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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12(g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

For the transition period from to

Commission file number 001-41773

Adlai Nortye Ltd.

(Exact name of Registrant as specified in its charter)

Cayman Islands

(Jurisdiction of incorporation or organization)

c/o PO Box 309, Ugland House
Grand Cayman, KY1-1104
Cayman Islands
(Address of principal executive offices)

Yang Lu, Chief Executive Officer
Building 6 & 8, 1008 Xiangwang Street
Yuhang District, Hangzhou
Zhejiang Province, 311121
The People's Republic of China
Tel: +86-0571-2891-8385
Email: ir@adlainortye.com

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
American Depositary Shares, each representing three Class A Ordinary Shares, par value $0.0001 per share	ANL	The Nasdaq Stock Market LLC (The Nasdaq Global Market)

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 110,700,805 ordinary shares, consisting of 93,710,805 Class A ordinary shares, par value US$0.0001 per share, and 16,990,000 Class B ordinary shares, par value US$0.0001 per share, as of December 31, 2023.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

☐ Yes ☒ No

Note – Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ 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 13(a) of the Exchange Act. ☐

†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.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934).

☐ Yes ☒ No

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

☐ Yes ☐ No

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INTRODUCTION

Unless otherwise indicated or the context otherwise requires, references in this annual report on Form 20-F 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;
- "China" or the "PRC" or "mainland China", unless otherwise specified herein, are to the People's Republic of China, excluding, for the purposes of this annual report only, Taiwan and the special administrative regions of 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$0.0001 per share;
- "Hangzhou Adlai" is to Adlai Nortye Biopharma Co., Ltd., our wholly foreign-owned enterprise incorporated in the PRC;
- "Hong Kong" is to Hong Kong Special Administrative Region of China;
- "Macau" is to Macau Special Administrative Region of China;
- "RMB" or "Renminbi" are to the legal currency of China;
- "shares" or "ordinary shares" are to our Class A ordinary shares and Class B ordinary shares;
- "US$," "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.

FORWARD-LOOKING STATEMENTS

This annual report on Form 20-F contains statements of a forward-looking nature. All statements other than statements of historical facts are forward-looking statements. These forward-looking statements are made under the "safe harbor" provision under Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and as defined in the Private Securities Litigation Reform Act of 1995. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. In some cases, these forward-looking statements can be identified by words or phrases such as "may," "will," "expect," "anticipate," "aim," "estimate," "intend," "plan," "believe," "potential," "continue," "is/are likely to" or other similar expressions. These forward-looking statements relate to, among others:

- our growth strategies;
- our future business development, results of operations and financial condition;
- trends in online consumer retailing;
- trends in Chinese manufacturing;
- the expected benefits of our acquisitions or investments;
- consumer and economic dynamics in the markets we serve;
- expected changes in our revenues and certain cost and expense items; and
- assumptions underlying or related to any of the foregoing.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs.

You should read these statements in conjunction with the risks disclosed in "Item 3. Key Information—D. Risk Factors" of this annual report and other risks outlined in our other filings with the Securities and Exchange Commission, or the SEC. Moreover, we operate in an emerging and evolving environment. New risks may emerge from time to time, and it is not possible for our management to predict all risks, nor can we assess the impact of such risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ materially from those contained in any forward-looking statements. The forward-looking statements made in this annual report relate only to events or information as of the date on which the statements are made in this annual report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this annual report and the documents that we have referred to in this annual report, completely and with the understanding that our actual future results may be materially different from what we expect.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

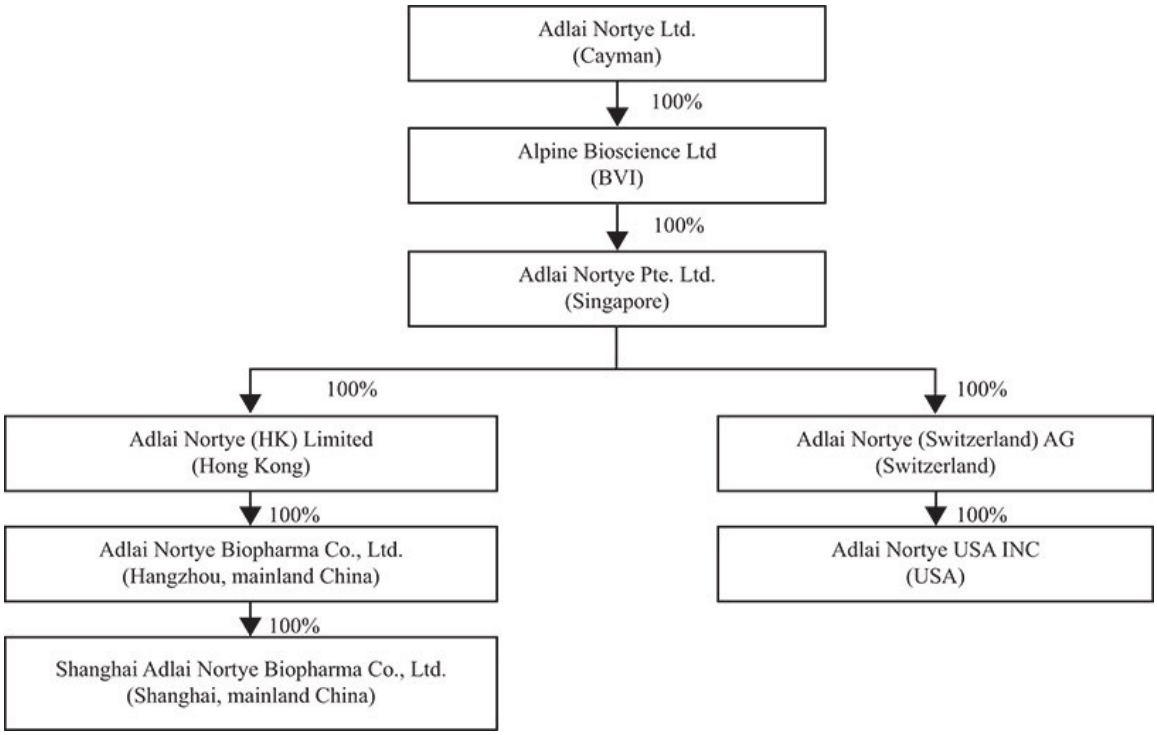
ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

Our Organizational Structure

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



Cash Transfers and Dividend Distributions

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.

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 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. 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.

As of the date of this annual report, our Cayman Islands holding company has not declared or paid any dividends or distributions on equity to its shareholders. 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., our Cayman Islands holding company, 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 "Item 10. Additional Information—E. 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 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.

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 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.

	For the Year Ended December 31,		
	2021	2022	2023
	US$	US$ (in thousands)	US$
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)	18,670	24,035	32,369
Capital contributions from Adlai Nortye (HK) Limited (Hong Kong) to its mainland China subsidiaries	33,960	19,394	10,826
Capital contributions from Adlai Nortye (HK) Limited (Hong Kong) to its non-mainland China subsidiaries	—	—	—
Capital contributions from Adlai Nortye Pte Ltd.(Singapore) to Adlai Nortye USA Inc.(US)	—	—	3,750
Intercompany Loan			
Intercompany loans from Adlai Nortye Ltd. (Cayman) to Adlai Nortye (HK) Limited (Hong Kong)	46,794	10,900	8,350
Intercompany loans from Adlai Nortye Ltd. (Cayman) to Adlai Nortye Pte Ltd.(Singapore)	—	—	11,500
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	257	—	—
Intercompany loans from Adlai Nortye Ltd. (Cayman) to Adlai Nortye USA Inc. (United States)	84	—	—
Intercompany loans from Adlai Nortye Ltd. (Cayman) to our non- mainland China subsidiaries	—	—	—
Intercompany loans from Adlai Nortye Pte Ltd. (Singapore) to Adlai Nortye Ltd. (Cayman)	—	—	12,280
Intercompany loans from Adlai Nortye Pte Ltd.(Singapore) to Adlai Nortye (HK) Limited (Hong Kong)	—	—	1,200
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	11,738
Intercompany loans from Adlai Nortye Biopharma Co.,Ltd to Hangzhou Tangchuang Weilai Technolegy Co., Ltd			51
Intercompany loans repaid by Shanghai Adlai Nortye Biopharma Co., Ltd to Adlai Nortye Biopharma Co., Ltd	—	—	7,210
Intercompany loans repaid by Adlai Nortye (HK) Limited (Hong Kong) to Adlai Nortye Ltd. (Cayman)	—	—	355
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	—	—	—
Intercompany loans repaid by Adlai Nortye USA Inc. (United States) to Adlai Nortye Ltd. (Cayman)	—	—	780
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)	—	—	—

The Holding Foreign Companies Accountable Act

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 "Item 3. Key Information—D. Risk Factors — Risks relating to our operation in the People's Republic of China." for a detailed discussion.

Our Operations are subject to PRC Laws and Regulations

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 evolving PRC laws and regulations. Recently, the PRC government has indicated an intent to strengthen regulatory oversight 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, 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 Commission, or the CSRC, or other PRC governmental authorities in connection with offshore offerings 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 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 uncertain as to how quickly the legislative or administrative regulation making bodies in China will respond to companies, 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 "Item 3. Key Information—D. Risk Factors — Risks relating to our operation in the People's Republic of China." The laws and regulations in China may change from time to time. These potential changes, as well as 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.

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Summary of Risk Factors

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.
- We may face force majeure risks.

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

- We have the majority of our operations in China and are subject to evolving PRC laws and regulations. Recently, the PRC government has indicated an intent to strengthen regulatory oversight 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. We may be subject to the approval, filing or other requirements of the CSRC or other PRC governmental authorities in connection with offshore offerings under current PRC laws, regulations and rules. See "Item 3. Key Information—D. 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 our offshore offerings 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, the implementation and interpretation of the Revised CAC Measures, and the decision as to 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, will be determined on an ad hoc basis depending on the facts and circumstances. See " Item 3. Key Information—D. 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 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 "Item 3. Key Information—D. 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 interpretation and enforcement of PRC laws, rules and regulations could materially and adversely affect us. See "Item 3. Key Information—D. Risk Factors — Risks relating to our operation in the People's Republic of China — Uncertainties with respect to the interpretation and enforcement of laws, and changes in laws and regulations in China could materially and adversely affect us."

- The Chinese government may intervene or influence our operations in accordance with laws and regulations, or may strengthen regulatory oversight 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 "Item 3. Key Information—D. Risk Factors — Risks Relating to our operation in the People's Republic of China — The PRC government may 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 "Item 3. Key Information—D. 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 the ADSs

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

Risks Relating 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$42.1 million, US$54.5 million, and US$58.2 million, for the years ended December 31, 2021, 2022 and 2023, 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.

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 annual report. 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 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, 2023, 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 enrollment 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.

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 "Item 4. Information on the Company—B. Business Overview— 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 enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated; and
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated.

In addition, some of our drug candidates are still considered as emerging 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 our initial public 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 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. If a prolonged government shutdown occurs, 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 "Item 4. Information on the Company—B. Business Overview— Regulation — PRC laws and regulations — PRC drug regulatory regime." in this annual report.

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. On September 29, 2023, such preferred shares had been automatically converted into our Class A ordinary shares upon the closing of our initial public offering. As a result, we are not profitable currently and have incurred net losses. Our net loss was US$56.7 million, US$58.8 million, and US$104.9 million for the years ended December 31, 2021, 2022 and 2023, respectively. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs, financial liabilities at FVTPL, 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$3.0 million, US$43.2 million and US$56.7 million, for the years ended December 31, 2021, 2022, and 2023, respectively.

We believe our available financial resources, including cash and cash equivalents and the estimated net proceeds from our initial public offering and the concurrent private placement will be sufficient to meet our anticipated cash needs for the next 12 months from the date of this annual report. 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 as of December 31, 2022 as well as accumulated deficits as of December 31, 2021, 2022 and 2023.

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$246.3 million and net current assets of US$50.9 million as of December 31, 2022 and 2023. In addition, we had net liabilities of US$185.4 million, US$241.3 million and net assets of US$79.4 million, as of December 31, 2021, 2022 and 2023, 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 automatically converted into shares upon completion of our initial public offering, at which time our working capitals turned 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 and 2022 and 2023, we recorded financial assets at FVTPL of US$53.8 million, US$21.3 million and US$7.0 thousand, respectively. 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, 2021, 2022, and 2023, we incurred share-based payment expenses of US$3.4 million, US$6.1 million, and US$4.3 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 our initial public 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 annual report, we and our independent registered public accounting firm identified 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 "Item 15. Controls and Procedures — 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 "Item 15. Controls and Procedures." 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.

We are subject to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. Section 404 of such Act, which requires 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 annual report 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.

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 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.

Mr. Yang Lu, our co-founder, chairman and the chief executive officer, may face a divorce lawsuit against him. If a case is brought to a court, and the court rules in favor of Mr. Lu's spouse, it could be detrimental to our business and reputation. For example, the litigation proceedings could divert a significant amount of Mr. Lu's attention and other resources from our business and operations, which could harm our results of operations. Also, the publicity of the divorce lawsuit could damage our brand or have material adverse effect on our business, results of operations and financial condition.

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.

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.

Cybersecurity 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 cybersecurity 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 approximately US$2,000.0, US$2.1 million and US$3.3 million for the years ended December 31, 2021, 2022, and 2023. 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 operational risks associated with being based in and having operations in China also apply to operations in Hong Kong and Macau. With respect to the legal risks associated with being based in and having operations in China, the laws, regulations and discretion of the governmental authorities in China discussed in this annual report are expected to apply to entities and businesses in mainland China, rather than to entities or businesses in Hong Kong and Macau which operate under different sets of laws from those of mainland China.

The approval, filing, or other procedures of the CSRC or other PRC regulatory authorities may be required in connection with our offshore offerings 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 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. Where a domestic company seeks to conduct indirect overseas offerings and listings, the issuer shall designate a major domestic operating entity. This entity shall act as the domestic responsible entity and be responsible for filing with 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 "Item 4. Information on the Company—B. Business Overview—Regulation — Regulations on M&A Rules and Overseas Listings."

If the filing procedure with the CSRC under the Trial Measures is required for any future offerings or any other capital raising activities, it is uncertain whether it would be possible for us to complete the filing, or how long it will take us to do so. Failure to complete the required filing may result in an investigation by the relevant authorities, as well as fines or penalties, and could lead to an order prohibiting us from conducting an offering. These risks have the potential to cause a material adverse change in our operations and the value of our ordinary shares. Moreover, they could significantly limit or completely hinder our ability to offer or continue to offer securities to investors, or cause such securities to significantly decline in value or become worthless.

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.

In addition, we cannot assure you that any new rules or regulations promulgated in the future will not impose additional requirements on us. If it is determined in the future that we are subject to the approval of the CSRC for our offshore offerings, 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 our offshore offerings, 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 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 the trading price of our listed securities.

The CSRC or other PRC regulatory authorities also may take actions requiring us, or making it advisable for us, to halt our offshore offerings before settlement and delivery of the shares offered. Consequently, if investors engage in market trading or other activities in anticipation of and prior to settlement and delivery, they do so at the risk that settlement and delivery may not occur. In addition, if any regulatory authorities later promulgate new rules or explanations requiring that we obtain their approvals or accomplish the required filing or other regulatory procedures for our 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. The procedure for obtaining such waiver must still be determined in conjunction with the legal and regulatory requirements in effect at the time. Concerning such approvals, filings, or other requirements, if they are not timely met, or if there are any negative reports or other unforeseeable circumstances, it could materially and adversely affect our business, prospects, financial condition, reputation, and this offering, and the trading price of our listed securities.

The impact of the CAC's increasing oversight over data security remains 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 annual report, 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 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 annual report.

However, the implementation and interpretation of the Revised CAC Measures , and the decision as to 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, will be determined on an ad hoc basis depending on the facts and circumstances. 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, regulation of foreign exchange and allocation of resources. 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 to varying degrees between different industries or different regions within the country. 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 interpretation and enforcement of laws, and changes in laws and regulations in China 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. Prior court decisions may be cited for reference but have limited precedential value. 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, will be determined on an ad hoc basis depending on the facts and circumstances. The laws and regulations are sometimes vague and the government authorities have a certain degree of discretion within their scope of authority to interpret and enforce such laws and regulations, and we may not accurately predict the results of their official interpretation and enforcement; these laws and regulations are subject to change in the future and there may be limited advance notice of such changes before they become effective or we may not have the opportunity to address such newly promulgated regulatory requirements in a timely manner. 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 is still in the process of perfecting its 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, 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, and some of which may have a retroactive effect. In view of the fact that we may be unable to be aware of or foresee some regulations, policies, and internal rules, along with their possible occasional adjustments, we may not become aware of our violation of these policies and rules until sometime after the violation has occurred. Any administrative and court proceedings in China or any jurisdiction where we operate our business may result in additional costs and diversion of resources and management attention. However, since administrative and court authorities have the right to exercise conclusive discretion and judgment in interpreting and implementing statutory and contractual terms, depending on the facts and circumstances, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy. 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 may exert influence on our operations in mainland China.

The PRC government has significant authority to exert influence on our operations in mainland China in various aspects in accordance with laws and regulations. Therefore, uncertainties in the PRC laws and regulations from time to time 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 affect 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.

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:

- changes in political or 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 this annual report, 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 are subject to these rules after our initial public 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 regulation in China.

Currently, the RMB cannot be freely converted into any foreign currency. The PRC government regulates 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 regulatory 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

The trading price of our ADSs may be volatile regardless of our operating performance, which could result in substantial losses to you.

The trading price of our 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 the above factors, the price and trading volume for our 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.

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 adopt a dual-class share structure such that our ordinary shares are divided into Class A ordinary shares and Class B ordinary shares. In respect of matters requiring the votes of shareholders, holders of Class A ordinary shares are entitled to one vote per share, while holders of Class B ordinary shares are entitled to 15 votes per share based on our proposed dual-class share structure. 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.

Our founder, Mr. Yang Lu beneficially owns all of our issued Class B ordinary shares. These Class B ordinary shares constitute approximately 15.3% of our total issued and outstanding share capital and 73.1% 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, as of the date of this annual report. As a result of the dual-class share structure and the concentration of ownership, the holder of our Class B ordinary shares has 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.

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 the proceeds from our initial public 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 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.

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 currently effective 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 currently effective 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 as well as 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 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 of substantial amounts of the ADSs could adversely affect their market price.

Sales of substantial amounts of our ADSs in the public market, or the perception that these sales could occur, could adversely affect the market price of our ADSs and could materially impair our ability to raise capital through equity offerings in the future. Shares held by our existing shareholders may be sold in the public market in the future subject to the restrictions in Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act and the applicable lock-up agreements. Certain holders of our ordinary shares may cause us to register under the Securities Act the sale of their shares. Registration of these shares under the Securities Act would result in ADSs representing these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. 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.

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). 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 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 this annual report 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 currently effective 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. 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 "Item 10. Additional Information—B. Memorandum and Articles of Association."

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;
- have regularly scheduled executive sessions with only independent directors each year;
- solicit proxies and hold meetings of our shareholders every year; or
- obtain shareholders' approval for certain issuances of securities, including shareholders' approval of stock option plans.

We may rely on home country practice with respect to our corporate governance. 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$1.235 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.

The deposit agreement 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) shall have exclusive jurisdiction over any suit, action or proceeding arising out of or relating in any way to the ADSs or the deposit agreement, which could limit the ability of owners and holders of the ADSs or other securities to obtain a favorable judicial forum for disputes with us, our directors and officers, the depositary, and potentially others.

The deposit agreement 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) shall have exclusive jurisdiction over any suit, action or proceeding against or involving us or the depositary, arising out of or relating in any way to the deposit agreement or the transactions contemplated thereby or by virtue of owning the ADSs. 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 or unenforceable. If a court were to find the federal choice of forum provision contained in the deposit agreement 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 provision in the deposit agreement may limit a security-holder's ability to bring a claim against us, our directors and officers, the depositary, and potentially others in his or her preferred judicial forum, and this limitation may result in increased costs for investors to bring lawsuits and discourage such lawsuits. Owners and holders of the ADSs will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder pursuant to the exclusive forum provision in the deposit agreement. In addition, the forum selection provision of the deposit agreement does not affect the right of an ADS holder or the depositary to require any claim against us, including a federal securities law claim, to be submitted to arbitration or to commence an action in any court in aid of that arbitration provision, or to enter judgment upon or enforce any arbitration award.

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 our initial public 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.

We are 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 are a "controlled company" as defined under the Nasdaq Stock Market listing rules because Mr. Yang Lu, our founder, controls more than 50% of our total voting power. Pursuant to our currently effective 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 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 "Item 3. Key Information—D. Risk Factors — Risks Relating 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 may 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 in ADSs or ordinary shares.

Based on current estimates of our gross income and the value of our gross assets (including goodwill) and the manner in which we conduct our business, we do not believe that we were a passive foreign investment company ("PFIC") for U.S. federal income tax purposes for the taxable year ended December 31, 2023. However, because PFIC status depends on the composition of a company's income and assets and the market value of its assets from time to time, there can be no assurance that we will not be a PFIC for any taxable year.

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. With certain exceptions, we do not currently generate any income from our primary business, and our gross income is currently comprised primarily of interest and other investment income (which is passive) and governmental grants and the option grant fee from Nippon Kayaku (the "Option Grant Fee") (which are both likely to be active income). Therefore, our PFIC status under the income test for any taxable year in which we do not generate significant income from our primary business, including the current taxable year, will likely depend on the relative amounts of government grants and the Option Grant Fee against the amounts of interest and other passive income we earn. The receipt of governmental grants is subject to various conditions and there can be no assurance that we will continue to receive governmental grants in future taxable years or as to the amount of governmental grants that we will receive in any taxable year. Additionally, the Option Grant Fee is not a reoccurring payment in future taxable years. Further, we will hold a substantial amount of cash and cash equivalents following the offering and while we continue to do so, our PFIC status for any taxable year will depend on the value of our goodwill. The value of our goodwill may be determined, in large part, by reference to the market price of our ADSs, which is likely to be volatile given the nature of our business and the current market conditions. Therefore, 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 our initial public offering and the concurrent private placement is substantial in comparison with the gross income from our business operation. Accordingly, we cannot assure you that we will not become a PFIC for the current or any future taxable year.

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 "Item 10. Additional Information—E. Taxation — United States Federal Income Tax Considerations." 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 ADSs or ordinary shares including the availability and the advisability of making certain elections under the PFIC rules.

We 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."

As a public company, we 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.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

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 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, the People's Republic of China. Our agent for service of process in the United States is Cogency Global Inc., with the address at 122 East 42nd Street, 18th Floor, New York, NY 10168.

In September 2023, we became a publicly traded company on the Nasdaq under the symbol "ANL." Our reports filed with or furnished to the SEC are available on our website at *https://www.adlainortye.com* as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The information contained on our websites is not a part of this annual report. The SEC maintains a website at *http://www.sec.gov* that contains reports and other information regarding us and other companies that file materials with the SEC electronically.

B. Business Overview

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 and developed a robust pipeline of six drug candidates. Currently, our pipeline includes three clinical-stage drug candidates, buparlisib (AN2025), palupiprant (AN0025), and AN4005, as well as three 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 completed the patient enrollment of this trial in November 2023. 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 to evaluating the combination of AN0025 and pembrolizumab, AN0025 is also being developed as a potential enhancer of radiotherapy in different indications. A phase 1b study to assess the safety, tolerability and efficacy of AN0025 in combination with definitive CRT in patients with locally advanced esophageal cancer is underway while another phase 1b study to evaluate AN0025 in combination with RT/CRT for the treatment of preoperative rectal cancer has been completed. 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 three in-house preclinical programs which we believe have high global commercial viability. Our preclinical candidates include: AN8025, a multifunctional antibody as T cell and antigen-presenting cell ("APC") modulator; AN1025, an oral small molecule degrader of β-catenin; and AN9025, an oral small molecule pan-KRAS inhibitor. We anticipate submitting the IND for AN8025 in the first half of 2025.

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; OS = overall survival; TNBC = Triple Negative Breast Cancer; NSCLC = Non-Small Cell Lung Cancer; MSS CRC = Microsatellite Stable Colorectal Cancer; UC = Urothelial Cancer, CC = Cervical Cancer; RP2D = Recommended Phase 2 Dose; RC = rectal cancer; LA = locally advanced; EC = esophageal cancer; FPI: first patient in; IND: Investigational New Drug; PCC: Pre-Clinical Candidate

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. We completed patient enrollment of the Phase III trial in November 2023, enrolling 487 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 OS data as primary endpoint, we expect to submit the NDA to the FDA in the first half of 2025, 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. We have completed the patient enrollment in the U.S. and France, and expect to obtain top-line results in the first half of 2024. 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. In addition to evaluating the combination of AN0025 and pembrolizumab, AN0025 is also being developed as a potential enhancer of radiotherapy in different indications. A phase 1b study to assess the safety, tolerability and efficacy of AN0025 in combination with definitive CRT in patients with locally advanced esophageal cancer is underway and the clinical update will be presented in ASCO 2024 as online poster. We also completed a phase 1b study to evaluate AN0025 in combination with RT/CRT for the treatment of preoperative rectal cancer and we have just initiated a phase II study in collaboration with Leeds University for further development.

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 first half of 2024.

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 first half of 2024.

Our preclinical programs

We continue actively advancing three in-house preclinical programs which we believe have high global commercial viability. Our preclinical candidates include: AN8025, a multifunctional antibody as T cell and APC modulator; AN1025, an oral small molecule degrader of β-catenin; and AN9025, an oral small molecule pan-KRAS inhibitor. We anticipate submitting the IND for AN8025 in the first half of 2025.

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.

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

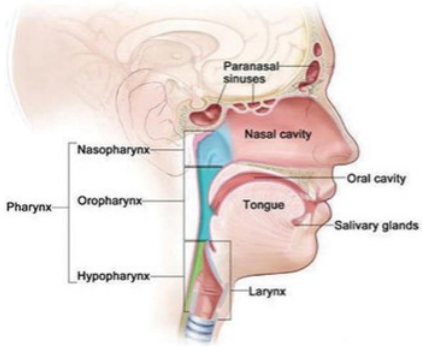
Overview

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-PD-1/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 completed the patient enrollment in November 2023 and expect to submit an NDA to the FDA, provided the OS benefit readout, in the first half of 2025, followed by further marketing approval applications to the NMPA, EMA, PMDA, and other authorities. To the best of our knowledge, AN2025 is currently the most advanced 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.

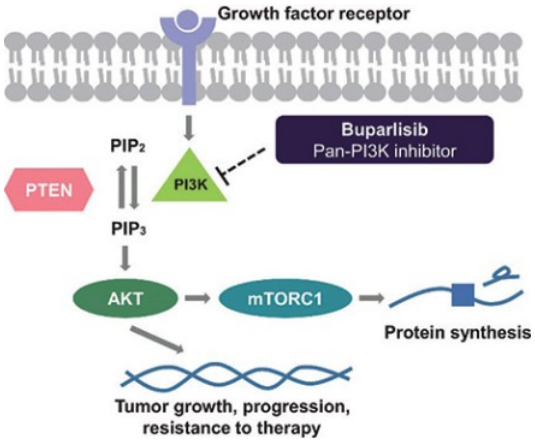
Mechanism of action

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.

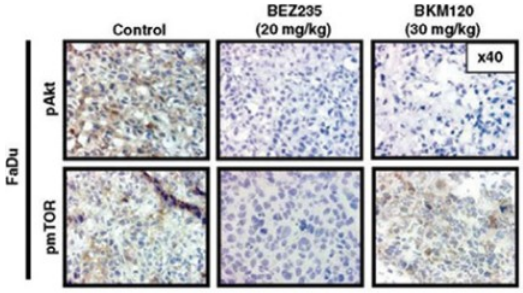
Evidence suggests that constitutive PI3K activation is a critical step in mediating the transforming potential and growth stimulating activity of various oncogenes and tumor suppressors, which contribute to the onset and growth of many solid tumors as well as tumors of the hematopoietic system. Activation 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

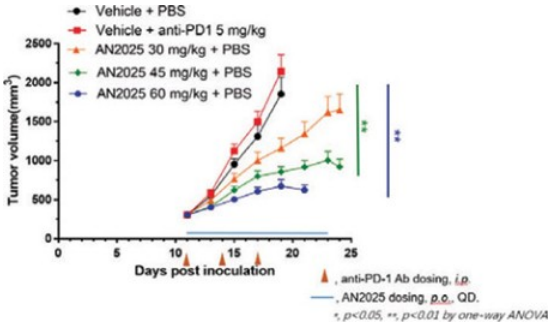
In a study conducted on mice transfected with FaDu cells, an HNSCC cell line, AN2025 (previously known as BKM120) showed down regulation of AKT in tumor in the animals treated with doses equivalent to patient's maximum tolerated dose ("MTD"), to an extent more significant than BEZ235 (also known as dactolisib, 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/m2 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.

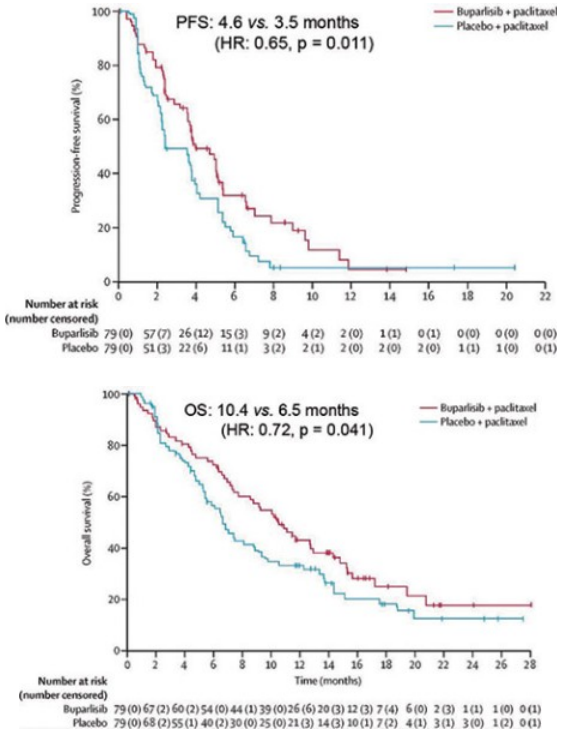
Demographic and baseline characteristics. The following table sets forth the age, demographic, and ECOG for the 158 randomized patients.

	AN2025 arm N=79	Placebo arm N=79
Median age in years (25th – 75th 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%). A summary of SAEs of AN2025 plus paclitaxel combination and placebo plus paclitaxel combination is set out below.

	Buparlisib + Paclitaxel Affected / at Risk (%)	Buparlisib Matching Placebo + Paclitaxel Affected / at Risk (%)
Total	43/76 (56.58)%	37/78 (47.44)%
Blood and lymphatic system disorders		
Anaemia†1	3/76 (3.95)%	3/78 (3.85)%
Febrile neutropenia†1	1/76 (1.32)%	1/78 (1.28)%
Leukopenia†1	1/76 (1.32)%	0/78 (0.00)%
Neutropenia†1	2/76 (2.63)%	0/78 (0.00)%
Thrombocytopenia†1	1/76 (1.32)%	0/78 (0.00)%
Cardiac disorders		
Cardiac arrest†1	1/76 (1.32)%	1/78 (1.28)%
Sinus bradycardia†1	0/76 (0.00)%	1/78 (1.28)%
Endocrine disorders		
Hypercalcaemia of malignancy†1	0/76 (0.00)%	1/78 (1.28)%
Eye disorders		
Blindness†1	0/76 (0.00)%	1/78 (1.28)%
Gastrointestinal disorders		
Abdominal pain†1	2/76 (2.63%)	1/78 (1.28%)
Aorto-oesophageal fistula†1	1/76 (1.32%)	0/78 (0.00%)
Diarrhoea†1	4/76 (5.26%)	0/78 (0.00%)
Dysphagia†1	2/76 (2.63%)	3/78 (3.85%)
Gastrointestinal haemorrhage†1	1/76 (1.32%)	0/78 (0.00%)
Mouth haemorrhage†1	0/76 (0.00%)	2/78 (2.56%)
Nausea†1	1/76 (1.32%)	0/78 (0.00%)
Oesophageal obstruction†1	0/76 (0.00%)	1/78 (1.28%)
Oesophagitis†1	1/76 (1.32%)	0/78 (0.00%)
Oral cavity fistula†1	1/76 (1.32%)	0/78 (0.00%)
Stomatitis†1	1/76 (1.32%)	0/78 (0.00%)
Upper gastrointestinal haemorrhage†1	1/76 (1.32%)	0/78 (0.00%)
Vomiting†1	2/76 (2.63%)	0/78 (0.00%)
General disorders		
Asthenia†1	2/76 (2.63%)	2/78 (2.56%)
Face oedema†1	0/76 (0.00%)	2/78 (2.56%)
Fatigue†1	1/76 (1.32%)	4/78 (5.13%)
General physical health deterioration†1	3/76 (3.95%)	0/78 (0.00%)
Non-cardiac chest pain†1	1/76 (1.32%)	2/78 (2.56%)
Pain†1	0/76 (0.00%)	1/78 (1.28%)
Pyrexia†1	0/76 (0.00%)	2/78 (2.56%)
Systemic inflammatory response syndrome†1	0/76 (0.00%)	1/78 (1.28%)
Hepatobiliary disorders		
Hepatic failure†1	1/76 (1.32%)	0/78 (0.00%)
Jaundice†1	1/76 (1.32%)	0/78 (0.00%)
Infections and infestations		
Anal abscess†1	2/76 (2.63%)	0/78 (0.00%)
Bronchitis†1	1/76 (1.32%)	2/78 (2.56%)

Candida sepsis†1	1/76 (1.32%)	0/78 (0.00%)
Chest wall abscess†1	0/76 (0.00%)	1/78 (1.28%)
Clostridium difficile colitis†1	1/76 (1.32%)	0/78 (0.00%)
Erysipelas†1	0/76 (0.00%)	1/78 (1.28%)
Herpes zoster†1	1/76 (1.32%)	0/78 (0.00%)
Lower respiratory tract infection†1	0/76 (0.00%)	1/78 (1.28%)
Lung abscess†1	1/76 (1.32%)	1/78 (1.28%)
Lung infection†1	2/76 (2.63%)	0/78 (0.00%)
Pneumonia†1	6/76 (7.89%)	6/78 (7.69%)
Post procedural infection†1	1/76 (1.32%)	0/78 (0.00%)
Pulmonary tuberculosis†1	1/76 (1.32%)	0/78 (0.00%)
Respiratory tract infection†1	1/76 (1.32%)	0/78 (0.00%)
Sepsis†1	0/76 (0.00%)	1/78 (1.28%)
Septic shock†1	3/76 (3.95%)	1/78 (1.28%)
Urinary tract infection†1	1/76 (1.32%)	0/78 (0.00%)
Wound infection†1	2/76 (2.63%)	0/78 (0.00%)
Injury, poisoning and procedural complications		
Femur fracture†1	0/76 (0.00%)	1/78 (1.28%)
Post procedural discharge†1	1/76 (1.32%)	0/78 (0.00%)
Post procedural fistula†1	0/76 (0.00%)	1/78 (1.28%)
Post procedural haemorrhage†1	0/76 (0.00%)	1/78 (1.28%)
Spinal compression fracture†1	0/76 (0.00%)	1/78 (1.28%)
Ivestigations		
Blood creatinine increased†1	1/76 (1.32%)	0/78 (0.00%)
Neutrophil count decreased†1	1/76 (1.32%)	0/78 (0.00%)
Metabolism and nutrition disorders		
Cachexia†1	1/76 (1.32%)	3/78 (3.85%)
Decreased appetite†1	3/76 (3.95%)	2/78 (2.56%)
Dehydration†1	2/76 (2.63%)	1/78 (1.28%)
Hypercalcaemia†1	1/76 (1.32%)	1/78 (1.28%)
Hyperglycaemia†1	3/76 (3.95%)	0/78 (0.00%)
Hypocalcaemia†1	1/76 (1.32%)	0/78 (0.00%)
Hypoglycaemia†1	1/76 (1.32%)	0/78 (0.00%)
Hypokalaemia†1	1/76 (1.32%)	2/78 (2.56%)
Hypomagnesaemia†1	1/76 (1.32%)	0/78 (0.00%)
Musculoskeletal and connective tissue disorders		
Spinal pain†1	1/76 (1.32%)	0/78 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Cancer pain†1	0/76 (0.00%)	1/78 (1.28%)
Malignant neoplasm progression†1	0/76 (0.00%)	1/78 (1.28%)
Tumour haemorrhage†1	3/76 (3.95%)	5/78 (6.41%)
Tumour invasion†1	0/76 (0.00%)	1/78 (1.28%)
Nervous system disorders		
Dizziness†1	0/76 (0.00%)	1/78 (1.28%)
Hypoaesthesia†1	1/76 (1.32%)	0/78 (0.00%)
Intracranial pressure increased†1	0/76 (0.00%)	1/78 (1.28%)
Ischaemic cerebral infarction†1	1/76 (1.32%)	0/78 (0.00%)
Neuralgia†1	1/76 (1.32%)	0/78 (0.00%)
Paraplegia†1	1/76 (1.32%)	0/78 (0.00%)
Somnolence†1	1/76 (1.32%)	0/78 (0.00%)
Spinal cord compression†1	1/76 (1.32%)	0/78 (0.00%)
Syncope†1	1/76 (1.32%)	2/78 (2.56%)
Product Issues		
Device connection issue†1	1/76 (1.32%)	0/78 (0.00%)

Psychiatric disorders		
Acute psychosis†1	0/76 (0.00%)	1/78 (1.28%)
Aggression†1	1/76 (1.32%)	0/78 (0.00%)
Completed suicide†1	1/76 (1.32%)	0/78 (0.00%)
Mental status changes†1	1/76 (1.32%)	0/78 (0.00%)
Renal and urinary disorders		
Renal failure†1	1/76 (1.32%)	0/78 (0.00%)
Respiratory, thoracic and mediastinal disorders		
Acute respiratory failure†1	0/76 (0.00%)	2/78 (2.56%)
Dyspnoea†1	2/76 (2.63%)	2/78 (2.56%)
Haemoptysis†1	1/76 (1.32%)	1/78 (1.28%)
Pneumonia aspiration†1	1/76 (1.32%)	0/78 (0.00%)
Pneumonitis†1	1/76 (1.32%)	0/78 (0.00%)
Pneumothorax†1	1/76 (1.32%)	2/78 (2.56%)
Pulmonary embolism†1	1/76 (1.32%)	0/78 (0.00%)
Respiratory arrest†1	1/76 (1.32%)	1/78 (1.28%)
Respiratory failure†1	1/76 (1.32%)	2/78 (2.56%)
Upper airway obstruction†1	1/76 (1.32%)	0/78 (0.00%)
Skin and subcutaneous tissue disorders		
Erythema†1	1/76 (1.32%)	0/78 (0.00%)
Vascular disorders		
Arterial rupture†1	1/76 (1.32%)	0/78 (0.00%)
Hypotension†1	1/76 (1.32%)	1/78 (1.28%)
Phlebitis†1	1/76 (1.32%)	0/78 (0.00%)

Notes:
1 Term from vocabulary, MedDRA (19.1)
† Indicates events were collected by systematic assessment
Source: clinicaltrials. gov

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/m2) 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. We completed the patient enrollment in November 2023 and submit an NDA to the FDA, provided the OS readout benefit, in the first half of 2025, 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. 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 III trial include: (1) Ficlatuzumab, an anti-HGF/c-MET antibody, in combination with cetuxima, developed by LG Chem/AVEO; the study was initiated in November 2023, targeting HPV negative patients; and (2) MRG003, an EGFR-ADC, developed by Lepu Biopharma; the China-only trial was initiated in March 2023; Phase II trial include: (1) Petosemtamab, an EGFR/LGR5 bispecific antibody, developed by Merus; it expects to initiate Phase III study in mid 2024; (2) 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; (3) Palbociclib in combination with cetuximab, targeting the HPV negative patients with CDKN2A mutation; and (4) ISA101, a cancer vaccine, in combination with cemiplimab, developed by ISA Pharma, targeting HPV positive patients.

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. We are also developing AN0025 as a potential enhancer of radiotherapy in locally advanced esophageal cancer. For more details, see "— License and Collaboration Agreements — Supply agreement with MSD." We have completed the patient enrollment of this trial in the U.S. and France and expect to obtain proof of concept clinical results in the first half of 2024.

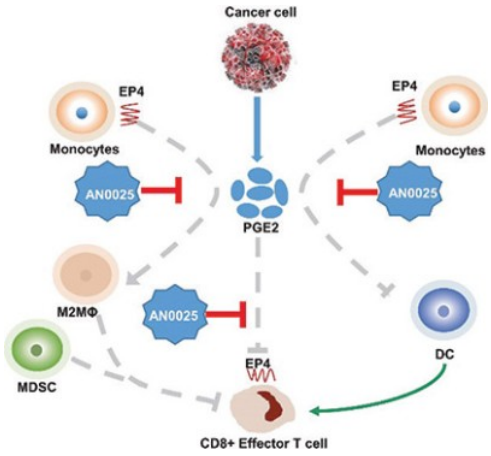
Mechanism of action

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.

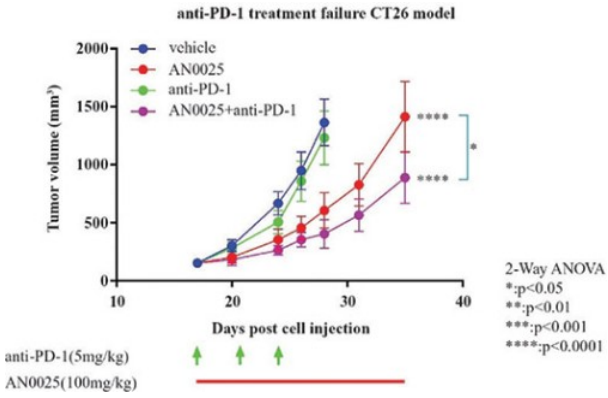
Our AN0025, a small molecule EP4 antagonist, is designed to prevent the binding of PGE2 to its EP4 receptor to change the immunosuppressive character of the tumor microenvironment. By blocking the downstream signaling of PGE2/EP4 pathway, AN0025 is designed to inhibit the differentiation and accumulation 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

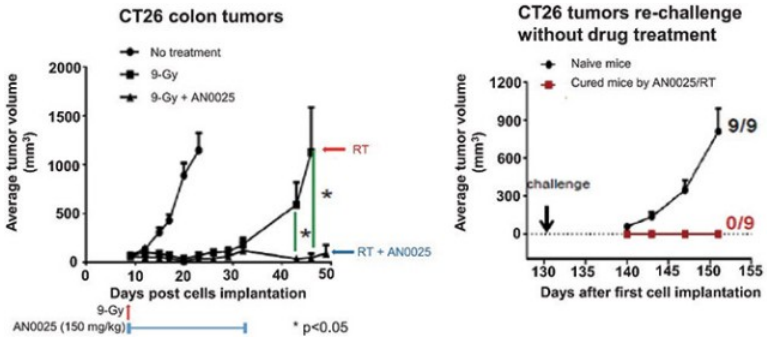
Animal studies supported the combination of AN0025 with PD-1 inhibitor for treating tumors that are not responsive to anti-PD-1 therapy. In the CT26 murine colon cancer model, a portion of non-responders after anti-PD-1 treatment were selected, re-grouped and re-treated by combining AN0025 with an anti-PD-1 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. We have completed the patient enrollment of this trial in the U.S. and France. We expect to obtain topline results of this trial in the first half of 2024, 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.

Phase Ib study for AN0025 in combination with chemoradiotherapy ("CRT") in locally advanced esophageal cancer

Trial design. This is an open-label, multicenter, phase Ib study to evaluate the safety, tolerability, and preliminary efficacy of AN0025 in combination with definitive CRT in patients with locally advanced/locally recurrent esophageal cancer in China. The study will include a dose escalation phase (DLT observation and determining MTD/RP2D) followed by an expansion phase. Based on the dose escalation study, an appropriate dose (RP2D) will be selected for the expansion phase, where approximately 40 patients will be enrolled.

CRT will begin with the first dose (Day 1) of study drug AN0025 administration (orally, QD) and will last 15 weeks. CRT consists of a total of 60 Gy (30 fractions) radiation administered in 2.0 Gy daily doses delivered on 5 consecutive days (Monday to Friday) every week for 6 weeks. Concurrent chemotherapy comprised paclitaxel and carboplatin, where paclitaxel (50 mg/m2) was administered intravenously once a week for 4 weeks (Day 1, 8, 15, 22), and carboplatin (AUC 2) was administered intravenously once a week for 4 weeks (Day 1, 8, 15, 22). Consolidation chemotherapy will be administered after concurrent chemoradiotherapy is completed, where the regimen is: 175 mg/m2 of paclitaxel + AUC 5 of carboplatin via intravenous injection at Day 50 (Week 8) and Day 78 (Week 12). Five weeks after the end of CRT (Week 17), patients will continue AN0025 (administered orally, QD) maintenance therapy until the patient experiences disease progression, initiates other anticancer therapy, withdraws consent, dies, experiences unacceptable toxicity, or investigator's decision, whichever occurs earliest.

Trial status and future plan. We have completed the patient enrollment of the dose escalation phase The clinical update will be presented in ASCO 2024 as online poster. Expansion phase is underway.

AN0025 in combination with RT/CRT for the treatment of rectal cancer

Trial design. This was a multicenter, open-label, Phase 1b study of the combination of AN0025 with preoperative chemoradiotherapy in subjects with locally advanced rectal cancer where primary resection without chemoradiotherapy is unlikely to achieve clear margins as defined by MRI. The study comprised AN0025 in combination with long course chemoradiotherapy (LCRT), and AN0025 in combination with short course radiotherapy (SCRT) followed by chemotherapy.

Both arms consisted of 3 study periods. The Neoadjuvant treatment period began with the first dose of AN0025 (Day 1) administration (orally, QD) and continued until the surgery for both LCRT and SCRT. The Postoperative period started at the date of the surgery and lasted 4 weeks after the surgery. The follow-up period started immediately after the end of the Postoperative period and continued as long as the study subject was alive, until the Sponsor terminated the study, or until the subject was lost to follow-up, or withdrew consent.

Trial status and future plan. 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. Given the promising results, we have just initiated a phase II study in collaboration with Leeds University for further development.

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. According to Informa forecast, in 2028, the incidences of neoadjuvant rectal cancer and locally advanced esophageal cancer will reach 19,000 and 9,500, respectively, in the US and 50,000 and 46,700, respectively in the aforementioned seven major markets. Effective treatments are therefore urgently needed to address these unmet medical demands.

Competitive landscape

Based on our knowledge, there are several programs also in early clinical development targeting EP4, including those run by 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

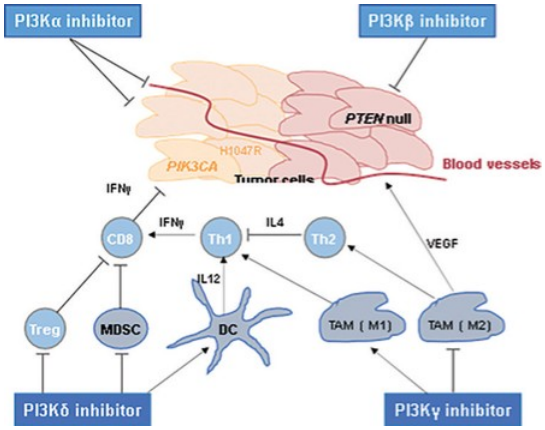
Overview

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 first half of 2024.

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.



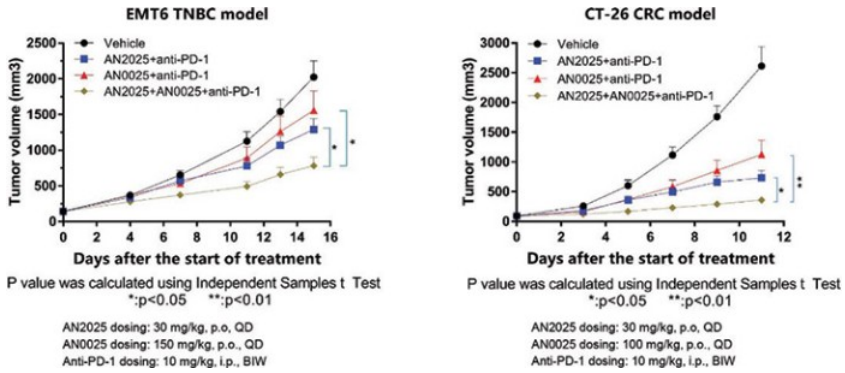
Leveraging the complementary and synergistic antitumor effects of our drug candidates in combination therapies, AN2025 is expected to mechanistically complement and synergize with the combination of anti- PD-1/PD-L1 antibody and AN0025 to form an improved treatment regimen for patients with multiple 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.

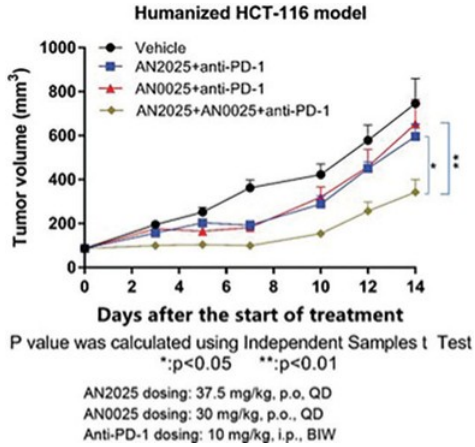
We conducted preclinical studies of the triple combination of AN2025, AN0025, and an anti-PD-1 antibody, and observed encouraging antitumor activity in the following studies. As illustrated by the figures below, the triple combination showed significantly stronger TGI compared with doublet combinations in syngeneic mice models:

Triple combination of AN2025, AN0025, and anti-PD-1 antibody in syngeneic mice models



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 first half of 2024.

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 first half of 2024.

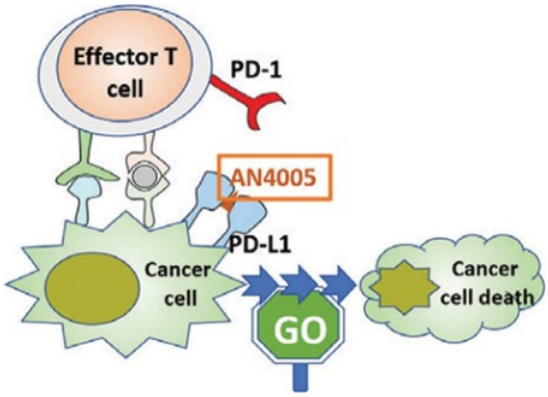
Mechanism of action

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.

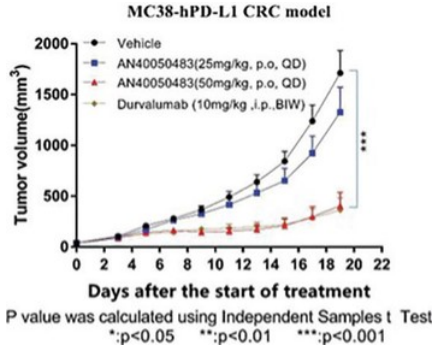
However, like normal cells, a wide range of cancer cells also express PD-L1 protein on the cell surface and sometimes in a vast amount. As a result, cancer cells can pretend to be normal cells by interacting with PD-1 on the T cells through their cell surface PD-L1 and thus avoid being attacked by the 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.

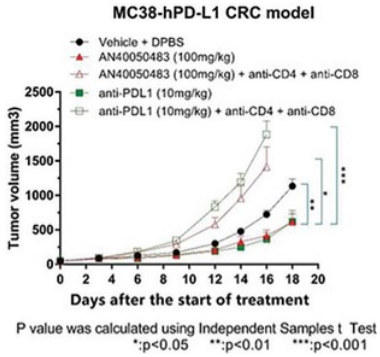


Summary of preclinical results

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 first half of 2024.

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.

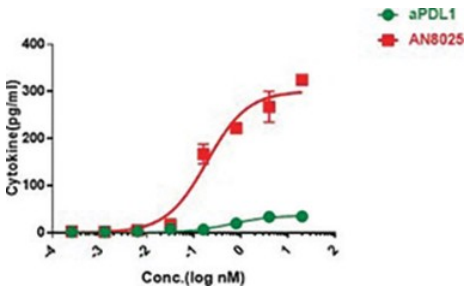
Our preclinical programs

AN8025: a T cell and APC modulator

AN8025 is an in-house developed multifunctional antibody, which serves asaT cell and APC modulator. We have already nominated the development candidate and expect to submit the IND in the first half of 2025.

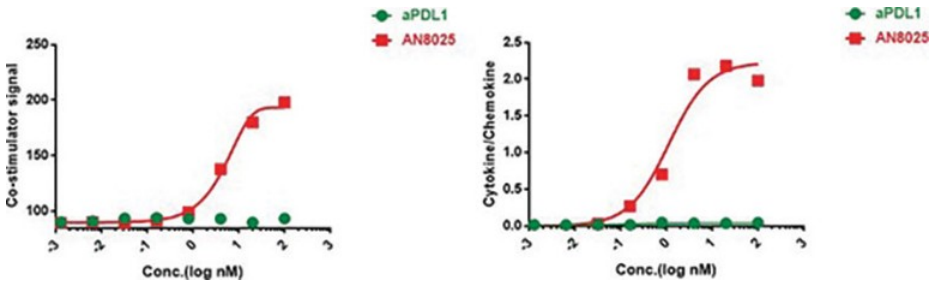
To confirm the ability of AN8025 to stimulate T cell activation, we conducted an enzyme-linked immunosorbent assay ("ELISA") to measure cytokine concentrations in vitro. The results demonstrated that AN8025 provides almost eight times cytokine concentration induced by an anti-PD-L1 mAb.

Comparison of T-cell activation by AN8025 and anti-PD-L1 mAb



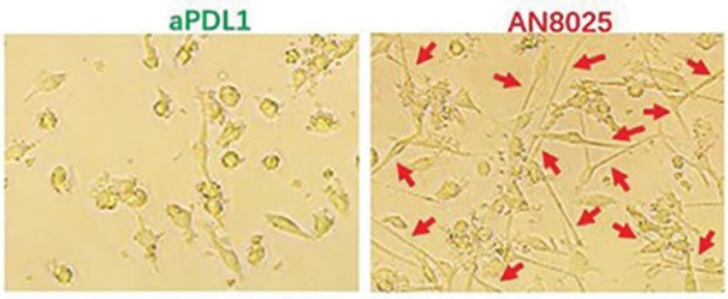
We also tested the T cell co-stimulation and relevant cytokines/chemokines to determine and compare AN8025's ability to fully induce immune response in vitro. Compared to an anti-PD-L1 mAb, where almost no co-simulation signals were detected, AN8025 showed significantly stronger co-stimulation signals, 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

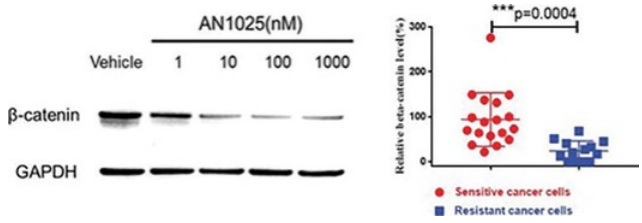


AN1025: a β-catenin degrader

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.

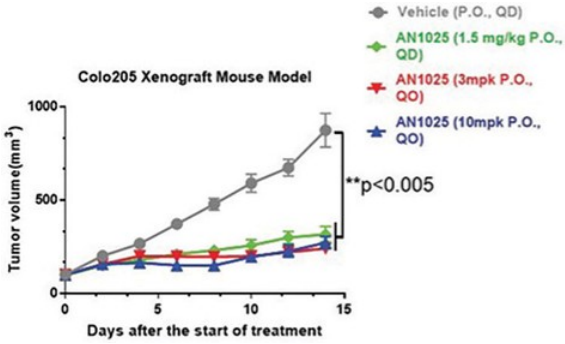
In our preclinical studies, we demonstrated that AN1025 efficiently inhibited Wnt signaling with a low nanomolar IC50. AN1025 treatment led to the reduction of β-catenin (a key component in Wnt signaling pathway) level in tumor cells. In addition, human cancer cell lines with high β-catenin expression 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.

B-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



AN9025: a Pan-KRAS inhibitor

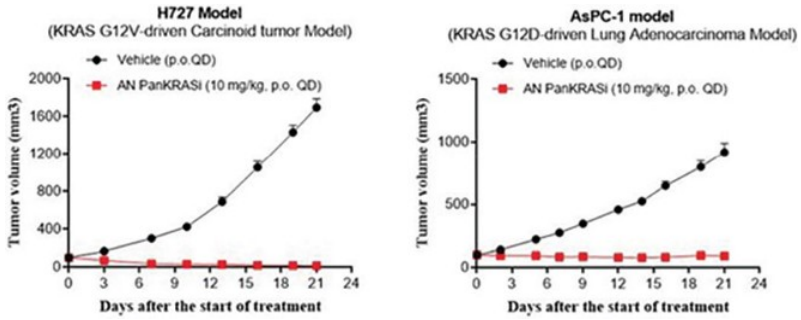
AN9025 is an in-house developed, oral small molecule pan-KRAS inhibitor to address a broad range of Kirsten rat sarcoma viral oncogene homologue ("KRAS") mutations in multiple tumor types. It is currently in the lead optimization phase.

As the most frequently mutated oncogene, KRAS has attracted substantial attention. However, it has been deemed a challenging therapeutic target, and efforts to directly inhibit its function have been continuing for decades. The most successful of these has been the development of covalent allele-specific inhibitors that trap KRAS G12C in its inactive conformation and suppress tumor growth in patients. Therefore, AN9025, as a pan-KRAS inhibitor, represents an urgent unmet medical need to target KRAS mutations other than KRAS G12C in KRAS-driven cancers.

In our *in vitro* studies, we demonstrated that AN9025 efficiently inhibited cancer types with KRAS mutations including pancreas adenocarcinoma, lung adenocarcinoma, and colorectal adenocarcinoma with low nanomolar IC50 values.

In addition, in our *in vivo* studies, we also demonstrated that deep, sustained, and durable anti-tumor efficacy of AN9025 in KRAS-driven xenograft mice models.

Antitumor effects of AN9025 in KRAS-driven xenograft mice models



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.

AN3025

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. In the preclinical studies, AN3025 demonstrated promising antitumor activity in MC38-hTNFR2 syngeneic mouse model. As another mechanism of immune checkpoint inhibitor besides PD-1/PD-L1 pathway, AN3025 showed comparable TGI compared to the mouse anti-PD-1 antibody. 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."

Research and development

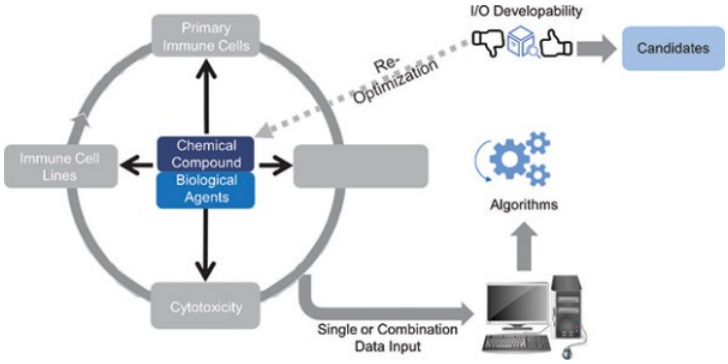
We believe that R&D is key to driving our therapeutic strategy and maintaining our competitiveness in the biopharmaceutical industry. Our in-house research and development function had 87 members with extensive drug discovery and development experience as of December 31, 2023. Around 83% of our research 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.

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-2DTM platform (i.e., the Platform for AN's Immune Therapeutics Discovery and Development) and ANEAT-IdTM platform (i.e., AN's high-Efficiency Antibody Technology for Identification/ Development).

PAINT-2DTM platform (the platform for AN's immune therapeutics discovery and development)

PAINT-2DTM 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-2DTM platform:

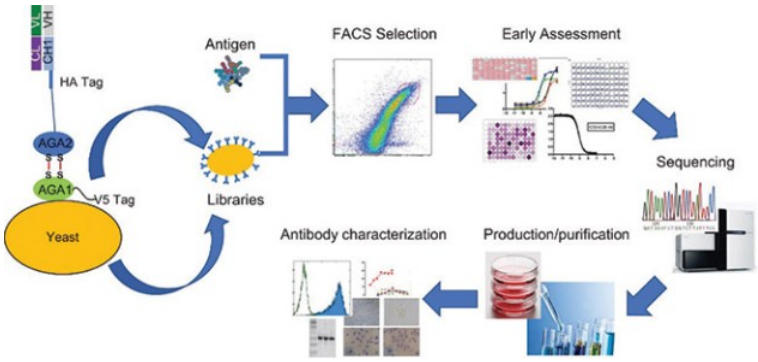


The platform begins with chemical compounds or biological agents first being tested in vitro in immune cell lines and/or primary immune cells to assess the preliminary activity as well as cytotoxicity. The effects of activity and cytotoxicity of potential candidate molecules are further tested in more 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-2DTM 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-IdTM platform (AN's high-efficiency antibody technology for identification / development)

ANEAT-IdTM 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 the date of this annual report, 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 annual report, 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. 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.

Option agreement with Nippon Kayaku

In April 2023, we entered into an option agreement (the "Nippon Kayaku Agreement") with Nippon Kayaku Co., Ltd. ("Nippon Kayaku") to grant Nippon Kayaku an exclusive option ("Option") to enter into a license agreement to further develop and commercialize products containing AN2025 in all therapeutic, prophylactic and/or diagnostic uses in humans in Japan.

According to the Nippon Kayaku Agreement, we shall immediately notify Nippon Kayaku if the AN2025 NDA is accepted by the FDA, and provide all documents included in the NDA submission to Nippon Kayaku. Nippon Kayaku has already paid us the agreed one-time option grant fee of US$5 million in full before the agreed due date, May 20, 2023. If the AN2025 NDA is accepted by the FDA without refusal or amendments (the "NDA Acceptance"), Nippon Kayaku may then exercise the Option provided that (1) Nippon Kayaku has already invested an agreed amount in us according to the terms and conditions of a separate commitment agreement, which provides that a concurrent private placement or a private equity investment agreement shall be entered into by Nippon Kayaku and us, and (2) Nippon Kayaku has notified us of its intention to exercise this Option.

Upon exercise of the Option by Nippon Kayaku, the parties will enter into a license agreement granting Nippon Kayaku exclusive rights to further develop and commercialize products containing AN2025 in all therapeutic, prophylactic and/or diagnostic uses in humans in Japan.

According to the form license agreement (the "License Agreement"), which is included as an exhibit to the Nippon Kayaku Agreement, once executed, we will grant to Nippon Kayaku an exclusive, royalty-bearing, sublicensable, assignable license under the licensed patents and know-how agreed upon between the parties under the License Agreement, to commercialize, develop, and manufacture the products containing AN2025 ("Licensed Products") for all therapeutic, prophylactic and/or diagnostic use in humans (the "Field") in Japan. We will also grant to Nippon Kayaku an exclusive, sublicensable, assignable, perpetual, irrevocable, royalty- free, and fully paid-up license for trademarks to commercialize, develop, and manufacture the Licensed Products in the Field in Japan. We will reserve the right to exercise full and unencumbered rights to exploit the Licensed Products outside the Field in Japan and in any field outside Japan.

According to the License Agreement, once executed, Nippon Kayaku will be solely responsible for the development, commercialization, and manufacturing (unless in bulk) of Licensed Products in the Field in Japan. For an invention solely made by one party, the party will solely own the invention. If an invention is jointly made by both parties, the invention will be jointly owned by the parties, unless otherwise agreed.

According to the License Agreement, once executed, we would be eligible to receive a series of payments from Nippon Kayaku, comprising milestone payments, royalty payments, and, if any, sublicense remuneration payments. Under the License Agreement, once executed, Nippon Kayaku will be obligated to pay us milestone payments up to an aggregate amount of approximately US$800 million upon (i) the achievement of regulatory milestones, including submission of an NDA and receipt of certain approvals from the PMDA for different indications, and (ii) the achievement of sales-based milestones based on annual sales for all Licensed Products.

Under the License Agreement, once executed, Nippon Kayaku will also pay royalties based on annual net sales during the royalty payment period, with royalty rate percentages ranging from mid-twenties to mid- thirties, subject to customary royalty rate reductions. The royalty term starts from the first commercial sale of the Licensed Products in Japan and shall continue until the latest of (a) the expiration of the last to expire valid claim of any licensed patent covering such Licensed Products in Japan; (b) the expiration of regulatory- based exclusivity for such Licensed Products in Japan; and (c) the ten (10) year anniversary of the date of the first commercial sale of such Licensed Product in Japan.

In addition, under the License Agreement, once executed, if Nippon Kayaku sublicenses its rights and license to a third party, Nippon Kayaku shall pay us sublicense remuneration payments with a percentage rate in the low-teen or mid-double digits of all net profits from any payments or other considerations attributable to such sublicenses, depending on the timing of the sublicense agreements.

Unless terminated earlier, the License Agreement shall remain in full force and effect. Either party may terminate this License Agreement for the other party's uncured material breach. In addition, Nippon Kayaku may terminate at its sole discretion without consequence upon providing at least 180 days' prior written notice to us. We may terminate the agreement by giving written notice upon an insolvency event of Nippon Kayaku.

As of the date of this annual report, Nippon Kayaku has not exercised the Option to enter into the License Agreement with us.

The Nippon Kayaku Agreement can be terminated at any time prior to Nippon Kayaku's exercise of the Option by the mutual written consent of the parties. In addition, each party has certain customary termination rights such as the right to terminate for the other party's uncured material breach of the Nippon Kayaku Agreement, or for either party's insolvency. We are entitled to terminate the Nippon Kayaku Agreement if Nippon Kayaku fails to complete the investment in us in accordance with the terms and conditions of the commitment agreement unless such failure is because we have prevented such investment solely through our actions. Nippon Kayaku may terminate the agreement if the NDA Acceptance does not occur before an agreed due date. In addition, Nippon Kayaku may demand in writing that we repay US$5.0 million, only when both of the following conditions are met by the agreed due date: (a) Nippon Kayaku has not acquired shares in us fully pursuant to the commitment agreement due to our actions preventing them from doing so; and (b) the NDA Acceptance is not satisfied.

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, 2023, we owned or had exclusive license rights to (i) 172 granted patents and 135 pending patent applications in jurisdictions such as the U.S., EPO, mainland China, Japan, South Korea, Canada, Australia, Taiwan, Mexico, and Brazil, and (ii) 14 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, 2023 are summarized below:

- ***AN2025***: As of December 31, 2023, we in-licensed 87 granted patents, including seven in the U.S., six in EPO, five in China, and 69 in other jurisdictions, including Canada and Japan, and 17 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 "Item 3. Key Information—D. 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, 2023, we in-licensed 25 granted patents, including three in the U.S., one in EPO, two in China, and 18 in other jurisdictions, including Canada and Australia, and two 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 PCT patent applications directed to a new formulation of AN0025 and a series of biomarkers to predict patients' responsiveness to the treatment with AN0025.

Product	Scope of patent protection	Jurisdiction	Status	Applicant	Patent Expiration[1]	Our Rights
AN2025	Directed to	PCT	Pending	Our Group	—	Ownership
	combination	United States			2034-05-09	
	therapy	EPO			2034-05-06	
		Mainland China	Granted	Novartis	2034-05-06	Exclusive
		Japan			2034-05-06	
		Others[2]			2034-05-06	
	Directed to	United States	Granted	Novartis	2034-03-04	Exclusive
	formulation	EPO			2034-03-04	
		Mainland China	Granted	Novartis	2034-03-04	Exclusive
		Japan			2034-03-04	
		Others[3]			2034-03-04	
	Directed to	United States			2033-10-21	
	process	EPO			2033-10-21	
		Mainland China			2033-10-21	
		Japan			2033-10-21	
		Others[4]			2033-10-21	
	Directed to	United States	Granted	Novartis	2027-12-05	Exclusive
	compound	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	United States EPO	Pending	Novartis	—	Exclusive
	therapy	Mainland China	Granted		2035-05-21	
		Australia Others[6]	Pending		—	
	Directed to	United States	Granted	Eisai	2031-09-12	Exclusive
	compound	EPO			2031-09-12	
		Mainland China			2031-09-12	
		Australia			2031-09-12	
		Others[7]			2031-09-12	
AN4005	Directed to compound	PCT United States, EPO, Mainland China, Japan, Taiwan	Pending	Our Group	—	Ownership

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 "阿諾医药." As of December 31, 2023, we had registered 70 trademarks in total. Among them, we registered 19 "Adlai Nortye" or "阿諾医药" trademarks in mainland China, five in Hong Kong, one in Macau, one in Taiwan, and applied for trademark registration of "Adlai Nortye" in other twelve jurisdictions including the U.S., Canada, Europe, U.K., Australia, Japan, and South Korea and have successfully obtained registrations in the U.S., Europe, U.K., Australia, Japan, and other five jurisdictions. In addition, there are three trademark applications of "Adlai Nortye" or "阿諾医药" pending potential registration in Canada, mainland China, and South Africa. As of December 31, 2023, 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, 2023, 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.

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.

Regulation

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. 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, which repealed the Interim Administrative Measures on Human Genetic Resources, and the Implementing Rules for the Regulations of the PRC on the Administration of Human Genetic Resources promulgated by the Ministry of Science and Technology in May 2023, further stipulate 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 medical and health institutions without exporting human genetic resource materials. This is provided that either of the following conditions is met: (1) relevant collection, testing, and analysis of human genetic resources, and the handling of the remaining materials of human genetic resources, among others, are conducted at clinical medical and health institutions; or (2) the collection of relevant human genetic resources is conducted at clinical medical and health institutions, while the testing and analysis of the human genetic resources and the handling of the remaining samples are conducted by the domestic entity as designated under the clinical trial protocol for the marketing authorization for relevant drugs and medical devices. Before commencing clinical trials, the two cooperating 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.

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.

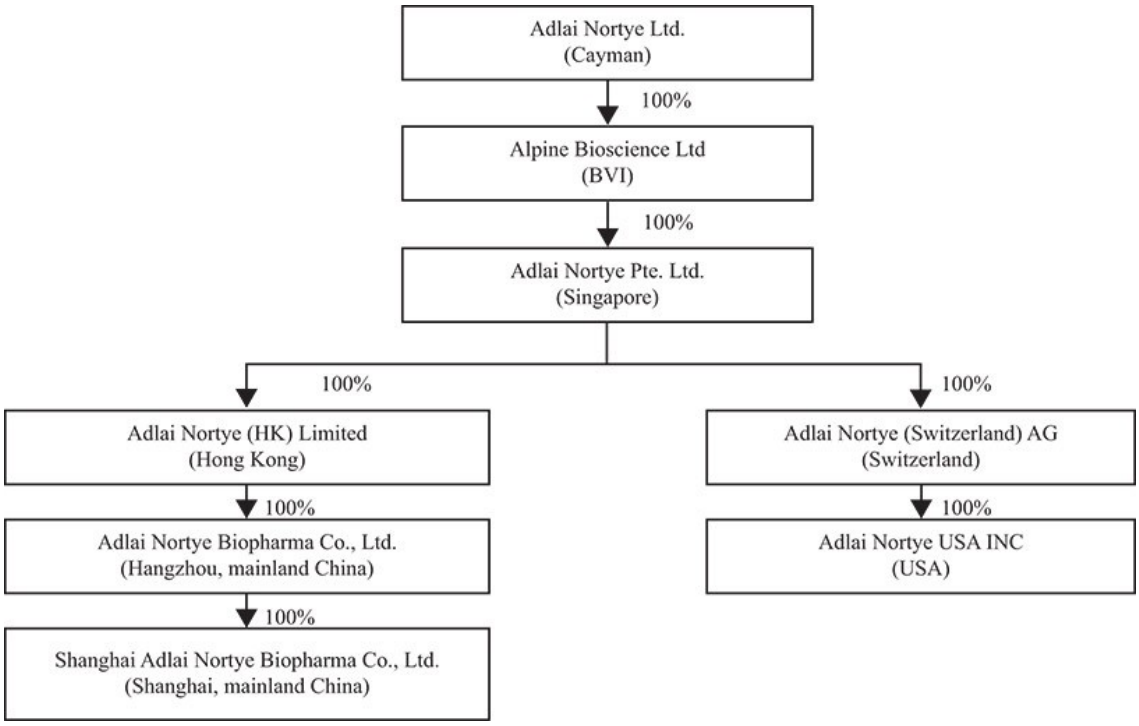
On July 12, 2018, the National Health Commission issued the Administrative Measures on National Health and Medical Care Big Data Standards, Security and Services (Trial), or the Measures on Health and Medical Care Big Data, which became effective therefrom. The Measures on Health and Medical Care Big 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.

C. Organizational Structure

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



D. Property, Plant and Equipment

We currently lease all properties for our business operations in the United States and China. As of the date of this annual report, we rent a total of approximately 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 approximately 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 as of the date of this annual report:

Location	Size (in square meters)	Usage of Property	Lease Term
New Jersey, the United States	623.20	Office and laboratory	July 15, 2021 to July 14, 2024*
Hangzhou, PRC	2,236.26	Office	June 1, 2020 to September 30, 2025
Hangzhou, PRC	2,303.9	Office and laboratory	June 1, 2020 to September 30, 2025
Shanghai, PRC	512.71	Office	January 1, 2022 to December 31, 2024

Note:

* Such lease commenced in July 2018. We renewed the lease agreement for another three years in July 2021.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements and the related notes included elsewhere in this annual report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Item 3. Key Information—D. Risk Factors" and elsewhere in this annual report.

A. Operating Results

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 and developed a robust pipeline of six drug candidates. Currently, our pipeline includes three clinical-stage drug candidates, buparlisib (AN2025), palupiprant (AN0025), and AN4005, as well as three 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$56.7 million, US$58.8 million, and US$104.9 million for the years ended December 31, 2021, 2022, and 2023, 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 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 "Item 4. Information on the Company—B. Business Overview — License and collaboration agreements — Collaboration with Biotime." In 2023, revenue of US$5.0 million was derived from the option grant fee for the sale of an exclusive option to enter into a license agreement to further develop and commercialize products to a single customer, recognized at a point in time, and there was no further performance obligation to be performed. For more details, see "Item 4. Information on the Company—B. Business Overview — License and collaboration agreements — Option agreement with Nippon Kayaku." 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 New Jersey state tax at a rate of 6.5% with net taxable income of $50,000 or less; 7.5% with net taxable income greater than US$50,000 and less than or equal to US$100,000; and 9% with net taxable income greater than US$100,000.

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 prevailing corporate income tax rate in Singapore is 17.0%, with 75% of up to the first SGD10,000 and 50% of up to the next SGD190,000 of a company's chargeable income (otherwise subject to normal taxation) being exempt from corporate tax (the "Partial Tax Exemption"). The remaining chargeable income that exceeds SGD200,000 will be fully taxable at the prevailing corporate tax rate.

In addition, subject to certain conditions and exceptions, newly established companies in Singapore will also be eligible for tax exemption on 75% of up to the first SGD100,000 and 50% of up to the next SGD100,000 of a company's annual normal chargeable income for each of the company's first three years of assessment from year of assessment 2020 onwards (the "Start-up Exemption"). The remaining chargeable income (after the tax exemption) will be taxed at the applicable corporate tax rate.

In the event a company claims the Start-up Exemption for its first three years of assessment, it will not be able to claim the Partial Tax Exemption. From the fourth year of assessment onwards, the company can enjoy the Partial Tax Exemption.

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 period presented 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/periods indicated:

	For the Year Ended December 31,		
	2021	2022	2023
	US$	US$ (in thousands)	US$
Selected consolidated statements of operations and comprehensive loss:			
Revenue	45,726	—	5,000
Other operating income, net	183	259	890
Administrative expenses	(12,450)	(13,039)	(15,289)
Research and development expenses	(42,105)	(54,490)	(58,152)
Total operating loss	**(8,646)**	**(67,270)**	**(67,551)**
Other income and gains.	213	2,079	3,303
Other expenses	(70)	(1,395)	(80)
Investment income	32	550	62
Fair value gain on financial assets at FVTPL	40	484	—
Fair value (loss)/gain on financial liabilities at FVTPL	(46,910)	7,195	(39,171)
Finance costs	(1,337)	(433)	(791)
Loss before tax	**(56,678)**	**(58,790)**	**(104,228)**
Income tax expense	—	—	(643)
Loss for the year/period	**(56,678)**	**(58,790)**	**(104,871)**
Attributable to:			
Ordinary equity holders of the parent	(56,678)	(58,790)	(104,871)

Comparison of the fiscal years ended December 31, 2023 and 2022

Revenue

We generated revenue of $5,000 in 2023 from the option grant fee for the sale of an exclusive option to enter into a license agreement to further develop and commercialize products to a single customer, recognized at a point in time, and there was no further performance obligation to be performed. And we did not generate any revenue in 2022.

Administrative expenses

Our administrative expenses increased by 17.3%, from US$13.0 million in 2022 to US$15.3 million in 2023, primarily attributable to an increase in IPO related professional service expenses in 2023.

Research and development expenses

Our research and development expenses increased by 6.7%, from US$54.5 million in 2022 to US$58.2 million in 2023, primarily attributable to an increase in the CRO service fees as we advanced some of our existing drug candidates into more advanced clinical development stages.

Other income and gains

Our other income and gains increased by 58.9% from US$2.1M in 2022 to US$3.3M in 2023, primarily attributable to additional government grants received in 2023.

Fair value changes on financial liabilities at FVTPL

We had fair value gain on financial liabilities at FVTPL of US$7.2 million in 2022 and fair value loss on financial liabilities at FVTPL of US$39.2 million in 2023. This change was primarily due to increased equity valuation of the company during 2023.

Loss for the period

For the reasons described above, our loss for the year increased from US$58.9 million in 2022 to US$104.9 million in 2023.

Comparison of the fiscal years ended December 31, 2022 and 2021

Revenue

We did not generate any revenue in 2022. We generate revenue of US$45.7 million from the sale of intellectual property pursuant to the collaboration agreement with Biotime.

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.

B. 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$56.7 million, US$58.8 million, and US$104.9 million for the years ended December 31, 2021, 2022, and 2023. We used US$3.0 million, US$43.2 million, and US$56.7 million in cash for our operating activities for the years ended December 31, 2021, 2022 and 2023, respectively.

Currently, our primary source of liquidity are cash and cash equivalents. As of December 31, 2023, we had US$91.5 million in cash and cash equivalents. Our cash and cash equivalents consist primarily of bank deposits.

Based on our current operating plan, we believe that our current cash and cash equivalents and proceeds from our initial public offering and the concurrent private placement 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/periods presented:

	For the Year Ended December 31,		
	2021	2022	2023
	US$	US$ (in thousands)	US$
Net cash used in operating activities	(3,034)	(43,223)	(56,652)
Net cash (used in)/generated from investing activities	(54,857)	28,376	(10,954)
Net cash from/(used in) financing activities	97,200	(6,780)	116,240
Net increase/(decrease) in cash and cash equivalents	**39,309**	**(21,627)**	**48,634**
Cash and cash equivalents at the beginning of the year/period	24,261	64,131	42,758
Effect of foreign exchange rate changes, net	561	254	100
Cash and cash equivalents at the end of the year/period	**64,131**	**42,758**	**91,492**

Operating activities

In 2023, we had US$56.7 million net cash used in operating activities. The difference with US$104.9 million of net loss before tax on accrual basis was mainly the result of adding back non-cash items such as US39.2 million fair value loss on financial liabilities at FVTPL, US$4.3 million of equity-settled share-based payment expenses and US$1.2 million and depreciation of property, plant and equipment. In 2023, US$1.8 million was released from operating assets and liabilities, mainly due to our trade payables increasing by US$1.3 million as a result of increased CRO expenses.

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 operating assets and liabilities, 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 operating assets and liabilities.

Investing activities

In 2023, our net cash used in investing activities was US$11.0 million, primarily as a result of purchases of US$ 31.8 million short-term investments at amortized cost, and disposal of US$21.0 million financial assets at FVTPL.

In 2022, our net cash generated from investing activities was US$28.3 million, primarily as a result of disposal of US$88.1 million financial assets at FVTPL and purchases of US$59.0 million 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.

Financing activities

In 2023, our net cash from financing activities was US$116.2 million, primarily as a result of the completion of our initial public offering.

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 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.

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 our initial public 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$1.1 million, US$1.2 million, and US$0.2 in 2021, 2022, and 2023 respectively. Our capital expenditures were primarily for the purchase of property, plant and equipment and the purchase of intangible assets.

Material Cash Requirements

Contractual obligations and commitments

The following table sets forth material cash requirements from our contractual obligations as of December 31, 2023:

	Less than 1 year	1 to 3 years	3 to 5 years	Total
		(in thousands)		
Lease liabilities	$ 722	$ 469	—	$ 1,191

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.

Holding Company Structure

We are a Cayman Islands holding company with no material operations of our own. We conduct our operations primarily through our operating subsidiaries in the United States and mainland China. As a result, our ability to pay dividends depends upon, among others, dividends paid by our subsidiaries. If our subsidiaries or any newly formed subsidiaries incur debt on their own behalf in the future, the instruments governing their debt may restrict their ability to pay dividends to us.

In addition, as determined in accordance with local regulations, our subsidiaries in certain of our markets may be restricted from paying us dividends offshore or from transferring a portion of their assets to us, either in the form of dividends, loans or advances, unless certain requirements are met, and regulatory approvals are obtained. Our subsidiaries in the PRC are also required to set aside a portion of their net income, if any, each year to fund general reserves for appropriations until this reserve has reached 50% of the related subsidiary's registered capital. These reserves are not distributable as cash dividends. In addition, registered share capital and capital reserve accounts are also restricted from distribution.

Recent Accounting Pronouncements

A list of recent issued accounting pronouncements that are relevant to us is included in Note 2.3 to our consolidated financial statements, which are included in this annual report.

C. Research and Development, Patents and Licenses, etc.

See "Item 4. Information on the Company—B. Business Overview— Research and Development." and "Item 4. Information on the Company—B. Business Overview—Intellectual Property."

D. Trend Information

Other than as disclosed elsewhere in this annual report, we are not aware of any trends, uncertainties, demands, commitments or events for the current fiscal year that are reasonably likely to have a material effect on our total revenues, income, profitability, liquidity or capital reserves, or that caused the disclosed financial information to be not necessarily indicative of future operating results or financial conditions.

E. Critical Accounting 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 annual report 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, our intention to complete and our ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and 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 annual report.

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 16 of our consolidated financial statements included elsewhere in this annual report.

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 annual report.

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 annual report.

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).

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth information relating to our directors and executive officers as of the date of this annual report.

Name (1)	Age	Position/Title
Yang Lu	44	Chairman of the Board of Directors, Chief Executive Officer
Ping Ji	59	Director
Lars Erik Birgerson	71	Director, President, Chief Medical Officer, Chief Executive Officer of U.S. Subsidiary
Shaorong Liu	45	Independent Director
Ming Lun Alan Tse	44	Independent Director
Cheguo Cai	47	Independent Director
Kaiyang Tang	60	Senior Vice President, Global Head of Clinical Operations
Wei (Vicky) Zhang	33	Chief Financial Officer
Victoria Elizabeth Demby	55	Senior Vice President, Global Head of Regulatory Affairs
Archie Tse	57	Head of Research & Development

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.

Ping Ji has served as our director since September 2023. She has over 25 years of experience in biopharmaceutical drug development. Since July 2017, Dr. Ji served as the global safety leader at Kyowa Kirin Co., Ltd. in the United States. Before that, from August 2011 to July 2017, she served as the global safety leader at Bayer HealthCare Pharmaceuticals Inc. in the United States. Dr. Ji has also served as the medical safety lead at Taiho in the United States from December 2006 to July 2011, as a medical reviewer at Bristol-Myers Squibb Company in the United States from June 2004 to December 2006, and as a clinical scientist at Sanofi S.A. in the United States from September 2002 to June 2004. Prior to that, from September 2000 to September 2002, she worked as a clinical scientist at Pfizer Corporation. Dr. Ji obtained her master of medicine from the cell biology program offered jointly by Graduated School-New Brunswick at Rutgers, the state University of New Jersey and the UMDNJ-Graduate School of Biomedical Sciences at Robert Wood Johnson Medical School in the United States in May 1993. She obtained her doctor of medicine from Capital Institute of Medicine in the PRC in August 1986.

Lars Erik Birgerson has served as our director since September 2023. He 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.

Shaorong Liu has served as our independent director since September 2023. Mr. Liu has approximately 15 years of experience in business management and consulting. Mr. Liu has been serving as the managing partner and senior consultant of Shanghai Zhiyi Enterprise Management Consulting Co., Ltd. since April 2008. Further, Mr. Liu has also been an independent non-executive director of Jiangsu CoCreation Grass Co., Ltd. (Shanghai Stock Exchange stock code: 605099) since April 2018. Mr. Liu obtained his master's degree in business administration from the China Europe International Business School in September 2012.

Ming Lun Alan Tse has served as our independent director since September 2023. 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.

Cheguo Cai has served as our independent director since September 2023. He has more than 17 years of experience in the biology and immunology industries. Dr. Cai has served as chief scientist at Shenzhen Beike Biotech Co., Ltd. since May 2021 and as professor at Hangzhou Institute for Advanced Study, UCAS since December 2022. From February 2017 to November 2022, Dr. Cai served as professor at the Medical Research Institute and Frontier Science Center for Immunology and Meta, Wuhan University. Dr. Cai served as associate professor and postdoctoral fellow at Shanghai Institute of Biochemistry and Cell Biology, Chinese Academy of Sciences since April 2015 to January 2017 and since October 2011 to March 2015, respectively. Before that, from October 2010 to September 2011, he served as postdoctoral fellow at Tulane University in the United States. From August 2005 to August 2007, he served as research assistant at Institut Pasteur of Shanghai, Chinese Academy of Sciences. Dr. Cai obtained his bachelor's degree and master's degree in biology in Xiamen University in July 2002 and July 2005, respectively. He obtained his doctoral degree in microbiology in Institut Pasteur of Shanghai, Chinese Academy of Sciences in July 2010.

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.

Archie Tse has served as our head of research and development since March 2024. Prior to joining us, Dr. Archie Tse served as the Chief Scientific Officer, Senior Vice President, Head of Research and Early Clinical Development, and Head of CMC Department of CStone Pharmaceuticals. Before that, Dr. Tse held leadership positions in multinational companies, including MSD and Daiichi- Sankyo. Dr. Tse obtained his Doctor of Medicine degree and his Doctor of Biochemistry and Molecular Biology degree from University of Southern California.

B. Compensation

For the fiscal year ended December 31, 2023, we paid an aggregate of approximately US$3.2 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

2020 Share Incentive Plan

We adopted a share incentive plan in June 2020 and amended it in May 2021 (the "**2020 Share Incentive Plan**"). 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.

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 our board of directors or officer as authorized by the board of directors (within its delegated authority) (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 of our employee benefit plans.

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.

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 or by trusts or companies established in connection with any employee benefit plan.

Acceleration of Awards upon Change in Control. In the event of any change in control event as defined in the plan, unless otherwise provided under the award agreement, each outstanding award shall be assumed or substituted by the successor corporation and our right to repurchase upon termination of an awardee's relationship as a service provider shall be assigned to the successor corporation, and if the award is not assumed or substituted or our right is not assigned, shall become fully vested and exercisable and be released from any of our repurchase or similar rights.

Amendment, termination and suspension. Unless terminated earlier, the 2020 Share Incentive Plan shall continue in effect for a term of ten years. Our board of the directors may at any time amend, alter, suspend, or terminate the 2020 Share Incentive Plan, subject to applicable laws and our articles of association. 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. No ordinary shares shall be delivered or sold under the plan after the termination thereof, except upon exercise of an award granted prior to the termination of the plan.

2023 Share Incentive Plan

In April 2023, we adopted our 2023 share incentive plan, which amended and replaced the 2020 Share Incentive Plan and became effective in September 2023. The maximum aggregate number of ordinary shares that may be issued under this 2023 Share Incentive Plan is 15,000,000, including any reserved and issued share under the 2020 Share Incentive Plan held by Nortye Talent Limited and Nortye International Limited. As of the date of this annual report, awards for an aggregate of 9,959,100 ordinary shares under the 2023 Share Incentive Plan have been granted.

The following paragraphs describe the principal terms of our 2023 Share Incentive Plan:

Type of awards. The 2023 Share Incentive Plan permits awards of options, restricted shares, restricted share units and other types of awards as the case may require.

Plan administration. The 2023 Share Incentive Plan is administered by our board of directors or committee or officer as authorized by the board of directors (within its delegated authority) (the "**Administrator**"). The Administrator determines, among other things, the participants eligible to receive awards, the type and number of the awards to be granted to each eligible participant and the terms and conditions of each award.

Eligibility. Awards may be granted to our employees, directors, consultants, or trusts or companies established in connection with any of our employee benefit plans.

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.

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 severance date, 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.

Acceleration of Awards upon Change in Control. In the event of any change in control event as defined in the plan, unless otherwise provided under the award agreement, each outstanding award shall be assumed or substituted by the successor corporation and our right to repurchase upon termination of an awardee's relationship as a service provider shall be assigned to the successor corporation, and if the award is not assumed or substituted or right is not assigned, shall become fully vested and exercisable and be released from any of our repurchase or similar rights.

Transfer restriction. Awards may not be transferred in any manner by the participant other than in accordance with the exceptions provided in the 2023 Share Incentive Plan or the relevant award agreement, such as transfers by will or the laws of descent and distribution or by trusts or companies established in connection with any employee benefit plan.

Amendment and termination. Unless terminated earlier, the 2023 Share Incentive Plan shall continue in effect for a term of ten years. Our board of the directors may at any time amend, alter, suspend, or terminate the 2023 Share Incentive Plan, subject to applicable laws and our articles of association. Termination shall not affect the Administrator's ability to exercise the powers granted to it under the 2023 Share Incentive Plan prior to such termination. No ordinary shares shall be delivered or sold under the plan after the termination thereof, except upon exercise of an award granted prior to the termination of the plan.

The following table summarizes, as of the date of this annual report, the number of ordinary shares underlying outstanding options that we granted to our directors and executive officers:

Name	Number of 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 as of the date of this annual report.

C. Board Practices

Board of Directors

Our board of directors consists of six directors. 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 have established three committees, an audit committee, a compensation committee, and a nominating and corporate governance committee, under our board of directors and adopted a charter for each of the three committees. Each committee's members and functions are described below.

Audit Committee. Our audit committee consists of Alan Ming Lun Tse, Shaorong Liu and Cheguo Cai. Alan Ming Lun Tse is the chairman of our audit committee. We have determined that Shaorong Liu and Cheguo Cai 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 Alan Ming Lun Tse 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 consists of Yang Lu, Shaorong Liu and Cheguo Cai. Yang Lu is the chairman of our compensation committee. We have determined that Shaorong Liu and Cheguo Cai 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 consists of Yang Lu, Shaorong Liu and Cheguo Cai. Yang Lu is the chairperson of our nominating and corporate governance committee. Shaorong Liu and Cheguo Cai 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 financial, reputational or other harm to us or material breaches of the employment agreement. We may also terminate an executive officer's employment without cause upon 60-day prior 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 terminate the employment at any time with a 60-day prior written notice.

Each executive officer has agreed to hold, both during the term of the employment and at all times thereafter, 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) approach the suppliers, clients, direct or end customers or contacts or other persons or entities introduced to the executive officers in his or her capacity as our representative for the purpose of doing business of the same or of a similar nature to our business or doing business that will harm our business relationships with the foregoing persons or entities; (ii) assume employment with or provide services to any of our competitors, or engage, whether as principal, partner, licensor or otherwise, any of our competitors, without our express consent; (iii) seek, directly or indirectly, to 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.

We have also entered into indemnification agreements with 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.

Board Diversity

Board Diversity Matrix
(As of the date of this annual report)

Country of Principal Executive Offices	Cayman Islands			
Foreign Private Issuer	Yes			
Disclosure Prohibited Under Home Country Law	No			
Total Number of Directors	6			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	1	5	—	—
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction			—	
LGBTQ+			—	
Did Not Disclose Demographic Background			6	

D. Employees

As of December 31, 2021, 2022 and 2023, we had 113, 129 and 127 full-time employees, respectively. Our employees are mainly based in China and the United States. The following table sets forth the number of our employees by function as of December 31, 2023:

	Number of Employees	**% of Total**
Research and Development	87	69
Management, Finance, Administrative and Others	40	31
Total	**127**	**100**

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 believe that we have a good working relationship with our employees and we have not experienced any strikes or labor disputes which had a material effect on our business.

E. Share Ownership

For information regarding the share ownership of our directors and officers, see "Item 7. Major Shareholders and Related Party Transactions—A. Major Shareholders." For information as to stock options granted to our directors, executive officers and other employees, see "Item 6. Directors, Senior Management and Employees—B. Compensation—Share Incentive Plans."

F. Disclosure of A Registrant's Action to Recover Erroneously Awarded Compensation

Not applicable.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information with respect to beneficial ownership of our ordinary shares as of the date of this annual report by:

- each of our directors and executive officers; and
- each person known to us to beneficially own 5% and more of our ordinary shares.

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.

The calculations in the table below is based on 93,710,805 Class A ordinary shares and 16,990,000 Class B ordinary shares outstanding as of the date of this annual report, being the total ordinary shares issued and outstanding.

	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)]	2,400,000	16,990,000	17.5	73.8
Lars Erik Birgerson	*	—	*	—
Kaiyang Tang	*	—	*	—
Wei (Vicky) Zhang	*	—	*	—
Victoria Elizabeth Demby	*	—	*	—
All directors and executive officers as a group	3,275,000	16,990,000	18.3	74.1
Principal Shareholders:				
Archer Future Limited[(1)]	—	16,990,000	15.3	73.1
Nortye Talent Limited[(3)]	9,000,000	—	8.1	2.6
ATCG Holdings Limited[(2)]	6,868,657	—	6.2	2.0
JIN YIN (BVI) LIMITED[(4)]	6,060,000	—	5.5	1.7
Nortye International Limited[(5)]	6,000,000	—	5.4	1.7
UNIQUE MARK VENTURES LIMITED[(6)]	5,750,790	—	5.2	1.6

Notes:

* Less than 1% of our total outstanding shares.

** 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 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 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 Class B 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 Class B 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; and (ii) 2,400,000 Class A ordinary shares issuable pursuant to options exercisable within 60 days after the date of this annual report that are held by Mr. Lu.

(2) Represents 6,868,657 Class A ordinary shares held by ATCG Holdings 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 Holdings Limited is Start Chambers, Wickham's Cay II, P.O. Box 2221, Road Town, Tortola, British Virgin Islands.

(3) Represents 9,000,000 Class A 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 Class A ordinary shares held by Nortye Talent Limited as of the date of this annual report. The registered address of Nortye Talent Limited is P.O. Box 146, Road Town, Tortola, British Virgin Islands.

(4) Represents 6,060,000 Class A ordinary 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 Class A 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 Class A ordinary shares held by Nortye International Limited as of the date of this annual report. The registered address of Nortye International Limited is P.O. Box 146, Road Town, Tortola, British Virgin Islands.

(6) Represents 5,750,790 Class A ordinary 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 Unit 9, 15/F., Laws Commercial Plaza, 788 Cheung Shan Wan Road, Lai Chi Kok, Kowloon, 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.

As of the date of this annual report, approximately 1.0% of our outstanding Class A ordinary shares are held by one record holder in the United States. None of our outstanding Class B 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.

B. Related Party Transactions

Employment Agreements and Indemnification Agreements

See "Item 6. Directors, Senior Management and Employees—C. Board Practices—Employment Agreements and Indemnification Agreements."

Shareholders Agreement

We entered into the shareholders agreement on April 15, 2021, with our shareholders, which consist of holders of ordinary shares and preferred shares.

The 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 have automatically terminated upon the completion of our initial public offering.

Share Incentives

See "Item 6. Directors, Senior Management and Employees—B. Compensation—Share Incentive Plans."

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

See "Item 18. Financial Statements."

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.

Dividend Policy

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 of directors 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 "Item 4. Information on the Company—B. Business Overview—Regulation— Regulations relating to foreign exchange control." and "Item 4. Information on the Company—B. Business Overview—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. Cash dividends on our ordinary shares, if any, will be paid in U.S. Dollars.

B. Significant Changes

Except as disclosed elsewhere in this annual report, we have not experienced any significant changes since the date of our audited consolidated financial statements included in this annual report.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our ADSs, each representing three of our Class A ordinary shares, have been listed on the Nasdaq Global Market since September 29, 2023 under the symbol "ANL."

B. Plan of Distribution

Not applicable.

C. Markets

Our ADSs, each representing three of our Class A ordinary shares, have been listed on the Nasdaq Global Market since September 29, 2023 under the symbol "ANL."

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

We incorporate by reference into this annual report the description of our seventh amended and restated memorandum and articles of association, the form of which was filed as Exhibit 3.2 to our F-1 registration statement (File No. 333-273465), as amended, originally filed with the SEC on July 27, 2023. Our shareholders adopted our seventh amended and restated memorandum and articles of association by a special resolution on April 17, 2023, which became effective immediately prior to completion of our initial public offering of ADSs representing our ordinary shares.

C. Material Contracts

We have not entered into any material contracts other than in the ordinary course of business and other than those described in "Item 4. Information on the Company" or elsewhere in this annual report.

D. Exchange Controls

See "Item 4. Information on the Company—B. Business Overview—Regulation— Regulations relating to foreign exchange control."

E. Taxation

The following is a general summary of the material Cayman Islands, the PRC and U.S. federal income tax consequences relevant to an investment in our ADSs or ordinary shares. The discussion is not intended to be, nor should it be construed as, legal or tax advice to any particular prospective purchaser. The discussion is based on laws and relevant interpretations thereof in effect as of the date of this annual report, all of which are subject to change or different interpretations, possibly with retroactive effect. The discussion does not address U.S. state or local tax laws, or tax laws of jurisdictions other than the Cayman Islands, the People's Republic of China and the United States.

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.

PRC 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 ADSs or ordinary shares by U.S. Holders (as defined below) as of the date hereof that hold 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 ordinary shares. This discussion is based on the Code, its legislative history, existing, temporary 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;
- mutual funds and pension plans;
- 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, qualified retirement plans, individual retirement accounts or other tax deferred accounts;
- S-corporations, partnerships or other entities treated as partnerships or other pass-through entities for U.S. federal income tax purposes or persons holding ADSs or ordinary shares through any such entities;
- regulated investment companies or real estate investment trusts;
- persons that hold ADSs or ordinary shares as part of a hedge, straddle, constructive sale, conversion transaction, or other integrated investment;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- persons whose functional currency for tax purposes is not the U.S. dollar;
- persons holding ADSs or ordinary shares in connection with a trade or business or permanent establishment outside the United States;
- U.S. expatriates; 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 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 ADSs or ordinary shares.

General

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of 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 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 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.

Recent Treasury regulations may in some circumstances prohibit a U.S. Holder from claiming a foreign tax credit with respect to certain non-U.S. taxes that are not creditable under applicable income tax treaties, or the Foreign Tax Credit Regulations. Accordingly, a U.S. Holder should consult their tax advisor regarding the credibility or deductibility of any PRC taxes imposed on dividends on, or on dispositions of, ADSs, particularly if the U.S. Holder is not eligible to claim Treaty benefits. The discussion below regarding the creditability of PRC taxes does not address the foreign tax credit consequences to the U.S. Holder if such U.S. Holder is not eligible to claim the benefits of the Treaty.

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 ADSs or ordinary shares, if any, will generally be treated as dividend income for U.S. federal income tax purposes. Dividends received on 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 ADSs (but not our ordinary shares), which we have been approved to list on the Nasdaq Global Market, will be considered readily tradeable on an established securities market in the United States, although there can be no assurance in this regard. U.S. Holders should consult their own tax advisors regarding the potential availability of the reduced dividend tax rate with respect of the ADSs and our ordinary shares.

As described under "Taxation — People's Republic of China taxation," we may be classified as a "resident enterprise" of China. In the event that we are deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law and are eligible for the benefits of the Treaty, dividends, if any, we pay on our ordinary shares, regardless of whether such shares are represented by ADSs, would be eligible for the favorable tax rate applicable to long-term capital gains, subject to applicable limitations and provided that we are not (and are not treated with respect to the U.S. Holder as) a PFIC for the taxable year of the distribution or the preceding taxable year. U.S. Holders should consult their tax advisors regarding the availability of this tax rate for dividends paid with respect to our ADSs and our ordinary shares. Dividends paid on 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. 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 ADSs or ordinary shares. For example, under the Foreign Tax Credit Regulations, in absence of a valid election to claim the benefits of an applicable income tax treaty, in order for any such foreign taxes to be creditable, foreign income tax rules of the applicable jurisdiction must be consistent with certain U.S. federal income tax principles. We have not determined whether the PRC income tax system meets these principles. Additionally, a U.S. Holder that is eligible to claim benefits under the Treaty will not be entitled to a foreign tax credit for the amount of any PRC withholding taxes with respect to which the holder is entitled to obtain a refund from the PRC taxing authorities. 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, and the various limitations on their ability to, claim 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 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 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 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 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 "— PRC 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 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 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 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

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 (subject to certain elections described below, if 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, 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 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.

Based on current estimates of our gross income and the value of our gross assets (including goodwill) and the manner in which we conduct our business, we do not expect to be a PFIC for U.S. federal income tax purposes for the 2023 taxable year, but there can be no assurance that we will not be a PFIC for 2023 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. With certain exceptions, we do not currently generate any income from our primary business, and our gross income is currently comprised primarily of interest and other investment income (which is passive) and governmental grants and the Option Grant Fee (which are both likely to be active income). Therefore, our PFIC status under the income test for any taxable year in which we do not generate significant income from our primary business, including the current taxable year, will likely depend on the relative amounts of government grants and the Option Grant Fee against the amounts of interest and other passive income we earn. The receipt of governmental grants is subject to various conditions and there can be no assurance that we will continue to receive governmental grants in future taxable years or as to the amount of governmental grants that we will receive in any taxable year. Additionally, the Option Grant Fee is not a reoccurring payment in future taxable years and is subject to repayment if certain conditions under the Nippon Kayaku Agreement are not satisfied. We cannot assure you that such conditions under the Nippon Kayaku Agreement will be satisfied and that the option grant fee will not be subject to repayment to Nippon Kayaku. Further, we will hold a substantial amount of cash and cash equivalents following the offering and while we continue to do so, our PFIC status for any taxable year will depend on the value of our goodwill. The value of our goodwill may be determined, in large part, by reference to the market price of the ADSs and ordinary shares, which is likely to be volatile given the nature of our business and the current market conditions. Therefore, 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. Accordingly, we cannot assure you that we will not become a PFIC for the current or any future taxable year. Our 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, the ADSs or ordinary shares. Distributions in respect of 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 were 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 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 ADSs, will be treated as ordinary income. Ordinary loss treatment also will apply to the deductible portion of any mark-to-market loss on ADSs, as well as to any loss realized on a sale or disposition of 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 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 ADSs or ordinary shares and the elections discussed above.

U.S. information reporting and backup withholding rules

Dividend payments with respect to ADSs or ordinary shares and the proceeds received on the sale or other disposition of 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. Backup withholding is not an additional tax. 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.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the periodic reporting and other informational requirements of the Exchange Act. Under the Exchange Act, we are required to file reports and other information with the SEC. Specifically, we are required to file annually a Form 20-F no later than four months after the close of each fiscal year, which is December 31. All information filed with the SEC can be obtained over the internet at the SEC's website at www.sec.gov or inspected and copied at the public reference facilities maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You can request copies of documents, upon payment of a duplicating fee, by writing to the SEC. As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the furnishing and content of quarterly reports and proxy statements, and officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

We will furnish The Bank of New York Mellon, the depositary of our ADSs, with our annual reports, which will include a review of operations and annual audited consolidated financial statements, and all notices of shareholders' meetings and other reports and communications that are made generally available to our shareholders. The depositary will make such notices, reports and communications available to holders of ADSs and, upon our request, will mail to all record holders of ADSs the information contained in any notice of a shareholders' meeting received by the depositary from us.

I. Subsidiary Information

Not applicable.

J. Annual Report to Security Holders

Not applicable.

ITEM 11. 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. Assuming Renminbi weakens by 10% against U.S. dollar, our cash and cash equivalents as of December 31, 2023 would decrease by US$4.4 million, or 3.5%.

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.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

As an ADS holder, you will be required to pay the following service fees to the depositary, The Bank of New York Mellon, and certain taxes and governmental charges (in addition to any applicable fees, expenses, taxes and other governmental charges payable on the deposited securities represented by any of your ADSs):

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 which are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	· Depositary services
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 have to pay on any ADS or Class A ordinary shares underlying an ADS, 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.

As an ADS holder you will also 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.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Material Modifications to the Rights of Security Holders

See "Item 10. Additional Information." for a description of the rights of securities holders, which remain unchanged.

Use of Proceeds

The following "Use of Proceeds" information relates to the registration statement on Form F-1, as amended (File No. 333-273465) (the "F-1 Registration Statement") in relation to our initial public offering of 2,500,000 ADSs representing 7,500,000 Class A ordinary shares, at an initial offering price of US$23.00 per ADS. Our initial public offering closed in September 2023. Cantor Fitzgerald & Co. acted as the representative of the underwriters and the sole book-running manager of our initial public offering.

The F-1 Registration Statement was declared effective by the SEC on September 28, 2023. For the period from the effective date of the F-1 Registration Statement to December 31, 2023, the total expenses incurred for our company's account in connection with our initial public offering was approximately US$10.0 million, which included approximately US$4.7 million in underwriting discounts and commissions for the initial public offering and approximately US$5.3 million in other costs and expenses for our initial public offering. We received approximately US$87.5 million in net proceeds after deducting underwriting commissions and discounts and the offering expenses payable by us. None of the transaction expenses included payments to directors or officers of our company or their associates, persons owning more than 10% or more of our equity securities or our affiliates. None of the net proceeds from the initial public offering were paid, directly or indirectly, to any of our directors or officers or their associates, persons owning 10% or more of our equity securities or our affiliates.

For the period from September 28, 2023, the date that the F-1 Registration Statement was declared effective by the SEC, to December 31, 2023, we used US$10.8 million of the net proceeds from our initial public offering and US$76.7 million have not yet used. As of the date of this annual report, there have been no material changes in the use of proceeds as disclosed in the F-1 Registration Statement.

We still intend to use the remainder of the proceeds from our initial public offering as disclosed in the F-1 Registration Statement. We may also use part of the proceeds to repurchase our ADSs.

ITEM 15. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to provide reasonable assurance that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized and reported within the specified time periods and accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, under the supervision and with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) or 15d-15(e) promulgated under the Exchange Act, on December 31, 2023. Based on that evaluation, our principal executive officer and principal financial officer have concluded that, as of December 31, 2023, our disclosure controls and procedures were not effective in ensuring that material information required to be disclosed in this annual report is recorded, processed, summarized and reported to them for assessment, and required disclosure is made within the time period specified in the rules and forms of the SEC.

Management's Annual Report on Internal Control over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Internal Control over Financial Reporting

In connection with the audits of our consolidated financial statements included in this annual report, 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 (for the year ended December 31, 2022); 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. During the audit for the year ended December 31, 2022, we revised 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. As we continued to implement a number of measures to address the material weakness, we recognized significant improvement during the audit for the year ended December 31, 2023.

We will continue to implement the following 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, and (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.

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 "Item 3. Key Information—D. Risk Factors — Risks relating 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."

Attestation Report of the Independent Registered Public Accounting Firm

As a company with less than US$1.235 billion in revenues for our last fiscal year, we qualify as an "emerging growth company" pursuant to the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other requirements 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.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this annual report on Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Alan Ming Lun Tse, the chairman of our audit committee, qualifies as "audit committee financial expert" as defined in Item 16A of Form 20-F. All three members of our audit committee 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.

ITEM 16B. CODE OF ETHICS

Our board of directors has adopted a code of ethics that applies to our directors, officers, employees and agents, including certain provisions that specifically apply to our executive officers, including our principal executive and financial officers, president and vice presidents and any other persons who perform similar functions for us. We have filed our code of business conduct and ethics as Exhibit 99.1 to our registration statement on Form F-1 (File Number 333-273465), as amended, initially filed with the SEC on July 27, 2023. The code is also available on our website at *https://www.adlainortye.com*. We hereby undertake to provide to any person without charge, a copy of our code of business conduct and ethics within ten working days after we receive such person's written request.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Audit Fees

The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered by our principal external auditors for the periods indicated.

	Year Ended December 31,	
	2022	2023
	(U.S. dollars in thousands)	
Audit Fees[1]		
Mazars USA LLP	489	757
Ernst & Young	75	—
Tax Fees[2]		
KPMG	48	162

(1) "Audit fees" represent the aggregate fees billed for each of the fiscal years listed for professional services rendered by our principal auditors for the audit or review of our annual or quarterly financial statements and fees for services rendered in connection with our initial public offering in 2023.

(2) "Tax fees" represent the aggregate fees billed in each of the fiscal years listed for professional services rendered by our principal auditors for tax compliance, tax advice, and tax planning.

The policy of our audit committee is to pre-approve all audit and non-audit services provided by our principal external auditors, including audit services, audit-related services, tax services and other services as described above, other than those for de minimis services which are approved by the audit committee prior to the completion of the audit.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

There were no purchases of equity securities made by or on behalf of us or any "affiliated purchaser" as defined in Rule 10b-18 of the Exchange Act during the fiscal year ended December 31, 2023.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

We are a "foreign private issuer" (as such term is defined in Rule 3b-4 under the Exchange Act), and our ADSs, each representing three Class A Ordinary Shares, are listed on the Nasdaq Stock Market. Rule 5615 of the Nasdaq Rules permits a foreign private issuer like our company to follow home country practice in certain corporate governance matters. However, if we choose to follow home country practice in the future, our shareholders may be afforded less protection than they otherwise would under the NASDAQ Global Market corporate governance listing standards applicable to U.S. domestic issuers. See "Item 3. Key Information—D. Risk Factors—Risks relating 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."

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 intend to follow home country practice in lieu of certain requirements, including (i) the independence requirements for compensation committee and nomination committee as provided in Nasdaq Listing Rule 5605(d) and (e); (ii) the requirement that a majority of the board must be independent as provided in Nasdaq Listing Rule 5605(b)(1); (iii) the requirement to have regularly scheduled executive sessions with only independent directors each year as provided in Nasdaq Listing Rule 5605(b)(2); (iv) the requirement to hold annual general meeting and solicit proxy as provided in Nasdaq Listing Rule 5620; (v) the requirement to obtain shareholders' approval prior to a plan or other equity compensation arrangement is established or materially amended as provided in Nasdaq Listing Rule 5635(c); and (vi) the requirement of shareholder approval for entering into any transaction, other than a public offering, involving the sale, issuance or potential issuance by the Company of ordinary shares (or securities convertible into or exercisable for ordinary shares) equal to 20% or more of the outstanding ordinary share of the Company or 20% or more of the voting power outstanding before the issuance as provided in Nasdaq Listing Rule 5635(d).

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

ITEM 16J. INSIDER TRADING POLICIES

Not applicable.

ITEM 16K. CYBERSECURITY

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information.

Our cybersecurity risk management aligns with and shares common methodologies and reporting channels with our broader risk management.

Key features of our cybersecurity risk management program include, but are not limited to, the following:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise IT Systems environment;

- a security team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- processes for monitoring for vulnerabilities of our technology which includes code review (as necessary), testing and analysis of software across the software lifecycle;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- physical and technical security measures, including encryption, authentication, and access controls;
- cybersecurity awareness training and internal cybersecurity resources for our employees;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for service providers, suppliers, and vendors who access our system and information.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. We face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. See "Item 3. Key Information—D. Risk Factors — Risks Relating to Our Business — Cybersecurity 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."

Cybersecurity Governance

Our board of directors considers cybersecurity risk as part of its risk oversight function and undertakes overall risk management, including oversight of cybersecurity and other information technology risks.

Our board of directors receives quarterly reports from management on our cybersecurity risks. In addition, management updates our board of directors, as necessary, regarding any significant cybersecurity incidents. Our board of directors also receives briefings from management on our cyber risk management program.

Our management has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our management and the security team, including our chief financial officer and our IT manager, is responsible for assessing and managing our material risks from cybersecurity threats. Our team's experience includes extensive knowledge in the industry, previous work experience being security supervisors for years and degrees in software engineering.

Our management oversees efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in our IT Systems environment.

PART III

ITEM 17. FINANCIAL STATEMENTS

We have elected to provide financial statements pursuant to Item 18.

ITEM 18. FINANCIAL STATEMENTS

The consolidated financial statements and the related notes required by Item 18 are included in this annual report, beginning on page F-1. The report of Mazars USA LLP, the Company's independent registered accounting firm with respect to the referenced financial statements, is included on page F-1.

ITEM 19. EXHIBITS

Exhibit Number	Description of Document
1.1*	Seventh Amended and Restated Memorandum and Articles of Association of the Registrant as currently in effect
2.1*	Specimen American Depositary Receipt (included in Exhibit 2.3)
2.2*	Registrant's Specimen Certificate for Ordinary Shares
2.3*	Form of Deposit Agreement, among the Registrant, the depositary and the owners and holders of American Depositary Shares issued thereunder
4.1*	Form of Employment Agreement between the Registrant and its executive officers
4.2*	Form of Indemnification Agreement between the Registrant and its directors and executive officers
4.3*	Adlai Nortye Ltd. 2020 Share Incentive Plan
4.4*	Adlai Nortye Ltd. 2023 Share Incentive Plan
4.5+*	License Agreement, dated as of December 22, 2017, between the Registrant and Novartis
4.6+*	License Agreement, dated as of January 19, 2018, between the Registrant and Eisai
4.7+*	Right and Interest Transfer Agreement dated as of November 15, 2021, between the Registrant and Biotime
4.8+*	Option agreement dated as of April 26, 2023, between the Registrant and Nippon
4.9*	Subscription Agreement between the Registrant and Nippon Kayaku Co., Ltd., dated July 27, 2023
8.1	List of Principal Subsidiaries of the Registrant
11.1*	Code of Business Conduct and Ethics of the Registrant
12.1	Principal Executive Officer Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2	Principal Financial Officer Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1	Principal Executive Officer Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2	Principal Financial Officer Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Recovery Policy
101	INS XBRL Instance Document
101	SCH XBRL Taxonomy Extension Schema Document
101	CAL XBRL Taxonomy Extension Calculation Linkbase Document
101	LAB XBRL Taxonomy Extension Label Linkbase Document
101	PRE XBRL Taxonomy Extension Presentation Linkbase Document

101	DEF XBRL Taxonomy Extension Definitions Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Previously filed with the Registration Statement on Form F-1 (File No. 333-273465), initially filed on July 27, 2023 and incorporated herein by reference.

\+ Portions of this exhibit have been omitted in reliance of the revised Item 601 of Regulation S-K.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing its annual report on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Adlai Nortye Ltd.

By: /s/ Yang Lu
Name: Yang Lu
Title: Chief Executive Officer

Date: April 19, 2024

ADLAI NORTYE LTD.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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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, 2022 and 2023, and the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for each of the two years in the period ended December 31, 2023, 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, 2022 and 2023, and the results of its operations and its cash flows for each of the two years then ended in the period ended December 31, 2023, 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 19, 2024

ADLAI NORTYE LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2023
(All amounts in thousands, except share and per share data, or as otherwise noted)

	Notes	Year ended December 31, 2022 $'000	2023 $'000
REVENUE	4	—	5,000
Other operating income, net		259	890
Administrative expenses		(13,039)	(15,289)
Research and development expenses		(54,490)	(58,152)
Total operating loss		(67,270)	(67,551)
Other income and gains		2,079	3,303
Other expenses		(1,395)	(80)
Investment income		550	62
Fair value gain on financial assets at fair value through profit or loss ("FVTPL")		484	—
Fair value (loss)/gain on financial liabilities at FVTPL	16	7,195	(39,171)
Finance costs	5	(433)	(791)
LOSS BEFORE TAX		**(58,790)**	**(104,228)**
Income tax expense	6	—	(643)
LOSS FOR THE YEAR		**(58,790)**	**(104,871)**
Attributable to:			
Ordinary Equity Holders of the Parent		(58,790)	(104,871)
OTHER COMPREHENSIVE LOSS			
Exchange differences on translation of the financial statements of subsidiaries		(3,157)	(82)
Other comprehensive loss for the year, net of tax		(3,157)	(82)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		**(61,947)**	**(104,953)**
Attributable to:			
Ordinary Equity Holders of the Parent		(61,947)	(104,953)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted			
Loss for the year ($ per share)	8	(2.31)	(2.42)
Weighted average common shares outstanding	8	25,440,000	43,342,068

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 AND 2023
(All amounts in thousands, except share and per share data, or as otherwise noted)

	Notes	Year ended December 31, 2022 $'000	2023 $'000
ASSETS			
Current assets			
Cash and cash equivalents		42,758	91,492
Financial assets at FVTPL	12	21,287	7
Prepayments, other receivables and other assets	11	2,258	2,696
Short-term investments at amortized cost	13	—	7,000
Total current assets		**66,303**	**101,195**
Non-current assets			
Property, plant and equipment	9	3,713	2,646
Right-of-use assets	10(a)	2,162	1,154
Other intangible assets		89	63
Prepayments, other receivables and other assets	11	327	282
Long-term investments at amortized cost	13	—	24,849
Total non-current assets		**6,291**	**28,994**
Total assets		**72,594**	**130,189**
LIABILITIES			
Current liabilities			
Trade payables		13,098	14,348
Other payables and accruals	14	3,877	4,890
Interest-bearing bank borrowings	15	4,307	30,357
Lease liabilities	10(b)	1,001	722
Financial liabilities at FVTPL	16	290,368	—
Total current liabilities		**312,651**	**50,317**
Non-current liabilities			
Lease liabilities	10(b)	1,236	469
Total non-current liabilities		**1,236**	**469**
Total liabilities		**313,887**	**50,786**
SHAREHOLDERS' (DEFICIT)/ EQUITY			
Ordinary shares (par value of $0.0001 per share; 442,456,586 shares authorized; 40,440,000 shares issued and outstanding as of December 31, 2022; and nil outstanding as of December 31, 2023)	17	4	—
Class A Ordinary shares (par value of $0.0001 per share; nil outstanding as of December 31,2022; and 93,710,805 shares outstanding as of December 31, 2023)	17		9
Class B Ordinary shares (par value of $0.0001 per share; nil outstanding as of December 31,2022; and 16,990,000 shares outstanding as of December 31, 2023)	17		2
Series A convertible preferred shares (par value of US$0.0001 per share; 14,560,000 and nil shares authorized, issued and outstanding as of December 31, 2022 and 2023, respectively)		10,980	—
Additional paid-in capital	18	6,415	438,707
Share option reserve	18	13,688	18,018
Exchange fluctuation reserve	18	(4,159)	(4,241)
Accumulated deficit	18	(268,221)	(373,092)
Total shareholders' (deficit)/equity		**(241,293)**	**79,403**
Total liabilities and shareholders' (deficit)/equity		**72,594**	**130,189**

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 AND 2023
(All amounts in thousands, except share and per share data, or as otherwise noted)

	Attributable to owners of the parent						
	Ordinary Shares $'000 (note 17)	Additional paid-in capital $'000 (note 18)	Series A convertible preferred shares $'000	Share option reserve $'000 (note 18)	Exchange fluctuation reserve $'000 (note 18)	Accumulated losses $'000	Total deficits $'000
At January 1, 2022	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)
Share-based compensation	—	—	—	6,082	—	—	6,082
At December 31, 2022	4	6,415	10,980	13,688	(4,159)	(268,221)	(241,293)
At January 1, 2023	4	6,415	10,980	13,688	(4,159)	(268,221)	(241,293)
Loss for the year	—	—	—	—	—	(104,871)	(104,871)
Other comprehensive income for the year							
Exchange differences on translation of the financial statements of subsidiaries	—	—	—	—	(82)	—	(82)
Issuance of ordinary shares	1	91,779	—	—	—	—	91,780
Conversion of Financial liabilities at FVTPL	5	329,534	—	—	—	—	329,539
Conversion of Series A convertible preferred shares	1	10,979	(10,980)	—	—	—	—
Share-based compensation	—	—	—	4,330	—	—	4,330
At December 31, 2023	11	438,707	—	18,018	(4,241)	(373,092)	79,403

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 AND 2023
(All amounts in thousands, except share and per share data, or as otherwise noted)

	Notes	Year ended December 31, 2022 $'000	2023 $'000
CASH FLOWS FROM OPERATING ACTIVITIES			
Net Loss	5	(58,790)	(104,871)
Adjustments for:			
Finance costs		433	791
Investment income		(550)	(62)
Fair value (gain)/loss on financial liabilities at FVTPL	16	(7,195)	39,171
Fair value gain on financial assets at FVTPL		(484)	—
Gain on disposal of items of property, plant and equipment		(7)	—
Depreciation of property, plant and equipment	9	931	1,213
Amortization of intangible assets		20	25
Depreciation of right-of-use assets	10(a)	1,090	984
Equity-settled share-based payment expenses	19	6,082	4,330
(Increase)/Decrease in prepayments, other receivables and other assets		4,346	(436)
(Increase)/Decrease in non-current assets		128	45
Increase in trade payables		10,117	1,252
Increase in other payables and accruals		656	906
Net cash flows used in operating activities		**(43,223)**	**(56,652)**
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment		(1,249)	(200)
Purchases of intangible assets		(19)	—
Proceeds from disposal of items of property, plant and equipment		17	1
Purchases of financial assets at FVTPL		(58,980)	(7)
Disposal of financial assets at FVTPL		88,057	21,039
Purchases of investments at amortized cost		—	(31,849)
Received investment income of financial assets at FVTPL		550	62
Net cash flows provided/(used in) from investing activities		**28,376**	**(10,954)**
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from issuance of ordinary shares		—	91,780
Addition of bank borrowings		7,897	50,234
Bank borrowings interest paid		(292)	(602)
Repayment of bank borrowings		(13,315)	(24,069)
Payment for lease liabilities		(1,070)	(1,103)
Net cash flows (used in)/from financing activities		**(6,780)**	**116,240**
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS		**(21,627)**	**48,634**
Cash and cash equivalents at beginning of year		64,131	42,758
Effect of foreign exchange rate changes, net		254	100
CASH AND CASH EQUIVALENTS AT END OF YEAR		**42,758**	**91,492**

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 AND 2023
(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 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	Two shars 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 200,000	—	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 %	Product research and development, technology transfer and consulting services business
杭州塘创未来科技有限公司 Hangzhou Tangchuang Weilai Technolegy Co., Ltd ("Hangzhou Tangchuang")		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 AND 2023 (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

As of December 31, 2023, the Group's balance of cash and cash equivalents was $91,492 and short-term investments of $7,000 and the Group had net current assets of $50,878. Management has evaluated the sufficiency of its working capital and concluded that the Group's available cash and cash equivalents and short-term investments will be sufficient to support its continuous operations and to meet its payment obligations when liabilities fall due within the next twelve months from the date of issuance of these consolidated financial statements. Accordingly, management continues to prepare the Group's consolidated financial statements on going concern basis.

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.

		Effective for accounting year beginning on or after
Amendments to IAS 1	*Classification of Liabilities as current and non-current*	January 1, 2024
Amendments to IFRS 16	*Lease Liability in a Sale and Leaseback*	January 1, 2024
Amendments to IAS 1	*Non-current Liabilities with Covenants*	January 1, 2024
Amendments to IAS 28 and IFRS 10	*Sale or contribution of assets between an investor and its associate or joint venture*	To be determined

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.

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2023 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

(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 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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs.

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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 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).

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at fair value through profit or loss

Financial liabilities at fair value through profit or loss include financial liabilities held for trading and financial liabilities designated upon initial recognition as at fair value through profit or loss.

Financial liabilities are classified as held for trading if they are incurred for the purpose of repurchasing in the near term. This category also includes derivative financial instruments entered into by the Group that are not designated as hedging instruments in hedge relationships as defined by IFRS 9. Separated embedded derivatives are also classified as held for trading unless they are designated as effective hedging instruments. Gains or losses on liabilities held for trading are 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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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.

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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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.

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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 realized 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.

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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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.

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.

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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 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).

2.4 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

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.

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 16 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.

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2023 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES (continued)

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)

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, 2022 and 2023, 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).

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4. REVENUE

An analysis of revenue is as follows:

	2022	2023
	$'000	$'000
Sales of an exclusive option.	—	5,000
Total	—	5,000

Revenue of $5,000 for the year ended December 31, 2023 was derived from the option grant fee for the sale of an exclusive option to enter into a license agreement to further develop and commercialize products 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,	
	2022	2023
	$'000	$'000
Interest expenses on bank and other borrowings	295	708
Interest expenses on lease liabilities	138	83
Total	433	791

6. INCOME TAX

The company 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.

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.

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.

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6. INCOME TAX (continued)

The income tax expense of the company for the Relevant Periods is analyzed as follows:

	Year ended December 31,	
	2022	2023
	$'000	$'000
Current	—	643
Deferred	—	—
Total	—	643

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:

	Year ended December 31,	
	2022	2023
	$'000	$'000
Loss before tax	(58,790)	(104,228)
Tax at the statutory tax rate (25%)	(14,698)	(26,057)
Foreign rate differential	2,933	14,711
Expenses not deductible for tax	2,171	126
Income not subject to tax	(4)	—
Additional deductible allowance for qualified research and development costs	(1,681)	(2,338)
Unrecognized deferred tax assets	11,279	14,201
Current income tax expense	—	643
Tax charge at the Group's effective rate	—	0.62 %

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6. INCOME TAX (continued)

Deferred tax

The Group considers positive and negative evidence to determine whether some portion or all of the deferred tax assets will be probable realized. 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.

	Year ended December 31	
	2022	2023
	$'000	$'000
Fixed assets	(13)	2
Capitalized R&D	5,494	11,050
Accrued and prepaid expenses	669	(101)
ROU Assets	(73)	5
Advertising expenses in excess of deduction limit	14	11
Allowance against receivables	—	3
State tax	(1)	(1)
Stock options	1,075	883
NOL	21,758	31,408
Subtotal	28,923	43,260
Unrecognized deferred tax assets	(28,923)	(43,260)
Total Deferred tax	—	—

The Group has accumulated tax losses arising in Adlai Hangzhou in Mainland China of $83,103 and $102,647 as of December 31, 2022 and 2023, 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 $46,201 and $54,168 as of December 31, 2022 and 2023, 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.

Uncertain Tax Position

The Company did not identify any significant unrecognized tax benefits for each of the periods presented. The Group did not incur any interest related to unrecognized tax benefits, did not recognize any penalties as income tax expense and also does not anticipate any significant change in unrecognized tax benefits within 12 months from December 31, 2023.

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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 and 43,342,068 in issue during the years ended December 31, 2022 and 2023, respectively.

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, 2022 and 2023.

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, 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. As of December 31, 2023 the Company had 3,869,554 dilutive shares 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, 2022 and 2023 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, 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 December 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

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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, 2023, net of accumulated depreciation	1,774	1,673	33	151	82	3,713
Additions	28	27	—	127	18	200
Depreciation provided during the year	(700)	(416)	(20)	(43)	(34)	(1,213)
Disposals	—	—	—	—	(1)	(1)
Exchange realignment	(25)	(23)	—	(3)	(2)	(53)
At Dec 31, 2023, net of accumulated depreciation	1,077	1,261	13	232	63	2,646
As of December 31, 2023						
Cost	2,519	3,373	148	322	228	6,590
Accumulated depreciation	(1,442)	(2,112)	(135)	(90)	(165)	(3,944)
Net carrying amount	1,077	1,261	13	232	63	2,646

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

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, 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**

	Offices	Office equipment	Total
	$'000	$'000	$'000
As of January 1, 2023	**2,086**	**76**	**2,162**
Additions	—	—	—
Depreciation provided during the year	(931)	(53)	(984)
Exchange realignment	(23)	(1)	(24)
As of December 31, 2023	**1,132**	**22**	**1,154**

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10. LEASES (continued)

(b) Lease liabilities

The carrying amount of lease liabilities and the movements during the Relevant Periods are as follows:

	Lease liabilities $'000
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)
As of January 1, 2023	(2,237)
Additions	—
Accretion of interest recognized during the year	(83)
Payments	1,103
Exchange realignment	26
As of December 31, 2023	(1,191)

	2022 $'000	2023 $'000
Analyzed into:		
Current portion	1,001	722
Non-current portion	1,236	469
Total	2,237	1,191

(c) The amounts recognized in profit or loss in relation to leases are as follows:

	Year ended December 31,	
	2022 $'000	2023 $'000
Interest on lease liabilities	133	83
Depreciation charge of right-of-use assets	1,090	984
Total amount recognized in profit or loss	1,223	1,067

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11. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

	As of December 31,	
	2022	2023
	$'000	$'000
Current:		
Prepayments (Note i)	1,912	2,337
VAT deductible tax	100	135
Deposits and other receivables	246	224
	2,258	2,696
Non-current:		
Deposits and other receivables	—	—
Prepaid expenses	327	282
	327	282
Total	2,585	2,978

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,	
	2022	2023
	$'000	$'000
Current:		
Wealth management product	21,287	7
Total	21,287	7

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 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 wealth management product held as of December 31, 2023 was an investment into a money market fund that invests in short-term debt instruments such as treasury bills, certain certificates of deposit, bonds, government gilts and commercial paper. The returns on all of the financial product was 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 Unaudited Condensed Consolidated Financial Statements.

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13. Investment at amortized cost

	As of December 31,	
	2022	2023
	$'000	$'000
Short-term investments at amortized cost	—	7,000
Long-term investments at amortized cost	—	24,849
Total	—	31,849

Short-term investment at amortized cost represent time deposits placed with banks with original maturities between three months and one year.

Long-term investment at amortized cost represent time deposits placed with banks with original maturities more than one year.

14. OTHER PAYABLES AND ACCRUALS

	As of December 31,	
	2022	2023
	$'000	$'000
Other payables and accruals (Note i)	255	303
Tax payable		773
Payroll and bonus payables	3,622	3,814
Total	3,877	4,890

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.

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15. INTEREST-BEARING BANK BORROWINGS

	As of December 31,	
	2022	2023
	$'000	$'000
Non-Revolving Facility, 5.22% interest, due March 22,2023, guaranteed (Note i)	1,436	—
Non-Revolving Facility, 4.8% interest, due April 24,2023, guaranteed (Note ii)	2,871	—
Non Revolving Facility, 4.2% interest, due March 26, 2024, guaranteed (Note iii)	—	2,824
Non Revolving Facility, 4.0% interest, due September 17, 2024, guaranteed (Note v)	—	1,412
Non Revolving Facility, 4.0% interest, due September 18, 2024, guaranteed (Note v).	—	1,412
Non Revolving Facility, 4.0% interest, due April 15, 2024, guaranteed (Note ii)	—	4,235
Non Revolving Facility, 6.78% interest, due November 27, 2024, guaranteed (Note vi)	—	3,000
Non Revolving Facility, 6.0% interest, due November 14, 2024, guaranteed (Note vii).	—	10,650
Non Revolving Facility, 6.3% interest, due December 26, 2024, guaranteed (Note vi).	—	4,000
Non Revolving Facility, 4.0% interest, due December 25, 2024, guaranteed (Note iv)	—	2,824
Total	4,307	30,357

	Bank borrowings	Total
	$'000	$'000
As of January 1, 2022	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
Additions	50,234	50,234
Repayments	(24,069)	(24,069)
Effect of foreign exchange rate changes	(115)	(115)
As of December 31, 2023	30,357	30,357

All of the Group's bank borrowings were obtained from third party financial institutions. As of December 31, 2022 and 2023, the Group's credit facilities were $4,307 and $30,357, respectively, of which nil and nil was unused by the Group.

Notes:

(i) 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.

(ii) 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. The non-revolving facility agreement was repaid at the maturity date of April 24, 2023.

In October 2023, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 30,000 and at an interest rate of 4.00% per annum, guaranteed by Mr. Yang Lu, the chief executive officer and chairman of our board of directors.

(iii) In March 2023, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 20,000 and at an interest rate of 4.20% 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 26, 2024. And in March 2024, Adlai Hangzhou repaid it at the maturity date.

(iv) In December 2023, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 20,000 and at an interest rate of 4.00% per annum, guaranteed by Mr. Yang Lu, the chief executive officer and chairman of our board of directors.

(v) In September 2023, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 10,000 and at an interest rate of 4.00% per annum, guaranteed by Mr. Yang Lu, the chief executive officer and chairman of our board of directors. And in March 2024, Adlai Hangzhou repaid it before the maturity date.

In September 2023, Adlai Hangzhou entered into a non-revolving facility agreement for a facility amount of RMB 10,000 and at an interest rate of 4.00% per annum, guaranteed by Mr. Yang Lu, the chief executive officer and chairman of our board of directors. And in March 2024, Adlai Hangzhou repaid it before the maturity date.

15. INTEREST-BEARING BANK BORROWINGS (continued)

(vi) In November 2023, Adlai US entered into a non-revolving facility agreement for a facility amount of USD 3,000 and at an interest rate of 6.78% per annum, guaranteed by the company.

In December 2023, Adlai US entered into a non-revolving facility agreement for a facility amount of USD 4,000 and at an interest rate of 6.30% per annum, guaranteed by the company.

(vii) In December 2023, the company entered into a non-revolving facility agreement for a facility amount of USD 10,650 and at an interest rate of 6.00% per annum, guaranteed by Adlai Hangzhou.

16. 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 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".

16. FINANCIAL LIABILITIES AT FVTPL (continued)

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 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.

16. FINANCIAL LIABILITIES AT FVTPL (continued)

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.

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.

16. FINANCIAL LIABILITIES AT FVTPL (continued)

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;

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;

(All amounts in thousands, except share and per share data, or as otherwise noted)

16. FINANCIAL LIABILITIES AT FVTPL (continued)

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.

The movements of the Group's financial liabilities at FVTPL are set out as follows:

	Series B Preferred Shares $'000	Series C Preferred Shares $'000	Series D Preferred Shares $'000	Total $'000
At January 1, 2022	**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**
Change in fair value	13,943	15,207	10,021	39,171
Conversion into ordinary shares upon IPO	(104,327)	(112,339)	(112,873)	(329,539)
At December 31, 2023	—	—	—	—

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16. FINANCIAL LIABILITIES AT FVTPL (continued)

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, 2022:

	As of December 31, 2022
Fair value of ordinary shares of the Company	$ 6.15
Risk-free interest rate (Note i)	4.68 %
Expected term	0.44 years
Volatility (Note ii)	52.86 %

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.

In September 29, 2023, each holder of Preferred Shares automatically be converted, based on the Applicable Conversion Price, into ordinary shares of the Company upon the closing of IPO.

17. ORDINARY SHARES

Issued and fully paid:

	Number of shares	Ordinary Shares $'000
As of 1 January 2023	25,440,000	3
Issuance of ordinary shares	12,717,391	1
Conversion of Series A convertible preferred shares	14,560,000	1
Conversion of Financial liabilities at FVTPL	42,983,414	5
As at 31 December 2023	**95,700,805**	**10**

The authorized share capital of the Company as of December 31, 2023 is $50 divided into 500,000,000 Shares of par value of $0.0001 each, including 442,456,586 ordinary shares.

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, 2022 and 2023. There was no movement in the Company's ordinary shares in 2022.

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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 $81 of share-based payment expenses prior to 2021, and nil and nil share-based payment expenses for the years ended December 31, 2022 and 2023, 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 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.

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19. SHARE INCENTIVE PLAN (continued)

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.

On April 2023, 352,500 options were granted to the employees with an exercise price of $2.20 under the 2020 Share Incentive Plan.

On April 2023, the Group adopted the 2023 Share Incentive Plan, which is effective upon the completion of this offering. The maximum aggregate number of ordinary shares that may be issued under this 2023 Share Incentive Plan is 15,000,000, including any reserved and issued share under the 2020 Share Incentive Plan.

On December 6, 2023, 121,200 options were granted to certain new employees; 25,414 options were granted to certain employees and managers for outstanding performance.

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19. SHARE INCENTIVE PLAN (continued)

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, 2022	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
Options granted	499,114	2.20	4.47	9.49	
Options forfeited/cancelled	(50,116)	2.30	5.36	9.51	
Options exercised	—	—	—	—	
Balances, December 31, 2023	9,959,100	1.83	1.91	7.44	11,596
Vested but not exercisable as of December 31, 2022	4,980,069	1.59	1.15	8.00	
Vested but not exercisable as of December 31, 2023	5,400,955	1.75	1.69	7.28	

As of December 31, 2022 and 2023, there were 15,000,000 and 15,000,000 shares reserved for the option plan and there were 5,489,898 and 5,040,900 shares available for issuance, respectively.

The fair value of the award granted during the years ended December 31, 2022 and 2023 were $ 6,913 and $2,231. The Group recognized share-based payment expenses of $6,082 and $4,330, respectively, during the years ended December 31, 2022 and 2023.

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:

	Jan 1, 2022	Apr 1, 2022	July 1, 2022	Oct 1, 2022	Apr 21, 2023	Dec 6, 2023
Dividend yield (%)	0.00	0.00	0.00	0.00	0.00	0.00
Expected volatility (%)	48.73	48.78	48.88	48.82	49.68	49.90
Risk-free interest rate (%)	1.66	2.52	3.03	3.98	3.98	4.30
Expected life of options (year)	10.00	10.00	10.00	10.00	10.00	10.00

As of December 31, 2022 and 2023, the Company had 9,510,102 and 9,959,100 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 9,510,102 and 9,959,100, respectively, additional ordinary shares of the Company and additional share capital of $1.0 and $1.0 (before issue expenses), respectively.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2023 (continued)
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20. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

During the year ended December 31, 2022 and 2023, the Group had non-cash additions to right-of-use assets and lease liabilities of nil and nil, respectively, in respect of lease arrangements for offices and equipment.

(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, 2022	**297,563**	**10,468**	**2,888**	**—**	**310,919**
Interest expense	—	295	133	—	428
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	(7,195)	—	—	—	(7,195)
Exchange adjustment	—	(741)	(177)	—	(918)
At December 31, 2022	**290,368**	**4,313**	**2,237**	**—**	**296,918**
Interest expense	—	708	83	—	791
Transaction costs for the issuance of convertible redeemable preferred shares	—	—	—	—	—
Additions	—	50,234	—	—	50,234
Conversion into ordinary shares	(329,539)	—	—	—	(329,539)
Payment					
– financing cash flows	—	(24,069)	(1,020)	—	(25,089)
– operating cash flows	—	—	—	—	—
Interest paid	—	(602)	(83)	—	(685)
Change in fair value	39,171	—	—	—	39,171
Exchange adjustment	—	(115)	(26)	—	(141)
At December 31, 2023	**—**	**30,469**	**1,191**	**—**	**31,660**

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2023 (continued)
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20. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

(c) Investment activities

	Dual currency structured deposit	investments at amortized cost	Wealth management product	Total
	$'000	$'000	$'000	$'000
Year ended December 31, 2022				
purchase	(14,900)	—	(44,080)	(58,980)
disposal	22,439	—	65,618	88,057
interest received	19	—	531	550
Year ended December 31, 2023				
purchase	—	(31,849)	(7)	(31,856)
disposal	—	—	21,039	21,039
interest received	—	—	62	62

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 15 (i) to 15 (v) to the consolidated financial statements, the RMB40,000 and RMB90,000 non-revolving facility agreements provided by five third party banks were guaranteed by the ultimate significant shareholder, Mr. Yang Lu for the years ended December 31, 2022 and 2023, respectively.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2023 (continued)
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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:

	As of December 31,	
	2022	2023
	$'000	$'000
Financial assets:		
Financial assets at FVTPL:		
Dual currency structured deposit	—	—
Wealth management product	21,287	7
Total	21,287	7
Other financial assets:		
Financial assets included in prepayments, other receivables and other assets	2,585	2,978
Cash and cash equivalents	42,758	91,492
Short-term investments at amortized cost.	—	7,000
Long-term investments at amortized cost	—	24,849
Total	45,343	126,319
Financial liabilities:		
Trade payables	13,098	14,348
Financial liabilities included in other payables and accruals	3,877	4,890
Interest-bearing bank and other borrowings	4,307	30,357
Total	21,282	49,595
Financial liabilities at FVTPL:		
Financial instruments measured at FVTPL	290,368	—
Total	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, 2022		As of December 31, 2023	
	Carrying amount	Fair value	Carrying amount	Fair value
	$'000	$'000	$'000	$'000
Financial assets				
Dual currency structured deposit	—	—	—	—
Wealth management product	21,287	21,287	7	7
Total.	21,287	21,287	7	7
Financial liabilities				
Financial liabilities at FVTPL	290,368	290,368	—	—
Total.	290,368	290,368	—	—

(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)

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 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, 2022

	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	—	—	—	—
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

As of December 31, 2023

	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	7	—	—	7
Total	7	—	—	7

(All amounts in thousands, except share and per share data, or as otherwise noted)

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 net loss $'000	Increase/ (decrease) in equity $'000
At December 31, 2022			
If the $ strengthens against the RMB	5	—	(1,939)
If the $ weakens against the RMB	(5)	—	4,081

	Increase/ (decrease) in $/RMB rate%	Increase/ (decrease) in net loss $'000	Increase/ (decrease) in equity $'000
As of December 31, 2023			
If the $ strengthens against the RMB	5	(1,010)	(943)
If the $ weakens against the RMB	(5)	1,116	1,042

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.

(All amounts in thousands, except share and per share data, or as otherwise noted)

25. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES (continued)

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, 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

	As of December 31, 2023				
	On demand	Less than 1 year	1 to 5 years	Over 5 years	Total
	$'000	$'000	$'000	$'000	$'000
Financial liabilities at FVTPL	—	—	—	—	—
Trade and bills payables	14,348	—	—	—	14,348
Financial liabilities included in other payables and accruals	4,890	—	—	—	4,890
Interest-bearing bank borrowings	—	30,357	—	—	30,357
Total	19,238	30,357	—	—	49,595

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,	
	2022	2023
	$'000	$'000
Total assets	72,594	130,189
Total liabilities	313,887	50,786
Asset-liability ratio (Note i)	0.23	2.56

Note i:

The asset-liability ratio is calculated by dividing total assets by total liabilities.

26. SUBSEQUENT EVENTS

(a) Bank loan

In February 2024, 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 4.0% per annum, guaranteed by Mr. Yang Lu and Adlai Shanghai. The maturity date is August 2, 2024.

In February 2024, Adlai US entered into a non-revolving facility agreement with a third party financial institution for a facility amount of USD3,000 at an interest rate of 6.57% per annum. The maturity date is February 26, 2025.

In February 2024, 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 March 4, 2024.And in March 2024, Adlai Hangzhou repaid a non-revolving facility amount of RMB30,000 at the maturity date.

In March 2024, Adlai Hangzhou entered into a non-revolving facility agreement with a third party financial institution for a facility amount of RMB60,000 at an interest rate of 3.5% per annum, guaranteed by Mr. Yang Lu and Adlai Shanghai. The maturity date is November 28, 2024.

In March 2024, Adlai Hangzhou repaid three non-revolving facility amount of RMB40,000 at the maturity date.

In April 2024, Adlai Hangzhou repaid a non-revolving facility amount of RMB30,000 at the maturity date.

(b) Subsidiaries

In March 2024, Shareholder of Hangzhou Tangchuang agreed to increase the company's registered capital to RMB100 million, with an additional investment of RMB70 million from Hangzhou Hongxi Business Management Co., Ltd and an additional investment of RMB20 million from Adlai Hangzhou. After this capital increase, the company accounting for 30% of the registered capital in Hangzhou Tangchuang. And Hangzhou Tangchuang would no longer be a subsidiary within the company’s scope of consolidation.

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.

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2023 (continued)
(All amounts in thousands, except share and per share data, or as otherwise noted)

27. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY (continued)

As of December 31, 2022 and 2023, 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.

PARENT COMPANY BALANCE SHEETS

	December 31,	
	2022	2023
	$'000	$'000
ASSETS		
Current assets		
Cash and cash equivalents	12,194	63,150
Prepayments, other receivables and other assets	36	44
short-term investments at amortized cost	—	7,000
Total current assets	**12,230**	**70,194**
Non-current assets		
Due from related parties	115,743	123,102
Investment in subsidiaries	94,300	129,711
Total non-current assets	**210,043**	**252,813**
Total assets	**222,273**	**323,007**
LIABILITIES		
Current liabilities		
Accounts payable	888	976
Other payables and accruals.	—	53
Due to related parties	—	40
Interest payables	—	10,650
Non-current liabilities due within one year		—
Financial liabilities at FVTPL	290,368	—
Total current liabilities	**291,260**	**11,719**
Non-current liabilities		
Long-term loans	—	—
Financial liabilities at FVTPL	—	—
Total non-current liabilities	**—**	**—**
Total liabilities	**291,260**	**11,719**
Ordinary shares (par value of $0.0001 per share; 442,456,586 shares authorized; 40,440,000 shares issued and outstanding as of December 31, 2022; and nil outstanding as of December 31, 2023)	4	—
Class A Ordinary shares (par value of $0.0001 per share; nil outstanding as of December 31,2022; and 93,710,805 shares outstanding as of December 31, 2023)	—	9
Class B Ordinary shares (par value of $0.0001 per share; nil outstanding as of December 31,2022; and 16,990,000 shares outstanding as of December 31, 2023)	—	2
Series A convertible preferred shares (par value of US$0.0001 per share; 14,560,000 and nil shares authorized, issued and outstanding as of	10,980	—
Additional paid-in capital	6,415	438,707
Share option reserve	11,730	16,059
Accumulated deficit	(98,116)	(143,489)
Total shareholders' deficit	**(68,987)**	**311,288**
Total liabilities and shareholders' equity	**222,273**	**323,007**

ADLAI NORTYE LTD.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2023 (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,	
	2022	2023
	$'000	$'000
REVENUE	—	—
Other operating income, net	156	242
Administrative expenses	(1,390)	(6,196)
Research and development expenses	—	—
Total operating loss	**(1,234)**	**(5,954)**
Other income and gains	—	—
Other expenses	—	—
Investment income	—	—
Fair value loss on financial liabilities at FVTPL	7,194	(39,171)
Finance costs	—	(249)
LOSS BEFORE TAX	**5,960**	**(45,374)**
Income tax expense	—	—
LOSS FOR THE YEAR	**5,960**	**(45,374)**
TOTAL COMPREHENSIVE (LOSS)/INCOME FOR THE YEAR	**5,960**	**(45,374)**

PARENT COMPANY STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2022	2023
	$'000	$'000
Net cash flows used in operating activities	(1,134)	(13,143)
Net cash flows used in investing activities	(35,035)	(38,082)
Net cash flows from financing activities	—	102,181
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	**(36,169)**	**50,956**
Cash and cash equivalents at beginning of year	48,363	12,194
CASH AND CASH EQUIVALENTS AT END OF YEAR	**12,194**	**63,150**

Exhibit 8.1

LIST OF PRINCIPAL SUBSIDIARIES OF THE REGISTRANT

Name	Place of Incorporation
Alpine Bioscience Ltd	British Virgin Islands
Adlai Nortye Pte. Ltd.	Singapore
Adlai Nortye (HK) Limited	Hong Kong
Adlai Nortye (Switzerland) AG	Switzerland
Adlai Nortye Biopharma Co., Ltd.	PRC
Adlai Nortye USA INC	United States
Shanghai Adlai Nortye Biopharma Co., Ltd.	PRC

Exhibit 12.1

Certification by the Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Yang Lu, certify that:

1. I have reviewed this annual report on Form 20-F of Adlai Nortye Ltd.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this annual report;

4. The company's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and

    (d) Disclosed in this annual report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

By: /s/ Yang Lu
Name: Yang Lu
Title: Chief Executive Officer

Date: April 19, 2024

Exhibit 12.2

Certification by the Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Wei (Vicky) Zhang, certify that:

1. I have reviewed this annual report on Form 20-F of Adlai Nortye Ltd.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this annual report;

4. The company's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    (e) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

    (f) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    (g) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and

    (h) Disclosed in this annual report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    (c) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    (d) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

By: /s/ Wei (Vicky) Zhang
Name: Wei (Vicky) Zhang
Title: Chief Financial Officer

Date: April 19, 2024

Exhibit 13.1

Certification by the Chief Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Adlai Nortye Ltd. (the "Company") on Form 20-F for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Yang Lu, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(a) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(b) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Yang Lu
Name: Yang Lu
Title: Chief Executive Officer

Date: April 19, 2024

Exhibit 13.2

Certification by the Chief Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Adlai Nortye Ltd. (the "Company") on Form 20-F for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Wei (Vicky) Zhang, chief financial officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(a) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(b) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Wei (Vicky) Zhang
Name: Wei (Vicky) Zhang
Title: Chief Financial Officer

Date: April 19, 2024

Exhibit 97.1

ADLAI NORTYE LTD.

POLICY FOR THE RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

A. OVERVIEW

In accordance with the applicable rules of The Nasdaq Stock Market (the ***"Nasdaq Rules"***), Section 10D and Rule 10D-1 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***") ("***Rule 10D-1***"), the Board of Directors (the "***Board***") of Adlai Nortye Ltd. (the "***Company***") has adopted this Policy (the "***Policy***") to provide for the recovery of erroneously awarded Incentive-based Compensation from Executive Officers. All capitalized terms used and not otherwise defined herein shall have the meanings set forth in Section H, below.

B. RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

(1) In the event of an Accounting Restatement, the Company will reasonably promptly recover the Erroneously Awarded Compensation Received in accordance with the Nasdaq Rules and Rule 10D-1 as follows:

(i) After an Accounting Restatement, the Compensation Committee (if composed entirely of independent directors, or in the absence of such a committee, a majority of independent directors serving on the Board) (the "***Committee***") shall determine the amount of any Erroneously Awarded Compensation Received by each Executive Officer and shall promptly notify each Executive Officer with a written notice containing the amount of any Erroneously Awarded Compensation and a demand for repayment or return of such compensation, as applicable.

(a) For Incentive-based Compensation based on (or derived from) the Company's stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement:

i. The amount to be repaid or returned shall be determined by the Committee based on a reasonable estimate of the effect of the Accounting Restatement on the Company's stock price or total shareholder return upon which the Incentive-based Compensation was Received; and

ii. The Company shall maintain documentation of the determination of such reasonable estimate and provide the relevant documentation as required to Nasdaq.

(ii) The Committee shall have discretion to determine the appropriate means of recovering Erroneously Awarded Compensation based on the particular facts and circumstances. Notwithstanding the foregoing, except as set forth in Section B(2) below, in no event may the Company accept an amount that is less than the amount of Erroneously Awarded Compensation in satisfaction of an Executive Officer's obligations hereunder.

(iii) To the extent that the Executive Officer has already reimbursed the Company for any Erroneously Awarded Compensation Received under any duplicative recovery obligations established by the Company or applicable law, it shall be appropriate for any such reimbursed amount to be credited to the amount of Erroneously Awarded Compensation that is subject to recovery under this Policy.

(iv) To the extent that an Executive Officer fails to repay all Erroneously Awarded Compensation to the Company when due, the Company shall take all actions reasonable and appropriate to recover such Erroneously Awarded Compensation from the applicable Executive Officer. The applicable Executive Officer shall be required to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

(2) Notwithstanding anything herein to the contrary, the Company shall not be required to take the actions contemplated by Section B(1) above if the Committee (which, as specified above, is composed entirely of independent directors or in the absence of such a committee, a majority of the independent directors serving on the Board) determines that recovery would be impracticable *and* any of the following three conditions are met:

(i) The Committee has determined that the direct expenses paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered. Before making this determination, the Company must make a reasonable attempt to recover the Erroneously Awarded Compensation, documented such attempt(s) and provided such documentation to Nasdaq;

(ii) Recovery would violate home country law where that law was adopted prior to November 28, 2022, provided that, before determining that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on violation of home country law, the Company has obtained an opinion of home country counsel, acceptable to the Nasdaq, that recovery would result in such a violation and a copy of the opinion is provided to Nasdaq; or

(iii) Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended, and regulations thereunder.

C. DISCLOSURE REQUIREMENTS

The Company shall file all disclosures with respect to this Policy required by applicable U.S. Securities and Exchange Commission ("***SEC***") filings and rules.

D. PROHIBITION OF INDEMNIFICATION

The Company shall not be permitted to insure or indemnify any Executive Officer against (i) the loss of any Erroneously Awarded Compensation that is repaid, returned or recovered pursuant to the terms of this Policy, or (ii) any claims relating to the Company's enforcement of its rights under this Policy. Further, the Company shall not enter into any agreement that exempts any Incentive-based Compensation that is granted, paid or awarded to an Executive Officer from the application of this Policy or that waives the Company's right to recovery of any Erroneously Awarded Compensation, and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date of this Policy).

E. ADMINISTRATION AND INTERPRETATION

This Policy shall be administered by the Committee, and any determinations made by the Committee shall be final and binding on all affected individuals.

The Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy and for the Company's compliance with the Nasdaq Rules, Section 10D, Rule 10D-1 and any other applicable law, regulation, rule or interpretation of the SEC or Nasdaq promulgated or issued in connection therewith.

F. AMENDMENT; TERMINATION

The Committee may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary. Notwithstanding anything in this Section F to the contrary, no amendment or termination of this Policy shall be effective if such amendment or termination would (after taking into account any actions taken by the Company contemporaneously with such amendment or termination) cause the Company to violate any federal securities laws, SEC rule or the Nasdaq rule.

G. OTHER RECOVERY RIGHTS

This Policy shall be binding and enforceable against all Executive Officers and, to the extent required by applicable law or guidance from the SEC or Nasdaq, their beneficiaries, heirs, executors, administrators or other legal representatives. The Committee intends that this Policy will be applied to the fullest extent required by applicable law. Any employment agreement, equity award agreement, compensatory plan or any other agreement or arrangement with an Executive Officer shall be deemed to include, as a condition to the grant of any benefit thereunder, an agreement by the Executive Officer to abide by the terms of this Policy. Any right of recovery under this Policy is in addition to, and not in lieu of, any other remedies or rights of recovery that may be available to the Company under applicable law, regulation or rule or pursuant to the terms of any policy of the Company or any provision in any employment agreement, equity award agreement, compensatory plan, agreement or other arrangement.

H. DEFINITIONS

For purposes of this Policy, the following capitalized terms shall have the meanings set forth below.

(1) "***Accounting Restatement***" means an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements (a "Big R" restatement), or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "little r" restatement).

(2) "***Clawback Eligible Incentive Compensation***" means all Incentive-based Compensation Received by an Executive Officer (i) on or after the effective date of the applicable Nasdaq rules, (ii) after beginning service as an Executive Officer, (iii) who served as an Executive Officer at any time during the applicable performance period relating to any Incentive-based Compensation (whether or not such Executive Officer is serving at the time the Erroneously Awarded Compensation is required to be repaid to the Company), (iv) while the Company has a class of securities listed on a national securities exchange or a national securities association, and (v) during the applicable Clawback Period (as defined below).

(3) "***Clawback Period***" means, with respect to any Accounting Restatement, the three completed fiscal years of the Company immediately preceding the Restatement Date (as defined below), and if the Company changes its fiscal year, any transition period of less than nine months within or immediately following those three completed fiscal years.

(4) "***Erroneously Awarded Compensation***" means, with respect to each Executive Officer in connection with an Accounting Restatement, the amount of Clawback Eligible Incentive Compensation that exceeds the amount of Incentive-based Compensation that otherwise would have been Received had it been determined based on the restated amounts, computed without regard to any taxes paid.

(5) "***Executive Officer***" means each individual who is currently or was previously designated as an "officer" of the Company as defined in Rule 16a-1(f) under the Exchange Act. For the avoidance of doubt, the identification of an executive officer for purposes of this Policy shall include each executive officer who is or was identified pursuant to Item 401(b) of Regulation S-K or Item 6.A of Form 20-F, as applicable, as well as the principal financial officer and principal accounting officer (or, if there is no principal accounting officer, the controller).

(6) "***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and all other measures that are derived wholly or in part from such measures. Stock price and total shareholder return (and any measures that are derived wholly or in part from stock price or total shareholder return) shall, for purposes of this Policy, be considered Financial Reporting Measures. For the avoidance of doubt, a Financial Reporting Measure need not be presented in the Company's financial statements or included in a filing with the SEC.

(7) "***Incentive-based Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

(8) "***Nasdaq***" means The Nasdaq Stock Market.

(9) "***Received***" means, with respect to any Incentive-based Compensation, actual or deemed receipt, and Incentive-based Compensation shall be deemed received in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-based Compensation award is attained, even if the payment or grant of the Incentive-based Compensation to the Executive Officer occurs after the end of that period.

(10) "***Restatement Date***" means the earlier to occur of (i) the date the Board, a committee of the Board or the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

Effective as of December 1, 2023.