement as the [***] transfer price. [***]

b. Product milestone fees and sales commission fees: Both parties acknowledge that Adlai Nortye shall, upon the effectiveness of this Agreement, have the right to obtain the corresponding payments for the development, production or commercialization of “AN0015”, “AN9015” and “AN6015” under this Agreement according to the development progress of New Drugs under Investigation and the sales results of the Cooperative Products after commercialization:

Milestone fees for AN0015		
Development milestones for AN0015	**1. [***]**	[***]
	2. [***]	[***]
	3. [***]	[***]
	[***]	**[***]**
	[***]	[***]
Sales milestones for AN0015	**1. [***]**	[***]
	[***]	**[***]**
Sales commission fees for AN0015		
[***]		

Milestone fees for AN9015		
Development milestones for AN9015	**1. [***]**	[***]
	2. [***]	[***]
	3. [***]	[***]
	[***]	**[***]**
	[***]	[***]
Sales milestones for AN9015	**1. [***]**	[***]
	[***]	**[***]**
Sales commission fees for AN9015		
[***]		

Milestone fees for AN6015		
Development milestones for AN6015	**1. [***]**	[***]
	2. [***]	[***]
	3. [***]	[***]
	[***]	**[***]**
	[***]	[***]
Sales milestones for AN6015	**1. [***]**	[***]
	[***]	**[***]**
Sales commission fees for AN6015		
[***]		

In respect of the product milestone fees, Biotime Biotechnology shall pay the corresponding milestone fees in full to Adlai Nortye within thirty (30) days from the date on which each product milestone is triggered. In respect of the sales commission fees, Biotime Biotechnology shall pay the corresponding fees to Adlai Nortye within thirty (30) days after the end of each financial year. For the avoidance of doubt, the [***] transfer price, product milestone fees and sales commission fees agreed under Article 4.2 of this Agreement are independent of each other. The fees for which the payment terms have been met and which has been paid will not be returned due to subsequent failure to meet other payment terms. The fees for which the payment terms have been met but has not been paid shall be paid in accordance with the provisions of this Agreement, otherwise the breaching party shall be liable for breach of contract in accordance with Article 9 of this Agreement.

4.3 Expense bearing

(1) Except as otherwise agreed herein, the taxes and other related expenses incurred in connection with the transfer of the Transaction Objects hereunder shall be borne by both parties in accordance with laws or provisions of this Agreement.

(2) After the Greater China rights and interests of “AN4005” and “AN3025” are transferred to Biotime Biotechnology, Biotime Biotechnology shall bear all R&D expenses incurred from the cooperative compound to the preclinical research, clinical trials and registration application of new drugs;

(3) After the Global rights and interests of “AN0015”, “AN9015” and “AN6015” are transferred to Biotime Biotechnology, Biotime Biotechnology shall bear all R&D expenses incurred from the Cooperative Compound to the preclinical research, clinical trials and registration application of new drugs;

(4) In order to ensure that all intellectual property rights related to the Transaction Objects can be applied for within the shortest time possible, after the effective date of this Agreement and before the completion of data handover, Adlai Nortye will continue to apply for all transaction compound patents and other intellectual property rights that Biotime Biotechnology agrees to apply for. All application fees for such intellectual property rights (including but not limited to agency fees, application fees, searching fees, change fees, etc.) from the date of submission of the application shall be paid by Biotime Biotechnology to Adlai Nortye within ten (10) days from the date of filing the application for change described in Article 3.2 of this Agreement.

5. Change Registration and Grace Period

5.1 Adlai Nortye undertakes to cooperate with Biotime Biotechnology to handle the registration application and change application registration of relevant intellectual property rights, regulatory approval and filing related to the Transaction Objects as well as other matters to achieve the purpose of this Agreement after the Agreement comes into force.

5.2 Special provisions regarding grace period: Biotime Biotechnology agrees to grant Adlai Nortye a reasonable grace period of [***] month(s), provided that Adlai Nortye has implemented the relevant patents involving the five Cooperative Compounds prior to the execution of this Agreement. Adlai Nortye shall cease to implement relevant patents within [***] month(s) after the signing of this Agreement.

6. Representations and Warranties

6.1 Representations and warranties of Adlai Nortye

(1) Adlai Nortye is a limited liability company established and duly existing in China according to law, and has the principal qualification to sign and perform this Agreement;

(2) Adlai Nortye has taken all appropriate and necessary corporate actions to authorize the execution, delivery and performance of this Agreement. The authorized representative signing this Agreement on behalf of Adlai Nortye has full authority to sign this Agreement and is binding upon it;

(3) Adlai Nortye has legal rights to the Transaction Objects hereunder and has the full right to perform the transaction. In addition, Transaction Objects or any rights and interests in connection with the Transaction Objects have no defects of right, nor have any encumbrance;

(4) The progress of New Drugs under Investigation, handover data list and all used intellectual property rights of this Transaction Objects are disclosed in Appendix I. All patents and patent applications owned and used by Adlai Nortye for the New Drugs under Investigation of this Transaction Objects are disclosed in Appendix II. Adlai Nortye legally owns or has the right to use all intellectual property rights and other civil rights within the scope of this Transaction Objects. In terms of “AN4005”, “AN3025”, “AN0015”, “AN9015” and “AN6015” of this Transaction Objects in the corresponding right and interest regions, the preclinical research, clinical development, registration, production and marketing of these Cooperative Compounds and their specific indications and/or non-specific indications (if any) do not infringe any third party’s patent rights or other intellectual property rights. The patents, know-how, design rights, inventions, licenses and other intellectual property rights owned or used by Adlai Nortye in connection with the Cooperative Compounds comply with the laws and regulations of China. With regard to the process of obtaining such intellectual property rights by Adlai Nortye or its subsidiaries, Adlai Nortye, its R&D personnel and consultants have not infringed on other people’s intellectual property rights and trade secrets or violated contracts that are binding on them. Adlai Nortye has been diligent in maintaining the validity of its intellectual property rights on the Cooperative Compounds. As of the date hereof, Adlai Nortye has not received any claims from any third party claiming that the Transaction Object infringes or may infringe the intellectual property rights of a third party, or raising any objection to the use of any Transaction Object by Adlai Nortye. As far as Adlai Nortye knows, no third party has infringed or may infringe on the Transaction Objects. Except for the publicly disclosed information, the intellectual property rights (including but not limited to the design scheme, parameters, specifications, processes and drawings of relevant cooperative products, etc.) related to the R&D and production of cooperative products involved in the Transaction Objects transferred by Adlai Nortye are the trade secrets of Adlai Nortye. Adlai Nortye has taken appropriate measures to keep such trade secrets confidential and has not disclosed such information in any way to any party other than key personnel to whom the trade secrets are disclosed on a need-to-know basis;

(5) Adlai Nortye has not made any agreement, arrangement or commitment that could or might lead to restrictions on the rights of Transaction Objects;

(6) The content of this Agreement and other transaction documents do not violate the Articles of Association or other forms of company documents of Adlai Nortye or the laws, regulations and the administrative orders of government authorities that should be applied to Adlai Nortye or other contracts or legal documents entered into by Adlai Nortye for which Adlai Nortye is a party. Nothing set forth in this Agreement shall relieve any third party from its obligations or grant it to exercise any right;

(7) Adlai Nortye has disclosed and provided to Biotime Biotechnology all the information and data that it has mastered regarding the Transaction Objects. In addition, such information and data are true and accurate without intentional concealment or material omissions.

6.2 Representations and warranties of Biotime Biotechnology

(1) Biotime Biotechnology is a limited liability company established and duly existing in China according to law, and has the principal qualification to sign and perform this Agreement;

(2) Biotime Biotechnology has taken all appropriate and necessary corporate actions to authorize the execution, delivery and performance of this Agreement. The authorized representative signing this Agreement on behalf of Biotime Biotechnology has full authority to sign this Agreement and is binding upon it;

(3) The execution and performance of this Agreement by Biotime Biotechnology will not violate any existing agreements or other documents binding on it;

(4) Biotime Biotechnology warrants that the sources of funds used to pay the transfer price under this Agreement are legal.

7. Priority Rights and Subsequent Arrangements

7.1 Biotime Biotechnology shall exclusively own all the rights in the Transaction Objects upon the effectiveness of this Agreement.

7.2 Both parties shall acknowledge and register the technology contract concerning the Transaction Objects, and where necessary, separately sign a technology transfer contract issued by the Ministry of Science and Technology. **However, both parties acknowledge that the technology transfer contract (the version from the Ministry of Science and Technology) signed separately is only for confirmation and registration by administrative departments. In case of any discrepancy between the terms of the transfer contract and those of this Agreement, this Agreement shall prevail. Adlai Nortye undertakes to complete the filing of the technology transfer contract with the competent department of science and technology within [***] days from the date of signing this Agreement. However, Adlai Nortye will not be liable for breach of contract, provided that the filing is delayed resulting from the reasons including but not limited to the changes in relevant national policies.**

7.3 Biotime Biotechnology shall make commercial and reasonable efforts to fulfill its tasks under the development plan of New Drugs under Investigation and obtain, or procure to obtain the relevant regulatory approvals of New Drugs under Investigation in the corresponding right and interest regions. In case that Biotime Biotechnology discontinues or delays the R&D of the project for more than [***] months without reasonable reasons, Adlai Nortye has the right to withdraw the contractual rights and interests (both parties need to enter into the Rights and Interests Transfer Agreement, and specify the price, change filing, etc.) of the New Drugs under Investigation. Biotime Biotechnology shall undertake and be responsible for the follow-up R&D, drug registration application and other matters (including but not limited to cost input and personnel arrangement) after the transfer of relevant technology, phased research results and other relevant property rights of the New Drugs under Investigation.

7.4 Upon effectiveness of the Agreement, Biotime Biotechnology will decide and lead the application and maintenance of all patents concerning the New Drugs under Investigation at its sole discretion, including but not limited to reply to review opinions, modification of patent application documents, response to third party's opinions or other administrative, civil and other legal procedures, payment of fees, etc. Adlai Nortye shall make every effort to assist Biotime Biotechnology in submitting and applying for patents for New Drugs under Investigation, including drafting, reviewing or revising the reply to the review opinions, and revising the patent claims as required by the Transferee. For one or more new drug(s) under investigation, if a proposed patent application (subject to Appendix I and Appendix II) is formed but has not been submitted prior to the effective date of this Agreement, such application shall, in principle, be submitted thereafter in the name of Biotime Biotechnology in the corresponding right and interest regions of Biotime Biotechnology or be submitted in the name of Adlai Nortye upon Biotime Biotechnology's written consent and review and confirmation of the patent application text, and then be transferred to Biotime Biotechnology.

7.5 In case that Biotime Biotechnology needs the assistance from Adlai Nortye in R&D matters that have been completed at present for the New Drugs under Investigation when applying for clinical approvals in the corresponding right and interest regions of New Drugs under Investigation or conducting other R&D works in the future, Adlai Nortye shall dispatch technical personnel to provide assistance and guidance. However, the relevant expenses incurred in the process of assistance and guidance shall be borne by Biotime Biotechnology. In case that Biotime Biotechnology needs relevant assistance data in the corresponding right and interest regions of New Drugs under Investigation in the future, including but not limited to the quality standards and technical parameters on production of drug substance and preparations, Adlai Nortye agrees to provide such assistance to Biotime Biotechnology at the cost price. After this Agreement comes into force, where necessary, the relevant parties may sign a data transfer agreement to stipulate the specific matters (as applicable).

7.6 [***]

7.7 In the follow-up R&D of the Cooperative Compounds, both parties agree to establish a R&D coordination group for the purpose of exchanging information on important matters such as R&D progress and intellectual property right changes of each cooperative compound every quarter, discussing the follow-up promotion plan of the R&D projects, and promoting the smooth progress of R&D projects. In addition, both parties may establish a joint supervisory committee composed of the same number of representatives appointed by both parties with respect to New Drugs under Investigation to advise, coordinate and supervise the development, commercial production activities and decision-making of New Drugs under Investigation.

7.8 [***]

7.9 [***]

7.10 Biotime Biotechnology undertakes that Adlai Nortye and its affiliates shall enjoy the priority right to the sub-contract production and sales of such cooperative products under the same conditions after obtaining the production license of any new drug under investigation in the Global Right and Interest Region (including the Greater China Right and Interest Region). After this Agreement becomes effective, the relevant parties shall separately sign a written agreement to stipulate the specific matters.

7.11 In case that Biotime Biotechnology transfers all or part of its rights and interests in any country or region or all regions, Biotime Biotechnology shall, within [***] days from the date of signing the first transfer agreement or other relevant documents, pay to Adlai Nortye in one lump sum all the product milestone fees and sales commission fees actually generated by such cooperation products. Under such circumstance, the third party shall take over the obligations and perform the reconciliation formalities corresponding to the product milestone fees and sales commission fees which are payable by Biotime Biotechnology and have not occurred at the time of transfer but may occur in the future in such countries or regions concerning such rights and interests under Article 4.2 of this Agreement.

7.12 In case that Biotime Biotechnology authorizes all or part of its rights and interests in any country or region or all regions, Biotime Biotechnology shall, within [***] days from the date of signing the first authorization agreement or other relevant documents, pay to Adlai Nortye in one lump sum all the product milestone fees and sales commission fees actually generated by such cooperation products. In the event that the third party triggers a product milestone under Article 4.2 of this Agreement after obtaining such authorization, Adlai Nortye has the right to treat such event as a product milestone triggered by Biotime Biotechnology, and Biotime Biotechnology shall pay the corresponding product milestone fees to Adlai Nortye in accordance with Article 4.2 of this Agreement. Meanwhile, the sales of related products produced by the third party after obtaining such authorization shall be included in the product sales of Biotime Biotechnology. Finally, Biotime Biotechnology will pay the sales commission fees of products to Adlai Nortye in accordance with Article 4.2 of this Agreement (authorization of such rights and interests to Adlai Nortye or its associated entity is not subject to this clause).

7.13 [***]

7.14 For the avoidance of doubt, in case that Biotime Biotechnology transfers/ authorizes all or part of its rights and interests to its associated entity, the transfer/authorization will not be subject to the provisions of 7.11, 7.12, and 7.13 above. However, the associated entity after transfer shall assume the responsibilities which should be assumed by Biotime Biotechnology in this Agreement but have not been actually performed or have not occurred, including but not limited to the payment of product milestone fees, sales commission fees and [***].

7.15 [***]

8. Trade Secrets

8.1 All data and information under this Agreement are classified as trade secrets. Neither party shall disclose or transfer the relevant technical data to any third party without the written consent of the other party, unless data and information is provided/publicly disclosed by both parties to a third party in the process of patent application, and drug approval and registration in accordance with relevant laws and regulations, or as required by relevant government authorities or the stock exchange where the securities of one party or its affiliates are listed (however, the providing/ disclosing party shall notify the other party in writing in advance). In case that the relevant technical data is disclosed due to any reason attributable to either party, the disclosing party shall compensate the other party for the losses.

8.2 The term of protection of the said trade secrets starts from the date on which either party becomes aware of the trade secret to the date on which the public can obtain and become aware of the trade secret through legal means.

9. Liability for Breach of Contract

9.1 Where Biotime Biotechnology fails to pay the transaction price to Adlai Nortye as agreed in Article 4.2 hereof, it shall pay Adlai Nortye liquidated damages equal to [***] percent of the transaction price overdue for each day. In the event that the overdue period exceeds [***] days, Adlai Nortye has the right to terminate this Agreement, and both parties shall reach an agreement on matters after termination through negotiations.

9.2 Adlai Nortye shall compensate Biotime Biotechnology for all losses suffered as a result of such violations that the representations and warranties made by Adlai Nortye in Article 6.1(4) are materially false or misleading, and Biotime Biotechnology has the right to suspend or terminate the performance of its obligations under this Agreement, provided that Biotime Biotechnology is unable to exercise its rights under this Agreement due to the said violations of Adlai Nortye.

9.3 Any breach of this Agreement by either party constitutes a breach of contract and the breaching party shall bear the corresponding liability for compensation to the non-breaching party. In addition, the non-breaching party shall have the right to terminate this Agreement and require the breaching party to compensate all losses on the condition that one party breaches this Agreement, fails to comply with its representations or warranties hereunder, or its representations or warranties hereunder are false or there are any material omission, which constitutes a material breach.

10. Confidentiality

Both parties to this Agreement undertake to keep confidential all information covered by this Agreement. Neither party shall disclose to any other party such information without the permission of the other party, except for the purpose of this transaction (except that provided by the legal and financial professional consultants hired by both parties, as well as their audit and evaluation agencies) or except as necessary to comply with the relevant laws, regulations or provisions of the relevant stock exchange. In addition to the confidentiality clauses of this Agreement, both parties shall strictly abide by the confidentiality agreement if it is otherwise signed by both parties.

11. Force Majeure

11.1 In the event of a force majeure event, the party suffering from such event shall immediately notify the other party in the fastest way, and provide supporting document within [***] days to explain the details of the event and the reasons for the failure or partial failure to perform or delay the performance of this Agreement. Then the parties shall negotiate whether to postpone the performance of this Agreement or terminate this Agreement. The failure or delay of the party suffering from such event in performing this Agreement shall not constitute a breach of contract, provided that the said party fulfills its obligations under this Article.

12. Applicable Law and Dispute Resolution

12.1 The conclusion, validity, interpretation, execution and dispute resolution of this Agreement shall be governed by the laws of Mainland China.

12.2 All disputes arising from or in connection with this Agreement shall be resolved by both parties through amicable negotiation. In case of failure to do so within [***] days from the date of occurrence of the dispute, either party shall have the right to submit such dispute to Shenzhen Court of International Arbitration for arbitration in accordance with its arbitration rules.

13. Notice

13.1 Notices under this Agreement shall be sent by personal delivery, fax, express or other means agreed by both parties. Where a notice is sent by express, it shall be deemed to have been served when the other party actually signs for it. In case that the other party refuses to sign for it without justifiable reasons, the notice shall be deemed to have been served five days after the date of mailing. Where a notice is sent by personal delivery or fax, it shall be deemed to have been served the next day after the date of delivery. Where a notice is sent by fax, the original copy shall be delivered to the other party by express or personal delivery immediately after sending.

13.2 Contact information of the parties hereto is as follows:

(1) Party A
Contact: [***]
Correspondence address: [***]
Zip code: [***]
Tel.: [***] E-mail: [***]

(2) Party B
Contact: [***]
Correspondence address: [***]
Zip code: [***]
Tel.: [***] E-mail: [***]

14. Miscellaneous

14.1 This Agreement shall be concluded upon signature and seal of the authorized representatives of both parties and shall come into force after this transaction is reviewed and approved by the Board of Directors of Adlai Nortye Group.

14.2 Unless otherwise stipulated in this Agreement, neither party shall transfer its rights and obligations hereunder to a third party without the prior written consent of the other party.

14.3 In the event that any one or more provisions of this Agreement become invalid, illegal or unenforceable under any law, the validity, legality and enforceability of the remaining provisions of this Agreement shall not be affected.

14.4 The appendixes hereto are an integral and effective part of this Agreement, and have the same legal effect as this Agreement. Any amendment to this Agreement and its appendixes shall become effective only by a written agreement signed by the parties hereto.

14.5 For unaccomplished matters, both parties shall separately negotiate and sign a written supplementary agreement, which shall have the same legal effect as this Agreement. In case of any discrepancy between the supplementary agreement and this Agreement, the supplementary agreement shall prevail.

14.6 This Agreement is executed in Chinese with four (4) original copies. Each party shall hold two (2) copies, each of which has the same legal effect.

(The remainder of this page is intentionally left blank)

There is no text in this page, which is the signature and seal page of Right and Interest Transfer Agreement.

Party A: Hangzhou Adlai Nortye Biopharma Co., Ltd. (seal)

Legal representative/authorized representative: [***]

Party B: Xiamen Biotime Biotechnology Co., Ltd. (seal)

Legal representative/authorized representative: [***]

Appendix I Introduction to the Progress of New Drugs under Investigation and Handover Data List of the Transaction Objects

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Appendix II List of Patents on New Drugs under Investigation

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